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WKMJ

World Korean Medical Journal

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FROM THE PUBLISHER

Keyword in Modern Healthcare: Integration

We are privileged to feature Dr. Kwang Tae Kim, the president of International Hospital Federation (IHF), a leading worldwide body for hospitals and healthcare organizations. As the current CEO of Daerim St, Mary's Hospital in Korea, he also served as the president of Korea Hospital Association and Asian Hospital Federation.

Dr. Kim is undoubtedly one of the most highly respected physicians in the global community with a strong vision in healthcare. He has background in both clinical medicine and hospital administration and has actively participated in numerous humanitarian and vocational services. Dr. Kim was a keynote speaker at our WKMO Convention held in New York City last year. He impressed me most with his humility, thoughtfulness and depths of vision towards global health. He told us then, the key word representing IHF is 'Integration'; that modern medicine needs to integrate new data and knowledge for the advancement of healthcare.

Integration is the same very keyword representing WKMO, WKMJ and NYHF, all aimed to bring diversity and new avenues of collaboration in all branches of healthcare. Healthcare today has evolved as a complex, challenging interdisciplinary field. Whether you are a physician, scientist, engineer, businessman, lawyer, or policy maker, we are all in this together to navigate the healthcare in today's ever-expanding multi-cultural, multi-ethnic society. To do this properly, we need to integrate the essence of various expertise and develop new perspectives.

As a continuance of our effort to develop new perspectives in global healthcare, WKMO is planning its 4th Annual Convention titled 'Trans-cultural Healthcare: Global Initiatives', which will be held during July 2-4, in Los Angeles. This convention will provide a platform for all of us to explore, interact, and establish a wholesome networking where we find innovative approaches to deal with a myriad of today's healthcare issues.

An excellent article in this issue 'Personalized Medicine' by Dr. Joe McMenamin is a great example illustrating the need of integration. Hippocrates must have also realized the need of personalized medicine when he said 'It is more important to know which kind of person suffers from a certain disease than knowledge from which disease somebody suffers'. The successful integration of a model scientific achievement such as pharmacogenomics into mainstream medical practice requires efforts from all fields. In addition to the roles of policy makers and healthcare authorities, physicians also need to play a leading role in implementation and operation of new tools. Primary care providers, for instance, need a thorough understanding of pharmacogenomics so they can utilize the test results appropriately in clinical setting. The lack of preparation by the healthcare providers may otherwise interfere with the process of the integration of genome medicine into mainstream clinical practice.

Thank you again for joining WKMJ community, and happy reading!

Chul S. Hyun, MD, PhD
Publisher
President of WKMO
Weill Cornell Medical College

FROM THE EDITOR IN CHIEF

Dear Colleagues,

It has been a busy year for WKMO with a regional forum in London in March. Enjoyed meeting with Korean UK Medical Association (KUMA) President Dr. Hyunick Kim and their members. The Keynote speaker Professor Paul Matthews of Imperial College recently visited Korea and what is remarkable is that the English National Health System is ranked as second most efficient and cost-effective compared to the America which is ranked as the last in 12 country studied, was impressed with the Korean medical system and sees potential of UK and Korean collaboration. If you are good you can still get better. He was also impressed with Korean medical students that are school in England and meeting some of them I concur.

This issue we feature Dr. Kwang-Tae Kim who is the current President of the International Hospital Federation (IHF). Dr Kim has a full career and he is the first Asian President of the IHF. Globalization of all disciplines include Medicine which is changing so fast and the IHF has the opportunity to improve healthcare delivery at cost effective manner is a challenge every country is facing. Hearing him speak at the WKMO meeting last year in NY he is well up to the challenge. We congratulate Dr. Kim and wish him a successful IHF meeting.

The 4th annual WKMO Annual Convention is coming up this July 3-4th holiday weekend in Los Angeles in the Beverly Hills area. The convention will have four interesting forums on Transcultural healthcare and Global Initiatives. One forum is on Hepatitis a common but treatable condition amongst Koreans. There will a forum on imaging and digital technology which is transforming healthcare. Another is a neurology psychiatry forum called the Brain as it requires two specialties to treat its many myriad disorders, and one talk that will be particularly interesting will be by Dr. Charles Cho of Stanford that is a talk on Immortality which will focus on research in living longer. The last forum will be Healthcare around the world and we will hear from speakers from different countries including North Korea. We have very special guest speaker Dr. David Roh who is the Dean of the first international medical school in North Korea thru PUST which is landmark medical opportunity to teach and improve healthcare in the Hermit Kingdom. We have many great speakers and there will be something for everyone, including a talk by Dr. Paul Song on the Affordable Care Act and its effects on Korean Americans. Please join us and interact with Korean physicians from all corners of the world. I personally welcome you all to Los Angeles.

David Y. Ko, MD
Editor in Chief
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WKMJ RECAP OF FEBRUARY ISSUE

Entrepreneur Interview

Inspirational Korean Healthcare Leader, "Dr. B.G. Rhee, CEO of Green Cross Holdings"

Dr.B.G. Rhee is the CEO of Green Cross Holdings, the number one leading Korean pharmaceutical company. In the interview Dr. Rhee talks about his strategies of successfully leading a global pharma company Green Cross Holdings. He discusses in further how his science background supported in making significant business decisions and plans. Read our Issue 5 to find out more about Dr. Rhee's interview.

Korean Medical Pioneer

Dr. Philip Jaisohn(Jae-Pil Seo)'s Legacy of Humanism

The first Korean American medical doctor to be, Dr. Philip Jaisohn (Jae-Pil Seo)'s journey through political turmoil of Korea to the US and back left an indelibl legacy of dedication, service and activism. Dr. Jaisohn, is still considered as the greatest gift to Korea, a founding father of Korea's modernization and democracy. Read our Issue 5 to find out more about Dr. Jaisohn.

Biopharmaceutical report 1

Diabetic Neuropathy Patient Stratification, Chances Boosted

BioDelivery Sciences International's topical clonidine gel has pain experts optimistic on Phase III painful diabetic neuropathy trial outcome by patient stratification. This could be a favorable treatment option for the patients as the patients would have more control over the application of the drug. Read our Issue 5 to find out more about the new technology.

Biopharmaceutical report2

Biosimilar Reference Products Expected to Grow

The demand for service providers who can source biological reference products for biosimilar trials is rising, with providers already in the space experiencing boosted business. The regulatory and logistical capabilities of product sourcing are a time-consuming process and the pharma focus on biosimilar development has increased demand. Reference batches can be sourced from manufacturers but more often from authorized distributors. Read our Issue 5 to find out more about this report.

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INSPIRATIONAL KOREAN HEALRHCARE LEADER

"Dr. Kwang Tae Kim, President of International Hospital Federation"

Dr. Kim giving his keynote speech at The 65th Annual National Convention of Philippine Hospital association and 1st Joint Conference with the Asian Hospital Federation held on Novermber 19th 2014.

1. Dr. Kim, you are world renowned successful physician. What was your motivation to become a doctor and did you face any significant trouble or obstacles during your physician life?

My mother had tuberculosis for several years and passed away when I was in second grade in middle school.
That had an impact on me to want to become a doctor. I entered medical school in 1955, two years after the Korean War ended. There were no Korean medical text books, so all the text books we used were in English. It was difficult at first, but eventually we got used to the medical terminology. I chose surgery as my specialty, because at the time, with lack of good drugs, surgery was the most effective way of cure. I had my residency training at the Seoul Capital Army Hospital. This hospial was the best training hospital for surgeons right after the war.

The 5th Korea Healthcare Congress 2014 & IHF 4th Hospital and Healthcare Association Leadership Summit

2. You have been recognized as a successful hospital executive with countless achievements. Beginning with only 20-beds, Daerim St. Mary's Hospital in Seoul has expanded to 405-beds in numbers and further developed to be the global hospital educating interns and residents with your leadership. What was your management philosophy and vision in hospital operating leadership?

I followed where the real need was. After working for one year at another hospital in Yeongdeungpo, I opened my hospital at Daerim-dong with 20 beds, because it was where most patients were coming from. At that time, there was no other hospital between Suwon and Namdaemoon. All the patients visiting my hospital recovered without complications, and the number of beds increased gradually upto 405.

Looking back, following the real need with passion and doing my best were the key to the success of my hospital. Patient-centered care and patient safety were my guiding principle.

Press conference of The 5th Korea Healthcare Congress 2014

Dr. Kwang-Tae Kim

3. Dr. Kim, you've served Asian Hospital Federation as president from 2007-2009. While you were active as the Chairman of the Organizing Committee of International Hospital Federation, you've successfully led 2007 IHF Congress's to be held in Seoul for the first time in history. Furthermore, you've become the first Asian to be elected as the President of IHF. Upon your appointment as President of IHF, you've proposed a statement, "a bigger, stronger and financially sustainable IHF." Can you describe your thoughts on this motto and organization operating philosophy?

Finding the real need is the key to success of any organization. For a hospital, satisfying patient's need is the key. At IHF, during my presidency we installed two innovative changes. First, IHF World Hospital Congress (WHC) was changed from biennial to annual event. Second, IHF Awards

2014 International Hospital Federation Governing Council Meeting in Seoul, Korea

program to recognize innovative ways of delivering healthcare has been initiated with the first awards to be given out at the 2015 IHF Chicago WHC.

Due to the aging population with chronic conditions, healthcare delivery system is faced with a major challenge. The era of medical treatment without consideration of cost is over. Now, new innovations in healthcare delivery such as accountable care, affordable care and well-dying are the emerging topics.

4. IHF CHICAGO will be held in October, 2015. What is the major topic and theme of the conference and what are your expectations from the conference? Also, as you complete your terms as the president of IHF, what is your new life goal(s) and plan?

Advancing Global Health and Healthcare will be the theme of the IHF 39th World Hospital Congress in Chicago during October 6 to 8, 2015.
Major topics being addressed are Equity and Access to care, Patient and Community Engagement and Empowerment, Quality and Safety, Healthcare Management and Leadership opportunities and challenges, Innovation in Healthcare Delivery, and Ethical Issues.

IHF hopes to move healthcare forward by exchange of knowledge and experence from around the globe.

After my role as IHF president, I will return to my hospital to do my best for patient-centered care.

High school graduation photos of young Kwang-Tae Kim

The 5th Korea Healthcare Congress 2014

5. Beyond your professional roles, you are known to be involved in numerous community activities. In Rotary services, you've served as member of Board of Directors from 2005-2007. These works have been recognized by 'Golden Century Award', 'Order of Civil Merit' and etc. As a physician, business executive, global leader, and community server, do you have any words to share with young generations?

In my practice, I realized that it is impossible to convince patients to follow my recommendation with only medical knowledge. 35 years ago, I joined Rotary International, and my leadership and management philosophy is influenced by what I learned from Rotary.

In Rotary, "He or She profits most who serves best."

6. WKMJ has readers from over 10 countries globally. Please share your final words with our readers.

Healthcare delivery system is faced with a major challenge due to the aging population with chronic conditions.

Oppotunities arise when we are faced with difficulties.

I would like to encourage the WKMJ readers to make this major global healthcare challenge an opportunity for innovation.

DUBAI IHF 2011, 37th World Hospital Congress

Dr. Kwang-Tae Kim

International Hospital Federation

The President of a private general hospital with 450-bed capacity, called Daerim St. Mary's Hospital established in 1969 in Seoul, Korea, Dr Kwang Tae Kim with a call name, Luke, has actively participated in humanitarian and vocational services all along his long social activities. His professional and social activities stretch to the presidency of Korean Hospital Association in 2002-04, the Governing Council Member of International Hospital Federation in 2003-05 and President in 2007-09 of Asian Hospital Federation. He has also engaged himself proactively in Rotary services, with top-notch positions, including the Rotary International Board of Directors member in 2005-07, for the last 34- year Rotary life. Dr Kim has since 1980's organized and conducted annually and periodical for the last 30 years "Free Medical Services" for those in need of health care and treatments, in the communities at home and abroad. It should be noted that during his tenure of the President of Korean Hospital Association in 2002-04, and as the Organizing Committee Chairman of 2007 IHF World Hospital Congress, he has become the One ever recorded in the IHF history who contributed to the IHF finances with a handsome amount of support as the "Congress Income" in the 2007 IHF GBP Account Budget, from benefits accrued out of the highly successful 2007 IHF Congress being held in November, 2007 in Seoul, Korea.

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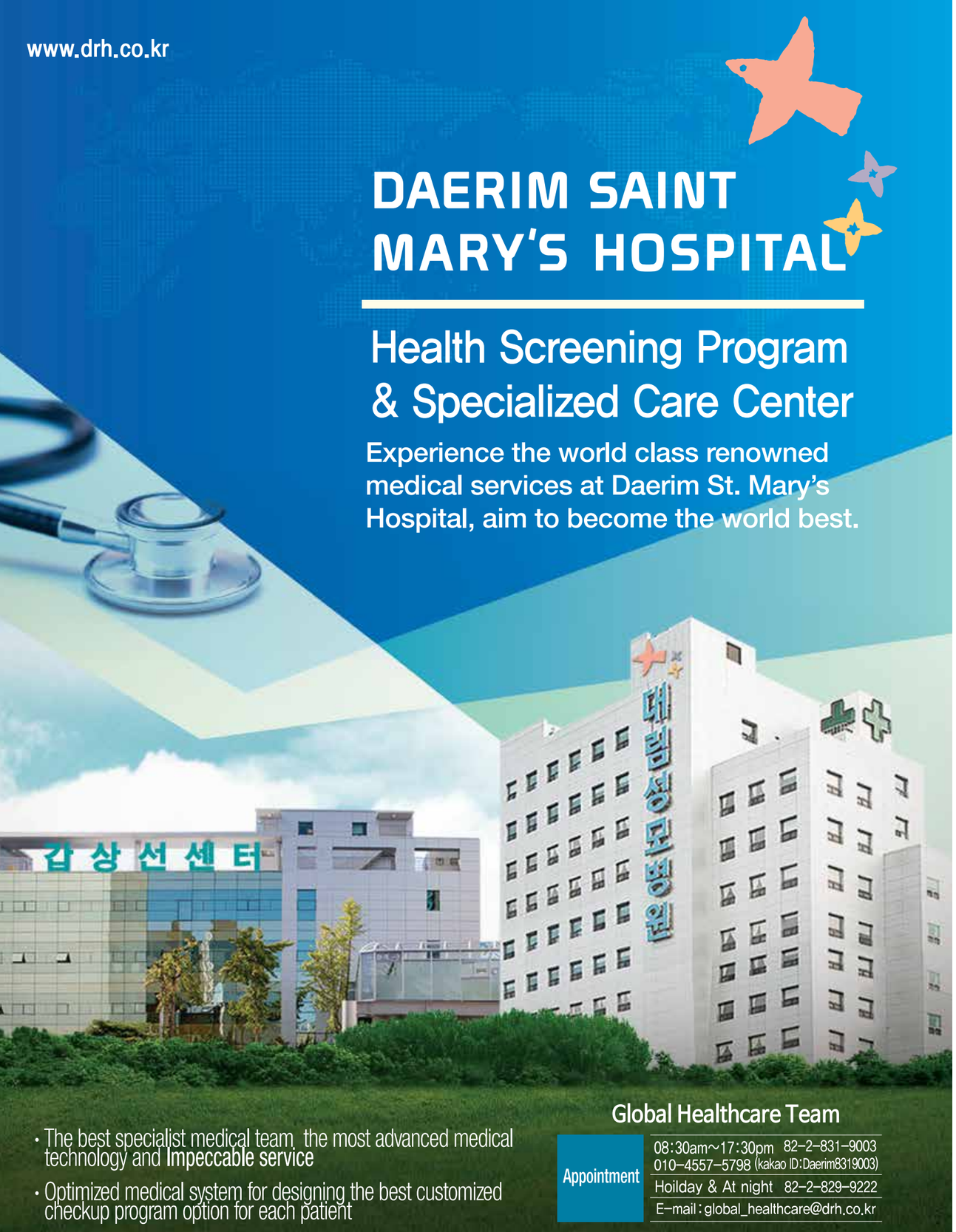

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Entrepreneur Interview

Chul Kyoon Park, President of it's a Wig.

1. President Chul Kyoon Park, please introduce your company, 'it's a Wig' to our readers.

For more than 40 years, it's a Wig' has been distributing wigs in the U.S. Our brand is the top seller in wig industry, holding the largest brand market share in the U.S. Our company is located in Moonachie, New Jersey. We are currently managing over thousands of retail customer accounts directly. We are dedicated to lead the fashion trends of wig with its various colors and styles providing satisfaction to our customer.

2. We've learned that it's a Wig has been supporting not only American Cancer Society but also number of Korean hospitals by donating wigs for cancer patients. Could you explain this community wig donation activities and your motivation for such activities?

When patients go through chemotherapy treatment, many tend to experience severe hair loss as side effect. This kind of physical figure change often causes depression which may negatively affect patients. Also, we noticed that cancer treatment could be very expensive, and some of the patients are going through financial hardship that purchasing a wig could be burdensome.

Sponsoring the annual event, 'George Washington Bridge Challenge' hosted by American Cancer Society since 2012. a. iT's Wig employees and family participating 'GWB Challenge' b. GWB Challenge participants wearing donated wig c. Chul Kyoon Park on 3rd from left receiving award from American Cancer Society for his dedicated works of supporting cancer patients

Thus, we donate wigs to the cancer patients so that they feel more confident about their look and have better self-esteem. Our donation activities started with supporting American Cancer Society in 2009 and continue to expand the size to over 2,000 wigs per year in 20 different locations currently.

This donation activity occurs quarterly, and we were selected as the best wig supporting company by the American Cancer Society since 2012.

On the other hand, we also support 'George Washington Bridge Challenge' hosted by the American Cancer Society. We support the event by donating color wigs for the event, but also support it by all company member participation.

Besides American Cancer Society, we support Holy Name Medical Center, Seoul National University Hospital/Children's Hospital, Kyung-Hee University Medical Center continuously.

3. Can you share any specific story or event that was special to you?

When we visited Princeton branch of American Cancer Society for a donation event, we've met a patient who was an Indian American in age of 40s. She tried couple of wigs but did not find anything she liked.

We considered her style and many other factors to recommend a suitable wig for her. We've found this particular style from the warehouse and shipped it overnight for her. She was in fact very satisfied and sent us a special 'thank you' message.

This incident was particularly memorable since it met our goal of satisfying the end user. Sponsorship or donation could be considered as on side giving and the other side receiving, however, we receive so much as return when we get to see the patients feel happy and confident just by wearing a wig.

Chul Kyoon Park, his wife and his two sons participating 'GWB Challenge'

iT's a Wig's products were featured by Aveda's models at Mercedes-Benz New York Fashion Week 2014 Fall/Winter

4. What is your goal and vision for this activity?

It's actually nothing huge or fancy. The very basic bottom of my motivation is that I wish this world to become a better place as we share and support each other.

As a wig industry leader, I wanted to find my own way to support others. I realized that there are a lot of people who need a wig so I started to share it with them. I do not think this is anything special but one ordinary thing that I am sharing something I have more than others with people who truly need them. I believe it is desirable to share information, things, food, anything others for a better world.

It's a Wig launched iT's a Nail recently. iT's a Nail is a nail polish strip line manufactured by Incoco.

Chul Kyoon Park at the Starting point of 'GWB Challenge' 2014. Part supports the event by not only the sponsorship but also his participation

5. WKMJ is read by various types of healthcare leaders and physicians worldwide. Please, introduce us on how to collaborate with 'it's a Wig'.

'it's a Wig' is a wig company. Even at this moment, we are ready to donate wigs to anyone or any organization, including hospitals, associations, healthcare leaders, physicians and patients who need them. We carry all kinds of wigs that can fit regardless of their sex, race, etc., so please do not hesitate to contact us. We welcome all interests in us and always look for taking an opportunity to share with world together.

Happy smile and hope after pain

D.K. Lee has related to It's A Wig that she will promote to cancer patients about the beauty classes and healing programs she attended. The beauty classes are held at Kyung Hee Medical Center and it is for cancer patients to help them feel more womanly during their hard times. She would like to thank all the people who gave her hope. "Thank you for giving me a second chance to live as a woman. With the hopes and gifts that I have received, it encourages me to work harder to volunteer my time for the people who are fighting against cancer."

Kyung Hee Medical Center patient
D. K. Lee

Cancer-free D.K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

WKMO Report

WKMO Global Leadership Series London Forum 2015

On March 21st, World Korean Medical Organization (WKMO) hosted its Regional Forum at Lancaster London hotel in London, UK. A substantial number of colleagues from out of UK attended including three from the US, one from Brazil, two from Korea, and the rest from Europe. Hoping to facilitate academic and bio-health industrial collaborations and exchanges amongst all health care professionals, WKMO organized 5 sessions of lectures from significant speakers under the topic of "Transcultural Healthcare & Global Initiatives." The London Forum's speakers, Drs. David Kim, David Ko, Ieehyok Woo, Ben Lee and Chul S. Hyun, spoke about great topics from various fields including OB/GYN, neurology, psychiatry, neonatology and gastroenterology/hepatology.

Ambassador Sungnam Lim giving a congratulatory remark


Gala dinner at Lancaster London while Dr. Hyunick Kim giving a welcome message


From left to right: Hyunick Kim, David Kim, David Ko, Chul S. Hyun, and Soo-Woong Kim.

Adding to the great speakers, there were noteworthy figures who made the London Forum much richer. Ambassador Sungnam Kim gave a congratulatory remark on behalf of the Embassy of the Republic of Korea in the United Kingdom. Also, Professor Paul Matthews, LHF President, Imperial College London, came to give a keynote speech in a topic of Korea – UK R&D Collaboration during the gala dinner.

As the Regional Forum was accomplished successfully, WKMO is now looking forward to the 4th Annual Convention which will be held at Intercontinental Hotel in LA, on July 2-4, 2015. If interested in attending, visit the WKMO website for detailed information (www.wkmonet.org).

Biopharmaceutical Report I

Spark's LCA2 gene therapy is likely to have greater benefit for younger patients

Spark Therapeutics' (NASDAQ:ONCE) subretinal gene therapy injection of SPK-RPE65, is likely to restore vision most effectively in younger Leber's Congenital Amaurosis (LCA2) patients, experts agreed.

Younger patients are likely to experience better treatment results because they tend to have more viable retinal area to salvage, some experts said.

However, the greater the salvageable retinal region and the younger the patient, the higher the risk of performing surgery, two experts noted. Experts are nonetheless cautiously optimistic about a potential treatment for a disease that eventually results in certain blindness. The treatment is worth the risk despite uncertain durability, most experts agreed.

The 28-patient Phase III randomized, open-label, safety and efficacy study, with a subretinal injection of 1.5E11 vector genomes of human RPE65 to each eye, includes patients aged four to 44, all of whom have now received the treatment, according to a company spokesperson. He declined to discuss the distribution of ages in the Phase III trial, but noted that it was "balanced among treatment arms." Nine patients were in the control group for one year prior to having the option to receive the treatment; all nine opted to receive treatment, he said.

Pediatric patients have more restorable cells

The nine control patients received no sham injection, but received the same monitoring as the active arms for one year, according to the spokesperson.

The Phase III, which initiated in November 2012, is expected to complete in 2H15, according to company information.

LCA is a group of hereditary retinal dystrophies characterized by the loss of retinal and visual functions early in life with progressive cellular degeneration. These functions include papillary light reflexes (PLRs), involuntary eye fixation instability and fundus abnormalities. LCA is usually inherited, and LCA2 accounts for 10% of all LCA. LCA2 is caused by mutations in the RPE65 gene. [Simonelli F et al. Molecular Therapy (March 2010) 18(3): 643-650].

Spark's therapy received breakthrough designation by the FDA, according to a November 2014 company press release. SPK-RPE65 comprises the AAV2 vector which carries the human RPE65 gene.

Viable photoreceptors

For gene therapy, one of the necessary conditions is that photoreceptors be there before treatment, explained Dr Jijing Pang, research professor, Department of Ophthalmology, University of Florida College of Medicine.

In most cases, the younger the patient, the more photoreceptors there are, he added.

If all photoreceptors are already gone before starting treatment, then the current gene replacement therapy cannot restore vision, said Pang, noting that in clinical trials for LCA2, most patients are typically younger than 18 years old.

"We cannot cure or restore vision from late-stage patients," said Pang.

The process is not regenerative; you want to save what is already present, explained Dr Demetrios Vavvas, co-director, Ocular Regenerative Medical Institute, Boston, Massachusetts. That doesn't mean it will have no restorative capacity, he added. The cell will still receive the gene and work better than it was working before, he explained. The treatment will still slow down the degenerative process, Vavvas said, adding that later stage patients still receive some benefit.

The inclusion criteria for Spark's Phase III lists "sufficient viable retinal cells as determined by non-invasive means," and the location of the subretinal injection of product is determined based on the location of viable cells, however, it can be difficult to establish when photoreceptor cells are too far gone, noted Dr Wadih Zein, staff clinician, Ophthalmic Genetics and Visual Function Branch, National Eye Institute. Researchers are still trying to come up with the best methods to identify areas of the retina with viable photoreceptors, that would allow for the best outcome following a subretinal injection, he added.

Age is a factor and benefit is expected to be more prominent for the younger patients who would have a larger area of viable retina, agreed Zein.

The optimal retinal sites for subretinal gene delivery to achieve efficacy are also likely to change with disease progression. [Jacbson S et al. Investigative Ophthalmology & Visual Science (May 2009) 50(5): 2368- 2375].

Age may influence efficacy in other ways, remarked Vavvas, citing a depressed immune system, environmental factors, less resilience and other factors associated with aging as possible reasons pediatric patients may fare better in Spark's trial. The photoreceptor cells may also degenerate at a faster rate in older people, he noted.

In Spark's Phase I trial, improvements in at least one measurement— pupillary light response (PLR) sensitivity— in the treated eye, was more notable among the youngest patients. **[Maguire A et al. The Lancet (November 2009) 374(9701): 1597-1605]**.

Safety risk highest in most salvageable cases

Safety

Subretinal surgery remains a major concern, and safety presents a contradiction in this trial, noted Pang. The injection involves detaching the retina, he added. If you don't transfect a large area, you don't see a dramatic improvement, but detaching too much retina can be harmful to the macula and foveal area, he explained. Giving the patient too much solution can also cause damage, Pang added.

Sometimes subretinal injections are too close to the fovea and can cause central vision loss, or the area doesn't respond as well as other areas, explained Pang.

Pediatric patients may have the most to gain, but they also have the most to lose, explained Vavvas, noting that the trial is definitely high risk. There is a risk of infection and detachment, which is especially high in pediatric patients who are at greater risk for proliferative vitreoretinopathy (PVR), a blinding condition, he said. A patient who is 44 and already nearly blind has much less to lose than a four-year-old, he added.

Acceptable high risk despite uncertain durability

There are also major risks with gene therapy, agreed investigator Dr Stephen Russell, professor, Department of Ophthalmology and Visual Sciences, University of Iowa Hospital.

The biggest concern is that by inserting the therapy into a gene, it may become integrated into the DNA and into a tumor suppressor gene, resulting in the development of tumors, explained Russell. The AAV2 vector is non-integrating, so it's less likely to result in tumor production, but it's still a worry, he said.

It's a non-integrating virus, but you never know whether there will be an alteration in other genes, and you might induce tumors or you might induce another type of malfunction in a different gene, explained Vavvas.

There was one significant adverse event in the Phase I trial, which was determined to be non-drug related, and was connected to the surgery itself, said the company spokesperson.

It's naive to think we can treat patients with gene therapy and not also protective therapies, noted Vavvas. If you think there is a gene mutation disease and you can supply the gene back, then that's the end of the disease, that's wrong, he said.

We have to use neuroprotective therapy at the same time as gene therapies, he said. Even after therapy for gene degradation, there is continued degeneration happening in patients. We need protective therapies in addition to the gene therapy, he said, adding that this is an area that is still being researched and not largely understood.

According to research, a second approach to coping with photoreceptor cell death, in addition to gene therapy, involves the use of neurotrophic growth factors to limit further damage. The aim is to provide a protective environment to prolong the viability of the photoreceptors by their effect on the secondary biochemical pathways. This can be achieved either by delivering neurotrophic growth factors, or inhibiting pro-apoptotic pathways, or implementing viability factors such as the rod-derived cone viability factor (RdCVF). [Sahni J et al. Current Genomics (June 2011) 12(4): 276-284].

Doctors are a ways off from having the perfect treatment, according to Pang. Researchers are working on developing novel generations of AAVs that can eventually penetrate the whole retina to reach RPE or photoreceptor cells, he explained. Research to find the best vectors to deliver gene therapy products is ongoing, and a major consideration in any study, agreed Zein. The ideal would be to have an IVT injection, which is safer and easier, said Pang.

There have been no adverse events reported in Phase III, according to the company spokesperson.

Durability

Durability is difficult to estimate at this stage, said Zein. There is some evidence in the literature that the functional benefit in the treated area regresses after a number of years, he added.

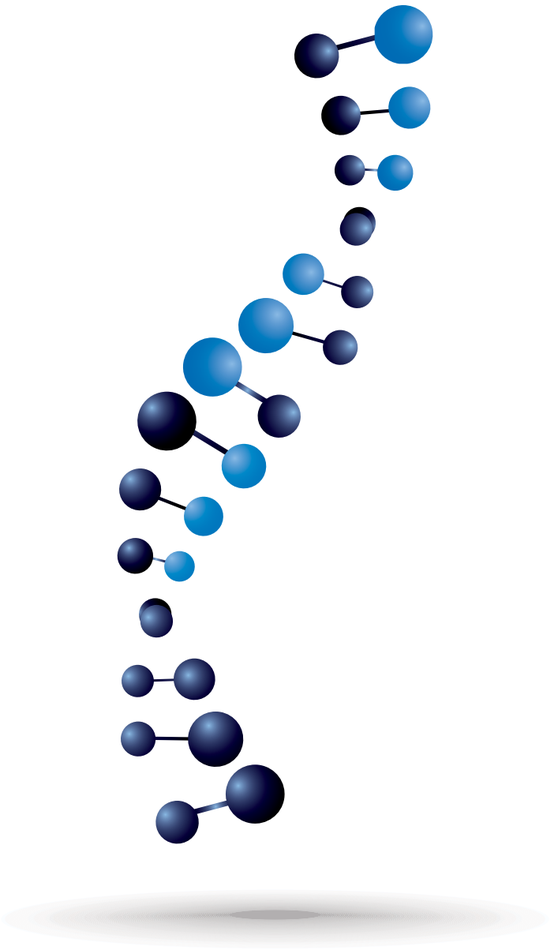
It's possible that in 10 to 15 years, patients will lose what visual acuity gain they had with this therapy, said Vavvas. The benefits still outweigh the risks despite safety concerns and uncertainty about durability, said Vavvas. The alternative is blindness, he remarked.

The risk to benefit ratio of performing this treatment will have to be determined per individual patient, depending on age, viable retina and retinal thickness at the area of projected delivery, just to consider a few factors, noted Zein.

It would be great if it were "one and done," said Russell, but the data right now on AAV2 is that the longest human treatment we know of is seven years, at which point it's still effective. Dogs, which have the same naturally occurring genetic mutation as humans, were treated in preclinical studies and the therapy's effectiveness has been maintained for 15 years, he said.

Additional research also needs to be conducted on determining the best vector in each case, experts agreed.

Spark's market cap is USD 1.50bn.



Alissa Fleck

Reporter, New York

Alissa is a former freelance editor and journalist who has been a regular contributor for Bankrate, the Huffington Post, Truthout, Global Post and three Straus News publications in Manhattan. She has written medical and health copy for websites including SF Gate (the San Francisco Chronicle online) and Livestrong as well as for private clients.

Biopharmaceutical Report II

Astellas/Medivation's Xtandi has questionable potential to displace bicalutamide, other therapies in prechemotherapy mCRPC

TERRAIN may not be sufficient to justify moving drug to earlier therapy lines

Astellas (TYO:4503)/Medivation's (NASDAQ:MDVN) Phase II TERRAIN study topline data on Xtandi has left experts questioning whether it will be moved into earlier lines of treatment for metastatic castration-resistant prostate cancer (mCRPC) patients naïve to chemotherapy.

While one oncologist said the TERRAIN data justifies moving Xtandi up, others said they would continue using it in later lines of treatment of pre-chemotherapy mCRPC. Meanwhile, the availability of the TERRAIN study's (NCT01288911) comparator drug, the generic bicalutamide, which belongs to the same class as Xtandi, may discourage payers and pharmacy benefit managers (PBMs) from covering Xtandi in earlier lines, two health system pharmacists said.

According to an analyst report, however, the TERRAIN data is expected to drive use of Xtandi over bicalutamide and eventually lead to the latter's replacement. The report noted that bicalutamide is currently the most-prescribed drug in prostate cancer. Bicalutamide is the generic name of AstraZeneca's (LON:AZN) Casodex, though several companies now make generic versions.

TERRAIN is a randomized, double-blind, parallel-assignment trial of Xtandi in 375 patients whose disease has progressed while on a luteinizing hormone receptor hormone (LHRH) agonist/antagonist or after receiving a bilateral orchiectomy, according to ClinicalTrials.gov.

The Astellas spokesperson declined to comment on how the TERRAIN results might affect uptake of Xtandi, but noted that the full TERRAIN data, including additional safety data, will be presented at the European Association of Urology's 2015 meeting, which takes place 20-24 March in Madrid, Spain.

Generic competitor, greater toxicity may discourage PBM coverage

Earlier treatment questionable

If patients' prostate specific antigen (PSA) rises after local therapy or if they have metastatic disease, then doctors can start with bicalutamide/ AbbVie's (NYSE:ABBV) LHRH agonist Lupron (leuprolide), and then stop bicalutamide in the first month, said Dr Tian Zhang, medical oncology fellow, Duke University, Durham, North Carolina. Sometimes, she said, patients will respond to that regimen, but if their PSA levels rise later, doctors will re-challenge with bicalutamide and see if the tumor responds. After exhausting those therapies, doctors will use Xtandi or Janssen's Zytiga (abiraterone), she said.

The TERRAIN trial showed a progression-free survival (PFS) benefit, and not an overall survival (OS) one, she said, and the improved PFS alone will not be enough to shift the drug to earlier lines of treatment. At the same time, some oncologists may use the TERRAIN data to give patients Xtandi instead of re-challenging with bicalutamide, but Xtandi and Zytiga come with greater toxicity as well as higher costs, she noted.

However, after the FDA obtained approval in September 2014 based on the PREVAIL data, the use of Xtandi is not predicated on whether a patient has received radium, Dendreon's (OTCMKTS:DNDNQ) Provenge (sipuleucel-T) or bicalutamide, said Dr Robert Den, assistant professor, radiation oncology and cancer biology, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania. It can be used once a patient has documented metastatic CRPC, he added. Xtandi appears to be considered a first-line treatment for mCRPC and is listed in the National Comprehensive Cancer Network guidelines, Den said.

According to a 22 January press release, TERRAIN's median PFS was 15.7 months for Xtandi, versus 5.8 months for bicalutamide. Serious adverse events respectively occurred in 31.1% and 23.3% of Xtandi-treated and bicalutamide-treated patients, while Grade 3 or higher cardiac events occurred in 5.5% and 2.1% of patients treated with Xtandi and bicalutamide, respecitively. Two Xtandi patients had seizures, compared with one bicalutamide patient.

Xtandi's superiority over bicalutamide in TERRAIN is not surprising, a Washington expert said, but superior PFS numbers do not mean Xtandi should be used earlier in treatment because they do not mean OS will be greater, and the results do not tell doctors anything about where in treatment Xtandi belongs.

Yet, Den said PFS and toxicity numbers should move Xtandi to earlier lines of treatment, noting that National Comprehensive Cancer Network guidelines list Xtandi, and the drug has shown a survival advantage in earlier trials and adding that it appears to be already considered a first-line treatment. In terms of toxicity, Den cited a need to wait for the manuscript to understand the results, such as whether toxicity data reflects Xtandi's toxicity or TERRAIN's low study population, he said. The toxicity signals are not very different from other Phase III results, noted a Washington state expert. Grade 3 or higher atrial fibrillation occurred in 2% of Xtandi-treated patients in PREVAIL versus 1% in the placebo group.

Xtandi was approved in the pre-chemotherapy setting in September 2014 based on data from the Phase III PREVAIL study (NCT01212991).

However, the Washington state expert added she prefers Provenge or radium and does not use bicalutamide anymore.

Testing Xtandi and Zytiga head-to-head would give the best evidence for determining which should be used, Den said, though greater experience with Zytiga drives its usage in Europe. But Xtandi is preferable for diabetic patients because Zytiga requires combination with prednisone, which adds toxicity for diabetics, Zhang and the Washington expert said. However, the Washington expert added, Zytiga has lower seizure risk.

Data unlikely to sway PBMs

PBMs Express Scripts (NASDAQ:ESRX) and Eagen, Minnesota-based Prime Therapeutics classify Xtandi as a Tier 5 drug, while Caremark (NYSE:CVS) classifies it as a specialty drug requiring prior authorization, according to the three largest PBMs' most recent formularies.

However, the TERRAIN safety and efficacy data is pretty weak and unlikely to move Xtandi higher within Tier 5, said John Waddell, consultant, TSM Associates, West Chester, Pennsylvania, noting the study's lack of OS data. The overall serious adverse event figures may not be too big a deal given that the study was not highly powered, but the cardiac toxicity is a red flag, he said. The cost differential is also a huge problem, he added.

Notwithstanding varying criteria and relationships with drug companies, PBMs may look at TERRAIN's toxicity data and decide generic bicalutamide is safer than Xtandi, said Harvey Arbit, professor, Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy, Minneapolis. Cardiac toxicity is not only a serious side effect, but a severe one, and such distinctions drive formulary decision making, he said.

In general, if there is a generic available in the same class as a branded drug, PBMs may only choose to cover the generic, Arbit noted. The Xtandi-bicalutamide situation may play out similarly to Pfizer's (NYSE:PFZ) Lipitor (atorvastatin) before it became generic in 2011, when PBMs would only cover generic simvastatin, despite Lipitor's greater efficacy, requiring patients who still wanted Lipitor to pay out of pocket, Arbit said.

If the Xtandi-bicalutamide price differential is 10-20%, then PBMs may choose to cover Xtandi, but if Xtandi is several times more expensive, they might not, said Stephen Schondelmeyer, professor, Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy. Even a 10-month improvement in PFS may not be worth doubling the risk of cardiac events for payers and PBMs, and those figures raise serious questions about the safety and efficacy between the two drugs, let alone the cost difference, he said, and they may question how Xtandi adds value.

Astellas' market cap is JPY 4.4trn (USD 36.5bn). Medivation's is USD 9.9bn.

Alaric DeArment

Reporter, New York

Alaric DeArment covers cancer drugs and vaccines for BioPharm Insight. Previously, he was associate editor at Drug Store News, covering retail and specialty pharmacy, pharmaceuticals, biologics and regulatory affairs. A native of Seattle, he graduated with honors with a bachelor degree in journalism from Ball State University and also lived in China from 2001-2004.

Manasi Vaidya

Reporter, New York

Manasi Vaidya has a Masters degree in biotechnology. After a stint in a research lab, she spent two years as correspondent in India for BioSpectrum, a publication focused on the Asian biotechnology industry. She then moved to the United States to pursue a Masters degree in Science, Health and Environmental Reporting at New York University. Manasi has reported primarily on topics that combine health and policy, and her work has appeared in Nature Medicine, Nautilus and Scienceline. Her coverage at BioPharm Insight focuses on cancer.

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Analysis of Bio - Pharma in East Asia - Trends Report

Featured Story of Korean Pharma: Hanwha confirms abandoning bid for Dow Chemical basic chemicals unit

Hanwha Corp is no longer seeking to buy Dow Chemical's [NYSE:DOW] chlorine and epoxy businesses following KRW 1.85trn (USD 1.7bn) deal with Samsung Group unveiled last week, a company spokesperson confirmed. Hanwha Chemical, a chemical unit of Hanwha Corp, said in March that it was reviewing the potential bid for Dow Chemical's basic chemical business although details had not then been finalized.

Following the agreement to acquire Samsung's chemical units, Hanwha does not now need the Dow assets and willfocus on growing the acquired petrochemical units and realigning its related chemical and materials operation, said the spokesperson. South Korea's largest conglomerate, Samsung Group, announced last Wednesday that it will transfer its chemical units to Hanwha Corp as part of a wider deal that saw the latter agree to buy 32.4% stake in Samsung Techwin, the parent company of Samsung Total, for KRW840b. Hanwha Chemical and Hanwha Energy acquired a 56.01% stake in Samsung General Chemicals for KRW 1.06trn (USD 953m). The transactions, in total worth around KRW 2trn (USD 1.8bn), will be completed by July 2015. Hanwha said it will settle the acquisitions in installments over two to three years. Hanwha Corp, Hanhwha Energy and Hanwha Chemical have healthy cash flow with an annual EBITDA of KRW 200bn, according to the spokesperson.
Hanwha Corp has internal cash of KRW 150bn, which could be used to finance the deal, he added.

by Kate Kim in Seoul

Daewoong Pharmaceutical reviewing Southeast Asian target after dropping Dipharma deal

Daewoong Pharmaceutical, a listed South Korean pharmaceutical company, has turned its attention to a SoutheastAsian target after abandoning a deal to acquire assets from Italian company Dipharma, a source familiar with situation said. The KRW 777.5bn (USD 704.5m) market cap company is still actively searching for overseas targets to expand its business and reach USD 2.5bn in sales by 2020, the source said. Its priority markets are Asian countries including China, Indonesia, Vietnam and Thailand, the source said.

Daewoong had mandated an undisclosed financial advisor for the Dipharma deal, but walked away from even before the due diligence stage because the transaction was too large, the source said. It had been reviewing Dipharma since 2013, the source added. Daewoong is looking at targets valued at less than KRW 50bn in the active pharmaceutical ingredients manufacturing and bio related industries, the source said. The company has overseas presence in Indonesia, Thailand, India, Vietnam, the Philippines and the US, as well as 12 affiliates including Daewoong Bio, Daewoong Life Science, Healience, ids Trust, Daewoong Management Institute and MD Well, according to the company's website.

Daewoong Pharmaceutical acquired Liaoning Baifeng Industry, a China bases pharmaceutical manufacturer, for USD 16.17m in 2013 to expand its business in China market, as reported. Its previous law firm is BKL, based on mergermarket's data. Daewoong has worked with financial advisor Samil Pw in the past, a person familiar with company noted. The company's core products are brain function improvement medicine, antiulcer drugs, high blood pressure treatment, liver disease medicine, diabetes treatment and botulinum toxin formulation (anti-¬wrinkle treatment).

Daewoong expects to generate at least KRW 170bn of sales with its anti wrinkle product, also known as 'NABOTA', after launching in the US in 2017, an analyst said. Founded in 1945, Daewoong posted KRW 675bn of sales with KRW 71.3bn of operating profits as of 2013--end, based on the company's financial report. Its cash and cash equivalents were at KRW 69.3bn as of June 2014.

by Soo Young Park in Hong Kong

Hubit welcomes partnership with dental materials maker, aims to list in midterm

Hubit, a private, South Korean orthodontic bracket manufacturer, welcomes strategic partnerships to help it improve its domestic market share, a source familiar with situation said. Partnership options could include a stake sale or a joint venture with dental material makers, especially those that manufacture implants and ceramic brackets, the source said. He named Osstem Implant, a listed dental implant manufacturer in South Korea, and Henry Schein, a listed US -based dental supplies equipment distributor, as industry peers. Hubit is currently supplying its orthodontic products to Henry Schein, he added. The company is also aiming to list on KOSDAQ in around three years' time, as financial investor Korea Development Bank Capital,and other venture capital funds expect to exit by then, the source said. These investors entered in 2007. Hubit is waiting to generate KRW 20bn (USD 20m) in revenues before it lists on KOSDAQ. Hubit will appoint an IPO advisor closer to this milestone, the source noted. It is likely to record approximately KRW 8bn in sales at the end of 2014, the source said. The company specializes in manufacturing orthodontic ceramic materials including brackets, wires, tubes and other accessories, according to its website. It supplies its products to 67 countries, including the US, China, and Russia, the source said, adding that overseas sales account for 60% of its total sales, respectively. Foreign orthodontic bracket materials makers have around 90% of the market in Korea, with Hubit's share at 5%. Other foreign peers are US-based 3M, Rocky Mountain Orthodontics, Japan's Tomy and Germany¬based Forestadent, the source said.

CEO HagDong Yoo is the largest shareholder in Hubit, which was founded in 2005, the source said.

by Soo Young Park in Seoul

Celltrion's infliximab biosimilar set to capture FDA regulatory nod experts

Celltrion should garner FDA approval for its biosimilar of Johnson & Johnson's (NYSE: JNJ) Remicade (infliximab), according to experts. They noted they were uncertain as to whether the agency will allow full label extrapolation. The company's previously announced data underscores approval, the experts agreed. Celltrion announced August 11th that it had completed the 351(k) filing procedure for its infliximab biosimilar Remsima. The product is the first monoclonal antibody (mAb) application to undergo the US biosimilar pathway, introduced in 2009, and the second drug filed under the pathway, according to a release. Celltrion could not be reached for comment. Approval expected there is no evidence to suggest that Celltrion's data is insufficient for the FDA to approve Remsima, said Kate Keeping, senior director of biosimilars research at Decision Resources Group. Both Canadian and EU regulators cleared the product based on Phase I and III data, as well as likely extensive nonclinical work to establish the molecule is highly similar to the reference product, the director said. These studies are arguably more important as the clinical efficacy study is meant to be confirmatory, the direcotr and a US biosimilars expert said. The randomized, double-blind PLANETAS Phase I study (NCT01220518) reported in 2012 that the pharmacokinetic (PK) profiles of Remsima and Remicade were equivalent in active ankylosing spondylitis (AS) patients (Park et al. Ann Rheum Dis. 2013 Oct; 72 (10): 160512).
It also reported Remsima was well-tolerated, with an efficacy and safety profile comparable to Remicade up to week 30. The randomized, double-blind Phase III PLANETRA study (NCT01217086) in rheumatoid arthritis (RA) patients reported Celltrion's drug demonstrated equivalent efficacy to Remicade at week 30, with a comparable PK profile and immunogenicity. Again, it was well tolerated, with a comparable safety profile to Remicade. It also reported Remsima was well-tolerated, with an efficacy and safety profile comparable to Remicade up to week 30.

After FDA consultation, Celltrion conducted additional clinical trials, lasting six months, to determine the bioequivalency of the originator products with Remsima. Specifically, Celltrion tested for PK/pharmacodynamic (PK/PD) equivalency and safety equivalency for the originator products sold in the US, the originator products sold in Europe, and its own product. This additional clinical trial data, along with Celltrion's global clinical trial data, were submitted to the FDA as part of its application, according to a Celltrion press release. The data, as well the Celltrion statement, is hopeful for approval, said a second US biosimilars expert and Nigel Rulewski, head, Global Biosimilar Unit, Quintiles.

"It's a slam-dunk" in terms of approval, said Dr. Nathan Wei, rheumatologist and founder, Arthritis Treatment Center, Frederick, Maryland.
The data is solid, including the PK/PD analysis and the studies' sample sizes are adequate, he noted. There is a strong case for approval based on the data, said Dr. Stephen Hanauer, professor in Medicine-Gastroenterology and Hepatology, Northwestern University Feinberg School of Medicine, Chicago, Illinois and previous chair of the FDA's Gastrointestinal Drugs Advisory Committee.

Full label extrapolation uncertain Remicade is indicated in the US for paediatric and adult CD, paediatric and adult UC, RA, psoriatic arthritis (PA), AS and plaque psoriasis (PS). Hanauer said he believed the efficacy in RA and other indications can be extrapolated to Crohn's disease (CD) and ulcerative colitis (UC), two other indications in which Remicade is approved. Hanauer said the data supports full label extrapolation.
The FDA is open to extrapolation as long as the product is highly similar and the criteria in the agency's draft guidance documents are met (such as respect to the same MOA), said a second US biosimilars expert.
Yet Keeping and Wei disagreed that RA and AS data can be extrapolated to gastrointestinal (GI) indications because of the potentially different MOA to the rheumatic/dermatology indications. Rulewski noted that extrapolation to other indications is still "an open question."
Extrapolation is more likely to happen when MOA is the same, the second expert said. When the MOA is different, full extrapolation is less likely. Thus, since the MOA for Remicade may be different in GI indications, "it will be interesting" to see whether the FDA will grant all indications since clinical trials have not been done in each unique disease state, the expert added.
Wei said he expected the FDA to require separate trials for GI indications. Health Canada did not permit full indication extrapolation while the EMA did, the experts noted. Health Canada approved in April Remsima for RA, AS, PA and PS. Celltrion announced on 28 June 2013 that the EMA's Committee for Medicinal Products for Human Use (CHMP) had given positive opinion for Remsima.

Unless Celltrion has submitted new information to justify extrapolation to CD/UC, there is a high risk that the FDA will come to the same conclusion as Health Canada, Keeping said. The risk is also underscored because there are known differences in the glycosylation pattern between Remsima and Remicade, Keeping said. Celltrion is conducting 214 patients, randomized, double-blind, switching study (NCT02096861) in active CD patients which started in July and ends in March 2017, according to ClinicalTrials.gov. The trial is not FDA required, a person familiar with the company said, but is intended to accumulate scientific data to bolster physician confidence to prescribe a biosimilar as interchangeable to the innovator product. The company indicated in the CHMP pharmacovigilance plan that it would conduct a randomized Phase III trial in CD, Keeping said. From a strategic perspective, conducting a CD trial should help assuage gastroenterologists' concerns about prescribing Remsima, assuming the results are positive, she said.
Celltrion's market cap is KRW 45bn (EUR 3.7bn).

by Jennifer C. Smith¬Parker and Jinan Harb in London

Kwang Dong Pharmaceutical seeks smaller acquisitions after dropping Dream Pharma bid

Kwang Dong Pharmaceutical is seeking smaller domestic acquisitions to fortify its ethical drug business after dropping its joint bid with South Korean private equity firm STIC Investment to acquire Dream Pharma, a source familiar with the situation said. The South Korean pharmaceutical and beverage company, which has a market capitalization of about KRW 501.1bn (USD 499m), considers KRW 50bn--KRW 100bn to be a suitable deal size. The source declined to comment on what sort of targets it could look at, but a 2013 report from Mergermarket noted that Kwang Dong was interested in acquiring peers specializing in cardiovascular systems and high blood pressure. Kwang Dong's over-the-counter and beverage business have grown, but

its ethical drug unit still has room to grow further, the source continued. It was previously reported that about 40% of the company's sales come from the pharma business while 60% comes from beverage sales.
Kwang Dong announced in June that it had decided to drop its bid for Dream Pharma, the pharmaceutical unit of South Korean conglomerate Hanwa Chemical Corporation. According to local reports, Dream Pharma could fetch about KRW 200bn. They noted that

Kwang Dong and STIC Investment had formed a consortium to bid but dropped out due to deal size, without elaborating whether or not price expectation was too high. Kwang Dong has a range of pharma products in the gastrointestinal, respiratory, central nervous system, anti-infective oncology, endocrine and metabolic, allergy and immune system, and dermatology spaces, according to the company's website. That said, the company will also continue to be opportunistic on beverage targets as that is its second priority, the source added. Kwang Dong's cash-cow products in the beverage segment include vitamin drinks Vita500, corn silk tea water, and ginseng cold medicine drink KDP Kwangdong Ssangwhatang, as reported by local media. Kwang Dong CEO Sung Won Choi and the company's executive members own a 17.79% stake in the company as the largest shareholder, according to the company's financial report. The company, founded in 1963, generated KRW 468.4bn in sales and KRW 44.4bn in operating profits as of the end of 2013, based on its financial report.

by SooYoung Park in Seoul

Bayer Korea/Korea MSD oral contraceptive business to attract buyers following regulatory order sources.

KFTC to send final order statement by end of April Yuhan Corp allowed to buy Mercilon if it terminates existing distribution license

The South Korea arm of Bayer AG's oral contraceptive pill (Mercilon) business is likely to attract South Korean pharmaceutical companies such as Kwang Dong Pharmaceutical, Hanmi Pharmaceutical, Il Dong Pharmaceutical, Yuhan Corporation, and Green Cross, considering its leading market position, three industry sources said. Korean strategic investors are monitoring the situation closely as the seller is expected to conduct an auction in order to meet the regulatory requirements and an end of September deadline. The deal value is expected to be more than KRW 20bn (USD 19m), although it is premature to give details, said a source. The six month deadline is not extendable and the company could face with penalties if it fails to comply, the source added. Mercilon generated sales of KRW 10.9bn and KRW 11.8bn in 2013 and 2014, respectively, according to financial statement of Yuhan Corporation, the Korean distributor of Mercilon. On March 23, 2015, the Korea Fair Trade Commission (KFTC) issued a conditional approval for Germany based multinational pharmaceutical company Bayer Korea's proposed acquisition of Korea MSD, the South Korea subsidiary of Merck & Co. Merck, the US based company headquartered in New Jersey, manufactures the oral contraceptive pill Mercilon. Under KFTC's order, Bayer and Merck should sell Mercilon rights including sales, trademark and imports, keeping just the manufacturing license within the six month period. The clock started ticking from the date of the statement, and the competition agency will issue a final order statement to Bayer by the end of April, according to a source close to the KFTC. Bayer Korea and Korea MSD will need to secure a buyer for the oral contraceptive unit by October, the source close to the regulator said Buyers could be both domestic and foreign investors, excluding the existing distributors of Bayer Korea or Korea MSD products in Korea, he added. The Korean distributors include Dong-A Socio Holdings which distributes Bayer's four oral contraceptive products, and Korea MSD's distributor Yuhan Corporation. However, Yuhan Corporation could bid for the asset if it were to terminate the existing licensing agreement with Korea MSD, he said.
Mercilon has the largest Korea market share with 43%. Dong-A Sociol, Il Dong Pharmaceutical have 39% and 14%, respectively as of 2013 end. Kwang Dong and Crown Pharm, the unlisted Korean pharmaceutical firm, hold 3% and 1% each in terms of market share in South Korea for the same period, according to KFTC data. Green Cross recently entered the business, launching the contraceptive pill 'Dear:me' in March 2015. Bayer Korea is currently working on the sale internally, a company spokesperson said, without further explanation. Korea MSD did not respond to a request for comment. A competition lawyer pointed out that the KFTC may have issued a conditional approval because oral contraceptives are categorized as an over the counter (OTC) medicine in South Korea. This means retail consumers are likely to be directly hit by any potential price hikes post the combination of two companies. In other jurisdictions, however, oral contraceptives are categorized as prescription based medicines which could be less accessible to the consumers. Therefore, there should be less risk of potential competition restriction, the lawyer said. In May 2014, Bayer announced the acquisition of Merck's consumer healthcare division for USD 14.2bn. In order to finalize the international transaction, Bayer's South Korea based subsidiary Bayer Korea filed for a merger review in October 2014 to acquire the licensing and relevant assets of Korea MSD's over the counter (OTC) medicine. Bayer AG was advised by BoAML and EY while JPMorgan and Morgan Stanley advised Merck, according to Mergermarket data.

by SooYoung Park and Danbee Lee in Seoul

Sharp agrees to settle CRT price fixing case against Panasonic

Sharp Electronics Corporation and Sharp Electronic Manufacturing Company of America agreed to settle with defendants Panasonic Corporation and its units, including Beijing Matsushita Color CRT Co. Ltd. (BMCC), in a price fixing case involving cathode ray tubes (CRTs), according to 24 March court documents. The parties stipulated dismissal of all claims with prejudice. The settlement is contingent upon final court approval. The litigation stems from an investigation by the US Department of Justice (DoJ) into a price fixing conspiracy by the makers of CRTs, an older technology used in the displays of televisions and computers. Plaintiffs ViewSonic Corporation and Target Corporation reached a settlement with defendant Technicolor SA and its subsidiary in February. Plaintiffs Sears, Roebuck and Co. and Kmart Corporation in February also dismissed their claims against defendant Chunghwa Picture Tubes Ltd. and its subsidiaries. The parties stipulated dismissal with prejudice.

In January, the trustee of the Circuit City Stores Inc. Liquidating Trust and defendant Toshiba Corporation and its subsidiaries reached a settlement and stipulated voluntary dismissal. Plaintiff Dell Inc. and defendant Koninklijke Philips Electronics NV also settled in January. In November 2013, Costco Wholesale Corp. agreed

to dismiss federal and state claims against BMCC and state claims against Samsung SDI Co. Sharp is represented by Paul, Weiss, Rifkind, Wharton & Garrison and Taylor & Co. Law Offices. Panasonic is represented by Winston & Strawn and Weil, Gotshal and Manges. The case is In Re: Cathode Ray Tube (CRT) Antitrust Litigation, 07cv05944 in the US District Court for the Northern District of California.

Proprietary extracts and summaries are provided by PaRR's global team on a daily basis.

Ybrain aims to launch wearable device for Alzheimer's in 2016 ahead of Series B funding

Ybrain, a privately held South Korean wearable medical device developer, plans to launch a wearable product for Alzheimer's disease by the first half of 2016 before it seeks Series B fundraising, said founder and CEO Lee KiWon. The company is currently focused on research and development to commercialize the product and generate revenues as it completed its Series A funding early this year. Ybrain expects to generate annual sales of KRW 10bn (USD 9m) after product launch, Lee said. Ybrain received Series A funding of KRW 3.5bn (USD 3.1m) from domestic investors Stonebridge Capital (KRW 1.5bn), DSC Investment (KRW 1bn), and Company K Partners (KRW1bn) in August 2014, according to the CEO. Ybrain also raised KRW 0.9bn from Korea's Ministry of Trade, Industry & Energy early this year.

Solborn Venture Investment, a South Korean venture capital firm, provided a seed funding of KRW 0.7bn, he said. The company could seek another round of funding but details on size and timing are not finalized since it has not finalized the clinical trials as yet, the CEO said. Ybrain is working with 14 major hospitals in South Korea for clinical trials and has appointed Quintiles Transnational Holdings and Seoul CRO as its Contract Research Organization, he said. Established in February 2013, Ybrain develops big data platforms and medical wearables such as an electric nerve stimulating headband, tentatively named Yband. The products are designed to analyze brain signals and diagnose and cure neurological disorders including Alzheimer's. The company is also considering overseas expansion, especially to the US and China, given the high growth potential of their medical sectors. It could start clinical trials in the respective foreign countries as early as next year, the CEO said. Ybrain, which is made up of engineers from Samsung, signed an R&D technology partnership with Mensia Technology, the unlisted French brain wave analysis company, last September, according to company's website. Lee owns a more than 50% stake in the company as the largest shareholder, he said.

by Jun Young Chun

GemVax & KAEL to raise USD 5m-10m by 2015 for US expansion and R&D

GemVax & KAEL, a listed South Korean vaccine developer, is looking to raise USD 5m-10m by 2015 through a stake sale to investors to fund its US expansion and research & development (R&D), said the company CEO SangJae Kim. The company has acquired Epimmune, a privately held San Diego, US based developer of drugs for genetic and infectious diseases, in 2009, according to the company report. Epimmune plans to go public in the US in the future, Kim mentioned without providing a detailed timeline. In addition, GemVax & KAEL is having internal discussions regarding Asian expansion, Kim added. The company would not hire advisors for its fundraising, a person claiming knowledge said, adding that it could however hire advisors for the potential IPO of its subsidiary in the US. The company has previously mentioned that it plans to further penetrate into the US market, according to a report by Mergermarket in December 2013.

Meanwhile, it will commercialize its therapeutic pancreatic cancer vaccine RIAVAX (GV 1001) this year since the product obtained the approval of the Ministry of Food and Drug Safety (MFDS) in September 2014, according to its investment relations report. GemVax has invested KRW 400bn for the RIAVAX trials, according to a local media report. It has completed Phase I, II and III trial tests in overseas countries including the US, France and the UK, as reported in November 2014. It has been working with UK based Liverpool Cancer Trial Unit on GV 1001, according to a previous report by Mergermarket. Its biological therapeutic portfolios are anti-cancer drugs, peptide treatments and DNA based infectious disease treatment, according to its company report. GemVax & KAEL's accountant is Jungil accounting and its legal advisor is KCL. It has two business units; biotechnology and semiconductor/ display. The company owns four subsidiaries; Samsung Pharmaceutical, Gemvax Technology, Norway based GemVax A/S and Epimmune. Founded in 1989, the company posted KRW 70.6bn in sales and KRW6bn in operating loss as of September 2014, based on its financial report.

Celltrion infliximab biosimilars to be priced 25% lower than J&J -Remicade in Spain

Celltrion Healthcare's and Hospira's Remicade (infliximab) biosimilars will each enter the Spanish market at a 25% discount, said Mercedes Martinez Vallejo, general sub-directorate for Quality of Medicines and Healthcare Products, Spain's Ministry of Health. Martinez Vallejo spoke on the sidelines of the World Pharma Pricing & Market Access Congress in London. Market entry into Spain for Celltrion's Remsima and Hospira's Inflectra is expected March 1st, she noted. Remicade's annual list price in Spain for a fully compliant patient is EUR 10,347, according to a paper by a Spanish patients' association.

Remsima and Inflectra are both brand names of the biosimilar infliximab which is developed and manufactured by Celltrion, a Celltrion spokesperson said. In Europe, The South Korea based company uses a two brand strategy and conducts the product's sales, marketing, and distribution through its partners, including Hospira which uses the brand name Inflectra. In some countries, like in Spain, both Remsima and Inflectra will be marketed and sold, she added. Remsima's price in the UK is at least 30% lower than that of Johnson & Johnson's (NYSE:JNJ) Remicade (imfliximab), according to news reports. The average price for Remicade varies per patient, but for a fully compliant patient the price is around GBP 9,164/patient per year, based on current market pricing. Others outlets have reported that Inflectra is priced 16% below Remicade in Germany but that Remsima is more expensive. Other biosimilars on the market filgrastim, epoetin alfa and human growth hormones carry 30% price reductions to the originator products, said Martinez Vallejo. Celltrion has a distribution agreement with Hospira on Inflectra. Alvogen, in partnership with Hospira, has launched Inflectra into Central and Eastern Europe. Pfizer and Hospira announced 5 February they had entered into a definitive merger agreement under which Pfizer will acquire Hospira, for approximately USD 17bn, according to a Pfizer press release. The transaction is expected to close in the 2015.

Celltrion's market cap is KRW 7.71trn (USD 7bn). Hospira's market cap is USD 15bn.

by Jennifer C. Smith Parker in London

MedyTox in strategic partnership talks to increase Chinese market share

MedyTox, a South Korea based bio pharmaceutical company that specializes in manufacturing botulinum products, is in talks with Chinese companies to establish a strategic partnership in China to increase its market share in the country, a source familiar with the company said. The company has just set up a joint venture with Taiwan based peer Dynamic Medical Technologies (DMT) in February 2015, the source said, adding that the company will select a suitable partner soon. The company is not likely to accept additional approaches from other Chinese candidates since it has already secured a list of potential partners, the source continued. MedyTox is considering various options for its strategic partnership in China. It may set up a JV with the Chinese partner or establish its own branch first, he continued. It is likely to take about two or three years to penetrate the Chinese market, the source added. The KRW 60.1bn (USD 59m) market cap Company's Taiwanese JV will seek to penetrate Taiwan and Chinese speaking markets like Hong Kong, as reported. MedyTox will hold a 60% stake in the JV Medytox Taiwan while DMT will hold 40%, according to a press release on 10, February. The company did not hire a financial advisor for this JV, but hired an undisclosed law firm as its legal advisor, the source said.

In China, Lanzhou Institute of Biological Products is the only legal producer of botulinum products, said an industry source. Its botulinum toxin type A for injection is marketed under the brand name Hengli. However, imported products have dominated the Chinese market, leaving little room for domestic products due to their weak marketing ability. As for the import market, only Botulinum Toxin Type A for Injection, or BOTOX, by the US based manufacturer Allergan is approved to be sold in the Chinese market, according to the website of the Chinese Food Drug Administration (CFDA). BOTOX is distributed by GSK and sub-distributed by Sinopharm in China, according to CFDA. Some Chinese companies such as Hualan Biological Engineering are also eyeing the botox manufacturing industry and are trying to develop the technology, the industry source mentioned. Hualan Biological Engineering could consider partnerships with foreign peers, said its spokesperson. It has been putting effort into the botox industry but has not had any realistic achievement, he added. Lanzhou Biological Institute and Sinopharm could not be reached for. MedyTox is currently generating sales in overseas countries, with exports and domestic sales each accounting for half of total sales, the source noted. MedyTox has entered more than 50 countries, including Japan, Thailand, India and Brazil, according to the company's.

MedyTox owns botulinum toxin, hyaluronic acid filler and toxin detection and antitoxin therapeutics businesses, according to its website. Its main botox brand is Neuronox and its hyaluronic acid filler, Neuramis Deep, temporarily improves facial wrinkles. Its global peers include Allergan, US based Solstice Neuroscience, France based Beaufour Ipsen, and China based Lanzhou Institute of Biological Products, while its domestic peers are Hugel and Daewoong Pharmaceutical, according to the company's financial statement. The company currently exports its products to Asian countries, South American countries and to Ukraine. MedyTox was selected as a WorldClass Advanced Technology Center in 2011 by the Ministry of Knowledge Economy, according to the company's website. Founded in 2000, the company generated KRW 61.5bn in sales and KRW 43bn in operating profits as of September 2014, according to its financial report.

by Soo Young Park in Seoul and Jane He in Shanghai

Min Wu

Analyst, Infinata Bio Pharm Insight

Min has worked with both BioPharm Insight's editorial team and commercial team. She was an account manager for the BioPham Suite in London before relocating back to the New York newsroom. Min was previously a risk arbitrage analyst at sister-publication deal Reporter, where she performed in-depth analysis on large-cap M&A transactions, as well as regulatory-clearance analysis. Prior to deal Reporter, she was a senior research associate at data analytics firm, Haver Analytics. She has a Masters in Financial Management from Pace University, Lubin School of Business. She also holds a B.Sc. in taxation from Tianjin University of Finance and Economics.

Special Report

SPECIAL REPORT I

THE 2ND NEW YORK HEALTH FORUM

SPECIAL REPORT II

PERSONALIZED MEDICINE;
TALK IS CHEAP

Special Report I

The 2nd New York Health Forum

Date: 2/11/15 | Place: Yale Club of New York City | Time: 12:30 ~4:30 pm

The 2nd New York Health Forum with the theme “The Pacific Connection: US-East Asia Pharma Collaboration” was held in Yale Club of New York City on February 11th, 2014. Over 100 individuals including investors, industry leaders, and physicians attended this forum. This forum was a jointed forum with New York Pharma Forum.
Dohyun Cho, PhD, the Chairman of New York Health Forum and Mark Dennish, the Vice President of New York Pharma Forum had given opening remarks to announce the forum. The goal and virtue of New York Health Forum is to build connection among healthcare leaders and business developers to collaborate their knowledge to target the future need in the human health. This forum was particularly important for East Asia pharma companies to expand their business in US or vise versa.

The 2nd New York Health Forum was composed of three sessions which were “Diverse Tracks to Global Market: Journey of Chinese, Japanese and Korean Pharma”, “Fitting into the Ecosystem: New Sustainable Strategies of Collaboration” and “Expansion Strategies of East Asian Pharma Companies: Shifting the Paradigm”.

Session 1: **“Diverse Tracks to Global Market: Journey of Chinese, Japanese and Korean Pharma”**

Mark S. Paxton, JD, EVP of W Medical Strategy Group moderated the first session along with three panelists from Daiichi Sankyo, Simcere Pharmaceuticals, and Yonsung Fine Chemicals.

Session 2: **“Fitting into the Ecosystem: New Sustainable Strategies of Collaboration”**

Kimberly Ha, Senior Director of FTI Consulting moderated the second session along with three panelists from Medidata, Esquared Asset Management, and Labrador Advisors.

Session 3: **“Expansion Strategies of East Asian Pharma Companies: Shifting the Paradigm”**

Last session was moderated by Joe P. McMenamin, MD, JD, Chief Legal Officer of W Medical Strategy Group and along with three panelists from Oracle Investment Management, UK ChemiPharm, and Pfizer.

At the end of each session, panelists and audiences had chance for Q&A. Since networking among the healthcare leaders and business providers were also a significant benefit for attending New York Health Forum, many of them were able to get opportunities to go beyond the forum.

Forum was co-hosted by W Medical Strategy Group and New York Pharma Forum and it was sponsored by Green Cross, Life Sciences Queensland, SLI Production corp, and Rivkin Radler. W Medical Strategy Group will host and organize New York Health Forum in May 21th Thursday. Location will be Explorer’s Club. For further information please visit www.newyorkhealthforum.net.

Mark Dennish who currently serves as Vice President at Daiichi Sankyo explained the importance of collaboration when doing business abroad. He mentioned that “collaboration is essential to companies in East-Asia to expand their business in US.”

Joy Wang who is the US office head of Sincere Pharmaceutical recapped on current status of Chinese companies opening US offices. She mentioned that “it is very important to have partners in US and how to get financial supports for further R&D.”

Howard Kim;
Director of BD for Yonsung Fine Chemical shared some essential tips when partnering with major pharma companies. “Korean pharma companies had been bystanders or observers of U.S. bio-pharmaceutical market so far. Now, they are willing to participate as players, and we are now witnessing increasing number of Korean companies knocking the doors of U.S. market.”

Bryan Spielman, EVP of Medidata mentioned, “It’s clear that using new technology to run clinical trials will make a huge difference in these emerging markets. There will be an interesting change in the way drugs are developed, prescribed and the way they are adhered to. We see a future where you are prescribed a compound as well as an app to ensure adherence. Asia has an opportunity to be out front from a regulatory position, as well. Technology will change how trials are conducted and commercialized.”

Les Funtleyder; Portfolio Manager of Esquared Asset Management has mentioned, “Major pharma and biotech companies are looking more to become capital allocators while minority investments are going to be the way to the future.”

Debra Yu, MD, Managing Director of Labrador Advisors mentioned that “there are lots of potentials in China. Chinese domestic companies are looking to access innovative drugs but at the same time, they want to export their products. In this moment, US is also looking to tab into China pharma market.”

Han Choi, MD, LLM, Principal of Oracle Investment Management talked about the key points which investors seeking in Pharma Companies. He pointed out two key factors which are pricing and volume of sales. He quoted, “Korean pharmaceutical and biotechnology companies have also been transitioning from
a licensing-based business model to models based more on broader partnerships and joint ventures with U.S. and European pharmaceutical companies. This transition is important because if Korean biotechnology companies discover global blockbuster drug candidates, monetizing them in the global market through their own subsidiaries would allow them much greater participation in the overall franchise revenue potential and thus lead to company and sector upward re-ratings.”

Young-Seok Byun, PhD; Head of R&D at UK ChemiPharm discussed the needs and factors to build a GMP facility
in US based on their recent experience. He quoted, “Developing global NCE products had been a long time goal for Korean pharma and biotech companies. But in reality, out-licensing activities were most common business transaction so far. I think building sustainable businesses through direct product revenue recognition will be much better strategy than having
a royalty stream. For such extend, we are looking into acquiring U.S. pharma companies, and more and more Korean companies are recognizing M&A significant collaboration model.”

Yuan-Hua Ding, PhD, Executive Director & Head of Asia/Pacific Pfizer said “it is essential to form external R&D team from academic institutes and partnering with other companies regardless of their business size.”

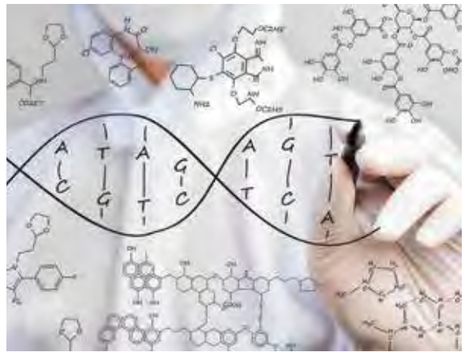
Special Report II

Personalized Medicine: Talk is Cheap

When I was a resident in the late 1970s and early 80s, I met my clinic patients every Friday afternoon. As inpatients, all of them had been under my care, and after their discharges I followed some of them in the clinic throughout my entire residency. Many had hypertension. In those days, the first line therapy was thiazide diuretics. We were taught to select and try a generic thiazide more-or-less randomly from the several on the formulary. If the blood pressure did not respond adequately, we'd go up on the dose. If at maximal doses the desired result was not being achieved, or if side effects at that dose or some lower one were unacceptable, we were to begin a second agent, typically a beta blocker, repeating the process. If that didn't work, we'd try something else. Eventually, we would hit upon a regimen that kept both pressures and side effects within acceptable limits.

Sometimes, this outcome could be achieved with gratifying promptness. Often, however, it took months. During those months the patient's pressure was inadequately controlled, so he was at risk for all the associated morbidity, including strokes and heart attacks. Since most of the patients had a variety of comorbidities, that risk was substantial. Non-response was hardly surprising. A 2001 study showed that patient response to medications of different therapeutic classes ranged from ~80% (analgesics) to ~25% (oncology).[1]

Worse than non-response were adverse reactions. As I was taught on the very first day of my very first course in pharmacology: 1. No drug has a single action; 2. Every drug has side effects. In the 36 years since, I have yet to find a single exception. When I wrote for thiazides, I also wrote for potassium supplementation required by the potassium-wasting so characteristic of that class of drugs. Though not insignificant, the hypokalemia was relatively mild and usually not life-threatening. The same cannot be said of the adverse effects of many other medications. An estimated 2.2 million adverse drug reactions occur each year in the United States, including more than 100,000 deaths.[2]



So, in my clinic I did the best I could, attempting to steer a safe course between inadequate treatment and unacceptable side effects. When I was in training, and indeed until quite recently, no one knew any model better than trial-and-error. Now we do. Unfortunately, we have apparently decided, at least for now, not to pay for it.

[1] Spear, B.B., et al., "Clinical Application of Pharmacogenetics," 7(6) Trends in Molec. Med. 201-204 (2001).
[2] Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society, "Realizing the Potential of Pharmacogenomics: Opportunities and Challenges," Washington, D.C. (2008) at 11, cited in FDA, "Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development," (2013), http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf.

Personalized Medicine Defined

Personalized medicine, also called precision medicine, means providing the right drug to the right patient at the right dose at the right time. [3]More formally, the National Academy of Sciences defines precision medicine as "the use of genomic, epigenomic, exposure and other data to define individual patterns of disease, potentially leading to better individual treatment." [4]

Pharmacogenomics (PGx), one variety of precision medicine, is "the study of variations of DNA and RNA characteristics as related to drug response."[5] PGx studies the role of genetic variation in drug response phenotypes. Pharmacogenomics uses genomic technology to understand the effects of all relevant genes on the behavior of a drug or conversely the effect of a drug on gene expression.[7]

Genetic Variability

An individual's drug response can range from serious, potentially life-threatening adverse drug reactions at one end of the spectrum to therapeutic ineffectiveness at the other. While many factors play a role in the safety and efficacy of a given drug in a given patient, his genetic endowment is critical. Hence, clinical implementation of PGx could avoid adverse drug reactions, maximize drug efficacy, and allow selection of medications to optimize effect for specific indications.[8]

It should come as no surprise that one's genetic makeup can have a significant impact upon the efficacy and toxicity of medications:

Examples of how these [gene-related variations in drug effects] manifest include:

- reduced or no response because of
  - the failure to convert a pro-drug to its active form
  - increased metabolism of an active drug to an inactive metabolite
- increased toxicity because of
  - more rapid conversion to the active form or to a metabolite which is more active than the parent drug
  - failure to metabolize an active drug to inactive metabolite(s).
  - ther genetic variations, such as genes coding for receptors or drug transporters also can influence overall response, e.g., the mu-opioid receptor or P-glycoprotein transporter and the response to opioids. Induction or inhibition of CYP450 activity also can result from a drug-drug or drug-food interaction causing similar manifestations to those resulting from genetic variation.[9]

The Promise of Precision Medicine

Precision medicine promises significant advances in the management of many of the most serious medical problems we face. It allows tumors with specific genetic characteristics, for example, to be identified by a companion diagnostic test, so that the physician knows in advance that he is prescribing a medicine likely to work against the patient's specific neoplasm.

As another example, consider warfarin, the most commonly used anticoagulant. Warfarin is prescribed for long-term treatment and prevention of thromboembolic events, with more than 21 million prescriptions annually in the United States alone. In use for six decades now, warfarin interferes with the function of Vitamin K, needed for the proper function of

clotting factors II, VII, IX, and X, and of certain anticoagulant proteins. Its indications include prophylaxis and treatment of venous thrombosis and pulmonary embolism; prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement; and reduction in the risk of death, recurrent myocardial infarction ("MI"), and thromboembolic events such as stroke or systemic embolization after MI. These are of course extremely serious problems, highly prevalent in the U.S. and in many other nations. Warfarin, then, is a critically important drug. It is readily available and comparatively cheap. Unfortunately, it is also a very dangerous drug, associated with increased risk of hemorrhage, potentially fatal or neurologically devastating. Nor is it easy to use: its therapeutic index is narrow. The warfarin dose needed to achieve target anticoagulation has been shown to vary by as much as 20-fold between patients.[10] Patients on warfarin are monitored by their prothrombin times (PTs) and their international normalized ratios (INRs). When a patient's INR falls below 2.0, thrombosis risk increases, and when it rises above 4.0 serious bleeding risk increases. Hence, the prescribing doctor can easily err by over-treating, perhaps causing serious bleeds, or by under-treating, putting the patient at risk for ischemia, including vital organ ischemia, as a result of thrombotic obstruction of blood flow.

In pharmacogenomics, the doctor has a solution. According to the FDA label for warfarin, identifying genetic variants in two genes --CYP2C9 and VKORC1-- can help determine the right warfarin dose. The VKORC1 gene is involved in the clotting process, and the blood of patients with mutations in this gene does not clot properly. Warfarin inhibits the enzyme vitamin K epoxide reductase, encoded in VKORC1, and decreases the amount of vitamin K available for synthesis of coagulation factors. Warfarin is metabolized by CYP450 enzymes, mainly CYP2C9. Patients with variations in this gene--particularly CYP2C9*2 or *3 alleles--cannot metabolize warfarin well. Both CYP2C9*2 and *3 cause a reduction in warfarin clearance, with 10-fold variation observed from the genotype linked with the highest (CYP2C9*1/*1) to lowest (CYP2C9*3/*3) activity. A combination of the effects of the VKORC1 genotype or haplotype together with those of the CYP2C9 genotype and factors such as age and body size are estimated to account for 35% to 60% of the variability in warfarin dosing requirements.[11]
Because of their genetic makeup, some patients are highly sensitive to warfarin, and for them

[3] See, Draft Guidance for Industry and Food and Drug Administration Staff: In Vitro Companion Diagnostic Devices, http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262292.htm.
[4] National Research Council: Committee on a Framework for Developing a New Taxonomy of Disease, "Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease," Washington, DC: The National Academies Press (2011), https://www.asc.upenn.edu/news-events/press-releases/your-privacy-online-health-information-serious-risk-abuse.
[5] FDA, Guidance for Industry: E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories (April 2008).
[6] Bielinski, S.J., et al., "Preemptive Genotyping for Personalized Medicine: Design of the Right Drug, Right Dose, Right Time Using Genomic Data to Individualize Treatment Protocol," 89(1) Mayo Clin. Proc. 25-33 (2014) at 25.
[7] Ginsburg, G.S. and Willard, H.F., "Genomic and personalized medicine: foundations and applications," 154 Transl. Res. 277–287 (2009) at 282.
[8] Bielinski, supra, at 25, 26.
[9] Twycross, R., et al., "Variability in Response to Drugs," 49(2) J. Pain Symptom Mgmt. 293-306 (2015) at 293.
[10] Lee J.W., et al., "The emerging era of pharmacogenomics: current successes, future potential, and challenges," 86 Clin. Genet. 21–28 (2014) at 22.
[11] Ginsburg, G.S., supra, at 282.

a lower dose is therefore appropriate. A large study just published demonstrates that in the first several months of warfarin therapy, patients who are sensitive or highly sensitive responders are at higher risk of bleeding. In those patients, who can be identified with pharmacogenomic testing, treating with edoxaban, a newer anticoagulant, was much safer than treating with warfarin. [12]In the first 90 days of starting on warfarin, the risk of overt bleeding was 1.3 times greater among sensitive responders and 2.7 times more among highly sensitive responders than in normal responders. During the same period, sensitive and highly sensitive patients who received edoxaban had fewer bleeding complications compared to those who received warfarin; for normal responders either treatment seemed to have comparable safety. As the authors stated in their abstract, "CYP2C9 and VKORC1 genotypes identify patients who are more likely to experience early bleeding with warfarin and who derive a greater early safety benefit from edoxaban compared with warfarin." [13] In light of the value of pharmacogenomics testing to warfarin prescribing, FDA has updated the warfarin product label to include a dosing table with recommended dose ranges according to VKORC1, CYP2C9*2 and *3 genotypes.[14]

Consider another example. Clopidogrel (Plavix) impairs the activation and aggregation of platelets, a key component of the coagulation mechanism. According to its label, clopidogrel is indicated for acute coronary syndrome ["ACS"] (unstable angina, STEMI [ST-segment elevation myocardial infarction], and non-STEMI), recent MI, recent stroke, and established peripheral artery disease. These are serious disorders, with high mortality and morbidity, and all too prevalent in the U.S. population, especially among seniors. Small wonder that clopidgrel is one of the most commonly prescribed medications in the entire therapeutic armamentarium. Since March, 2010, however, the drug's label has also featured a black box warning: "Diminished effectiveness in poor metabolizers." The warning is needed because clopidogrel's activity arises mainly from activation to a metabolite by CYP2C19, and those unable to achieve adequate levels of the metabolite "exhibit higher cardiovascular event rates following ACS or percutaneous coronary intervention than patients with normal CYP2C19 function." "Cardiovascular events" refers to such life-threatening and major organ-threatening disorders as heart attack and stroke. Approximately 2% of whites, 4% of blacks and 14% of Chinese are poor CYP2C19 metabolizers. The label points out that genetic tests can identify the patient's 2C19 genotype, and prescribers are admonished to try a different approach in patients identified as poor metabolizers. For patients afflicted with any of the indications for clopidogrel, distinguishing between those who need that medicine and those who need another can quite literally be a matter of life or death.

Over the past decade, numerous other PGx variants have also been identified, and FDA has required the information to be incorporated into drug labels.[15]

The U.S. Government Recognizes the Value of Pharmacogenomics

Recognition of the promise of precision medicine reaches the highest office in the land. In his 2015 State of the Union address, President Obama spoke eloquently of the benefits now possible with this technology: "I want the country that eliminated polio and mapped the human genome to lead a new era of medicine--one that delivers the right treatment at the right time." Nor was this the first time Mr. Obama had advocated for pharmacogenomics. During his tenure in the Senate, he co-sponsored a bill to promote personalized medicine. S. 3822, 2006, "A Bill To improve access to and appropriate utilization of valid, reliable and accurate molecular genetic tests by all populations thus helping to secure the promise of personalized medicine for all Americans."

> Over the past decade, we have unlocked many of the mysteries about DNA and RNA... Moreover, scientists have translated this genetic knowledge into several treatments and therapies prompting a bridge between the laboratory bench and the patient's bedside.[16]

HHS has also recognized the value of personalized medicine:

> If we are to achieve higher quality care for all Americans at a sustainable cost, we must look to those changes that improve the productivity of healthcare…Personalized medicine seeks to use advances in knowledge about genetic factors and biological mechanisms of disease coupled with unique considerations of an individual's patient care needs to make healthcare more safe and effective. As a result of these contributions to improvement in the quality of care, personalized medicine represents a key strategy of healthcare reform. The potential application of this new knowledge, especially when supported through the use of health information technology in the patient care setting, presents the opportunity for transformational change. Today, it is common for a medical product to be fully effective for only about 60 percent of those who use it. As the medical community is now learning, this in part reflects biological variation among individuals that affects the clinical response to medical interventions. In the past, they have not had the tools or knowledge to understand those differences. In the future, when doctors can truly prescribe the right treatment, to the right person, at the right time, we will have a new level of precision and effectiveness that will provide the knowledge-driven power that is necessary to achieve our highest goals in healthcare reform— including more effective disease prevention and early disease detection.[17]

These pronouncements are not without a measure of fiscal support. The President's 2016 budget, for example, includes his Precision Medicine Initiative, "a bold new research effort to revolutionize how we improve health and treat disease." The Initiative proposes:

- $130 million to NIH for development of a voluntary national research cohort of a million or more volunteers to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing.

[12] Edoxaban is not risk-free, either. No drug is. Apart from its cost, far higher than warfarin's, edoxaban will carry a boxed warning that it is less effective in atrial fibrillation patients with a creatinine clearance >95 mL/min; kidney function should be assessed before starting treatment. FDA has determined that patients with a creatinine clearance >95 mL/min are at greater risk of stroke compared with similar patients treated with warfarin. O'Riordan, M., "FDA Approves Edoxaban for Stroke Prevention in AF and DVT/PE Prevention," Medscape Multispecialty (2015), http://www.medscape.com/viewarticle/837837.

[13] Mega, J.L., et al., "Genetics and the clinical response to warfarin and edoxaban: findings from the randomised, double-blind ENGAGE AF-TIMI 48 trial," Lancet (10 March 2015) http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61994-2/abstract.

[14] Lee, supra, at 23.

[15] US Food and Drug Administration, Table of pharmacogenomic biomarkers in drug labels, http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm. Updated June19, 2013, and cited in Bielinski, et al., supra, at 26

[16] Senator Barack Obama on the Genomics and Personalized Medicine Act (S.976), March 23, 2007, a proposal to create the resources and integrate government stakeholders to advance personalized medicine, quoted in Ginsburg and Willard, supra, at 278. See also, http://www.personalizedmedicinebulletin.com/wp-content/uploads/sites/205/2015/01/3822.pdf.

[17] Kathleen Sebelius, former Secretary, HHS, Testimony given during Senate confirmation hearings, April 2, 2009. See, Personalized Medicine Coalition, "The Case for Personalized Medicine," (2009), http://lbnc.epfl.ch/teaching/BIO-469/2014/TheCaseforPersonalizedMedicine_5_5_09.pdf.

- $70 million to the National Cancer Institute (NCI), part of NIH, to scale up efforts to identify genomic drivers in cancer and apply that knowledge in the development of more effective approaches to cancer treatment.
- $10 million to FDA to acquire additional expertise and advance the development of high quality, curated databases to support the regulatory structure needed to advance innovation in precision medicine and protect public health.
- $5 million to ONC to support the development of interoperability standards and requirements that address privacy and enable secure exchange of data across systems.[18]

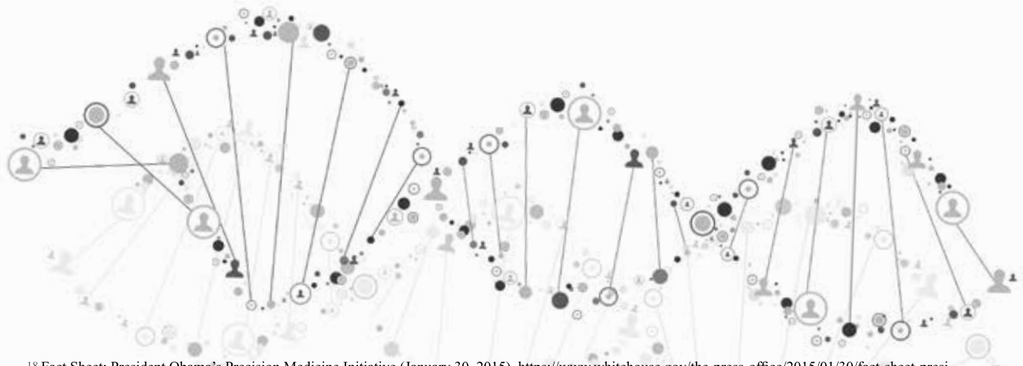
Testifying before a U.S. House subcommittee on March 3 in support of the Initiative, NIH Director Francis Collins, M.D., said that scientific advances are accelerating progress toward a new era of precision medicine.

Historically, doctors have been forced to base their recommendations for treatment on the expected response of the average patient. But recent advances, including the plummeting costs of DNA sequencing, now make possible a more precise approach to disease management and prevention that takes into account individual differences in genes, environments, and lifestyles.[19]

Congressional action suggests interest, as well. The recently released draft 21st Century Cures Act[20] includes a "placeholder" for the Precision Medicine Initiative. Beginning in 2017, the Protecting Access to Medicare Act of 2014 (PAMA)[21] will provide special payment terms under Medicare for certain advanced diagnostic tests.

The Disconnect

Unfortunately, despite support at the highest levels of government, in most parts of the country the genetic testing required to permit personalized prescribing is not covered under Medicare. By a Local Coverage Determination ("LCD") issued last year, a Medicare Administrative Contractor ("MAC") has decided that the evidence for the value of such testing is insufficient to justify coverage. And since commercial carriers often follow Medicare's lead, reimbursement is a problem.



18 Fact Sheet: President Obama's Precision Medicine Initiative (January 30, 2015), https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative. See also, HHS Secretary Burwell's February, 2015 testimony before the House Energy and Commerce Committee's Subcommittee on Health, http://docs.house.gov/meetings/IF/IF14/20150226/103028/HMTG-114-IF14-Wstate-MathewsBurwellS-20150226.pdf.
19 Jayanthi, A., "EHRs critical to precision medicine," Becker's Health IT and CIO Review (6 March 2015), http://www.beckershospitalreview.com/healthcare-information-technology/ehrs-critical-to-precision-medicine.html.
20 See, e.g., http://energycommerce.house.gov/cures.
21 H.R. 4302; Pub.L. 113–93.

Consider clopidogrel, discussed above. Under the LCD, genetic testing of the CYP2C19 gene is considered medically necessary, and thus covered, for patients with ACS undergoing percutaneous coronary interventions who are initiating or reinitiating clopidogrel treatment. Only for those Medicare beneficiaries fitting that description, however, is coverage available. That the label makes clear that the drug is indicated in many other situations, and that poor metabolizers ought to be treated with other therapies, seems to make no difference.

Coverage for genetic testing for patients under consideration for warfarin therapy is even stingier. Testing for the CYP2C9 gene to predict warfarin responsiveness is covered under NCD 90.1 only (coverage with evidence development). That is, Medicare will cover CYP2C9 testing only in the context of a clinical study. All other CYP2C9 testing for warfarin is deemed investigational, and is therefore not covered.

Certain members of the California Clinical Laboratory Association and a Medicare beneficiary who was denied coverage for pharmacogenetic testing are suing HHS, alleging that the use of private contractors by the Centers for Medicare & Medicaid Services to establish local coverage decisions for lab tests is illegal and unconstitutional. That case is pending and its outcome is difficult to predict. In the meantime, however, Medicare coverage is not available.

As a result of the MAC's decision, fewer Medicare beneficiaries will be tested. Fewer doctors will be able to design therapy with the guidance of pharmacogenetic data. More adverse events will occur. Some will be serious; some will be fatal. The problem will be compounded if commercial carriers follow Medicare's lead, as they often do.

All the rhetoric from the President, members of his cabinet, and other national leaders rings rather hollow when we realize that a refusal to cover the services that permit identification of genetic information to guide therapy means that the potential benefits of this technology will not be realized. During residency, I could not have provided to my patients the benefits of pharmacogenomics because the science simply had not been developed yet. In 2015 I would still be unable to offer them the benefits of the technology because, while the science is well-developed, we have not decided to pay for it.

Joseph P. McMenamin, MD, JD

Chief Legal Officer, W Medical Strategy Group

Joseph P. McMenamin, MD, JD is an Executive Vice President of W Medical Strategy Group, specialized in regulatory and litigation of pharmaceutical, medical device, and bio-technologies. Joe has more than 25 years of experience in defending organizations such as these against a variety of allegations in state and federal court. He also has advised them on Internet and marketing communications, informed consent, risk management, regulatory, and contract issues. Joe has counseled hospitals, nursing homes, physicians, and other health care providers with respect to a wide array of legal issues as well, including their interactions with regulated industry. For much of his career, Joe practiced as a partner at McGuireWoods LLP. Previously, he practiced emergency medicine for seven years at hospitals in Pennsylvania and Georgia.

Joe earned a B.S. in chemistry from Washington & Lee University in 1974, an M.D. from the University of Pennsylvania in 1978, and a J.D. from the same university in 1985. Between 1978 and 1981 he served a residency in internal medicine at Emory University Hospital and Grady Memorial Hospital in Atlanta.

Not an actual patient, but is representative of a real patient type. Models are used for illustrative purposes only.

IN THE TREATMENT OF CHRONIC HEPATITIS B (CHB) IN ADULTS WITH COMPENSATED LIVER DISEASE

TAKE A CLOSER LOOK AT LAMIVUDINE (LAM) RESISTANCE

MORE THAN 50% of Americans living with CHB are Asian and Pacific Islanders[1]

NEARLY 70% of Asian Americans were born or have parents born in countries where CHB is common[1]

70% of patients receiving lamivudine develop resistance at 5 years[2]

2% of patients in the United States use lamivudine; **up to 88%** in Asia[3]

Indication and Usage

VIREAD® (tenofovir disoproxil fumarate) is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older.

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on data from treatment of subjects who were nucleoside–treatment-naïve and treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

Important Safety Information

BOXED WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals**
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted**

Warnings and Precautions

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of VIREAD. In all patients, assess estimated creatinine clearance (CrCl) prior to initiating and during therapy. In patients at risk for renal dysfunction, including those who previously experienced renal events while receiving adefovir dipivoxil, additionally monitor serum phosphorus, urine glucose, and urine protein. In patients with CrCl <50 mL/min, adjust dosing interval and closely monitor renal function. Avoid concurrent or recent use with a nephrotoxic agent. Cases of acute renal failure, some requiring hospitalization and renal replacement therapy, have been reported after initiation of high dose or multiple NSAIDs in HIV-infected patients with risk factors for renal dysfunction; consider alternatives to NSAIDs in these patients. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function
- **Coadministration with other products:**
  - Do not use in combination with other products containing tenofovir disoproxil fumarate
  - Do not administer in combination with adefovir dipivoxil
- **Patients coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD
- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with VIREAD. Consider assessment of BMD in adult and pediatric patients who have a history of pathologic bone fracture or other risk factors for bone loss. In a clinical trial conducted in pediatric subjects 12 to <18 years of age with chronic hepatitis B, total body BMD gain was less in VIREAD-treated subjects as compared to the control group. In patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms, hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered

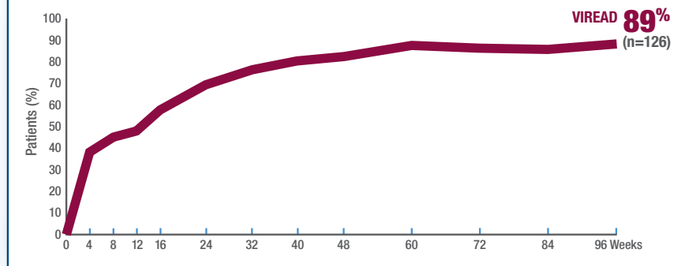
Adverse Reactions

- **In HBV-infected subjects with compensated liver disease:** Most common adverse reaction (all grades) was nausea (9%). Other treatment-emergent adverse reactions reported in >5% of patients treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash

TAKE A CLOSER LOOK AT VIREAD

LAM-resistant VIREAD patients (Study 121)

achieving viral suppression (HBV DNA <400 copies/mL) at 96 weeks of treatment[4,5]



Study 121 was a randomized, double-blind, active-controlled 96-week trial evaluating the safety and efficacy of VIREAD (n=141) compared to an unapproved antiviral regimen (n=139) in subjects with CHB, persistent viremia (HBV DNA ≥1000 IU/mL), and genotypic evidence of LAM resistance. The primary endpoint in Study 121 was HBV DNA <400 copies/mL (69 IU/mL) at Week 96.[4,5]

- As a secondary endpoint, **no HBV resistance (0%)** was detected at **96 weeks** in CHB patients with LAM resistance[4]

Important Safety Information (cont'd)

- **In HBV-infected subjects with decompensated liver disease:** Most common adverse reactions (all grades) reported in ≥10% of patients treated with VIREAD were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%)

Drug Interactions

- **Didanosine:** Coadministration increases didanosine concentrations. Use with caution and monitor for evidence of didanosine toxicity (e.g., pancreatitis, neuropathy). Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD and in patients weighing <60kg, the didanosine dose should be reduced to 200 mg once daily when coadministered with VIREAD
- **HIV-1 protease inhibitors:** Coadministration decreases atazanavir concentrations and increases tenofovir concentrations; use atazanavir given with ritonavir. Coadministration of VIREAD with atazanavir and ritonavir, darunavir and ritonavir, or lopinavir/ritonavir increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity
- **Drugs affecting renal function:** Coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir

Dosage and Administration

- Recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), for the treatment of chronic hepatitis B: one 300 mg tablet, once daily, taken orally, without regard to food
- In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown
- Safety and efficacy in pediatric patients <12 years of age or weighing <35kg with chronic hepatitis B have not been established
- The dosing interval of VIREAD should be adjusted (using recommendations in the table below) and renal function closely monitored in patients with baseline creatinine clearance <50 mL/min

Dosage Adjustment for Patients with Altered Creatinine Clearance

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

[a]Calculated using ideal (lean) body weight.

[b]Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

- The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients
- No dose adjustment is necessary for patients with mild renal impairment (creatinine clearance 50-80 mL/min). Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein should be performed in these patients
- No data are available to make dose recommendations in pediatric patients with renal impairment

Please see Brief Summary of full Prescribing Information, including **BOXED WARNING**, on the adjacent pages.

References: 1. CDC Web site. CDC Features-August 2011: Chronic hepatitis B and Asian & Pacific Islanders. Centers for Disease Control and Prevention. http://www.cdc.gov/Features/ChronicHepatitisB/. Accessed June 26, 2013. **2.** European Association for the Study of the Liver. EASL Clinical Practice Guidelines: Management of chronic hepatitis B virus infection. *J Hepatol.* 2012;57:167-185. **3.** Data on file, Gilead Sciences, Inc. Gilead HBV LAM assessment, IMS MIDAS data. May 2013. **4.** Data on file, Gilead Sciences, Inc. 0121 CSR. **5.** VIREAD Prescribing Information, Foster City, CA: Gilead Sciences, Inc.; October 2013.

300mg tablets®
Viread®
tenofovir disoproxil fumarate

VIREAD® (tenofovir disoproxil fumarate) tablets

Brief summary of full Prescribing Information. Please see full Prescribing Information including Boxed WARNING. Rx only

WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals *(See Warnings and Precautions)***
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted *(See Warnings and Precautions)***

INDICATIONS AND USAGE: VIREAD is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on safety and efficacy data from treatment of subjects who were nucleoside-treatment-naïve and subjects who were treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease *(See Adverse Reactions)*
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease *(See Adverse Reactions)*
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

DOSAGE AND ADMINISTRATION: For the treatment of chronic hepatitis B the recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), is one 300 mg tablet, once daily, taken orally, without regard to food. In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown. Safety and efficacy in pediatric patients <12 years of age with chronic hepatitis B weighing <35 kg have not been established. **Dose Adjustment for Renal Impairment in Adults:** Significantly increased drug exposures occurred when VIREAD was administered to subjects with moderate to severe renal impairment. Therefore, the dosing interval of VIREAD tablets 300 mg should be adjusted in patients with baseline creatinine clearance <50 mL/min using the recommendations in Table 1. These dosing interval recommendations are based on modeling of single-dose pharmacokinetic data in non-HIV and non-HBV infected subjects with varying degrees of renal impairment, including end-stage renal disease (ESRD) requiring hemodialysis. The safety and effectiveness of these dosing interval adjustment recommendations have not been clinically evaluated in patients with moderate or severe renal impairment, therefore clinical response to treatment and renal function should be closely monitored in these patients *(See Warnings and Precautions)*. No dose adjustment of VIREAD tablets 300 mg is necessary for patients with mild renal impairment (creatinine clearance 50–80 mL/min). Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose and urine protein should be performed in patients with mild renal impairment *(See Warnings and Precautions)*.

Dosage Adjustment for Adult Patients with Altered Creatinine Clearance

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

a. Calculated using ideal (lean) body weight.
b. Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients. No data are available to make dose recommendations in pediatric patients with renal impairment.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with VIREAD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations). **Exacerbation of Hepatitis after Discontinuation of Treatment:** Discontinuation of anti-HBV therapy, including VIREAD, may be associated with severe acute exacerbations of hepatitis. Patients infected with HBV who discontinue VIREAD should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, resumption of anti-hepatitis B therapy may be warranted. **New Onset or Worsening Renal Impairment:** Tenofovir is principally eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of VIREAD *(See Adverse Reactions)*. It is recommended that estimated creatinine clearance be assessed in all patients prior to initiating therapy and as clinically appropriate during therapy with VIREAD. In patients at risk of renal dysfunction, including patients who have previously experienced renal events while receiving adefovir dipivoxil , it is recommended that estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein be assessed prior to initiation of VIREAD, and periodically during VIREAD therapy. Dosing interval adjustment of VIREAD and close monitoring of renal function are recommended in all patients with creatinine clearance <50 mL/min *(See Dosage and Administration)*. No safety or efficacy data are available in patients with renal impairment who received VIREAD using these dosing guidelines, so the potential benefit of VIREAD therapy should be assessed against the potential risk of renal toxicity. VIREAD should be avoided with concurrent or recent use of a nephrotoxic agent (e.g., high-dose or multiple non-steroidal anti-inflammatory drugs (NSAIDs)) *(See Drug Interactions)*. Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on tenofovir DF. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered, if needed, in patients at risk for renal dysfunction. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at-risk patients. **Coadministration with Other Products:** VIREAD should not be used in combination with the fixed-dose combination products ATRIPLA®, COMPLERA®, STRIBILD® or TRUVADA® since tenofovir disoproxil fumarate is a component of these products. VIREAD should not be administered in combination with adefovir dipivoxil *(See Drug Interactions)*. **Patients Coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD. It is also recommended that all patients with HIV-1 be tested for the presence of chronic hepatitis B before initiating treatment with VIREAD.

Bone Effects

Bone Mineral Density: In clinical trials in HIV-1 infected adults, VIREAD was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism, suggesting increased bone turnover relative to comparators. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in subjects receiving VIREAD *(See Adverse Reactions)*.

Clinical trials evaluating VIREAD in pediatric and adolescent subjects were conducted. Under normal circumstances, BMD increases rapidly in pediatric patients. In HIV-1 infected subjects aged 2 years to less than 18 years, bone effects were similar to those observed in adult subjects and suggest increased bone turnover. Total body BMD gain was less in the VIREAD-treated HIV-1 infected pediatric subjects as compared to the control groups. Similar trends were observed in chronic hepatitis B infected adolescent subjects aged 12 years to less than 18 years. In all pediatric trials, skeletal growth (height) appeared to be unaffected *(See Adverse Reactions)*.

The effects of VIREAD-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Assessment of BMD should be considered for adults and pediatric patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Although the effect of supplementation with calcium and vitamin D was not studied, such supplementation may be beneficial for all patients. If bone abnormalities are suspected then appropriate consultation should be obtained.

Mineralization Defects: Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with the use of VIREAD *(See Adverse Reactions)*. Arthralgias and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving products containing tenofovir DF *(See Warnings and Precautions)*.

ADVERSE REACTIONS: Clinical Trials in Adult Subjects with Chronic Hepatitis B and Compensated Liver Disease: *Treatment-Emergent Adverse Reactions:* In controlled clinical trials in subjects with chronic hepatitis B (0102 and 0103), more subjects treated with VIREAD during the 48-week double-blind period experienced nausea: 9% with VIREAD versus 2% with adefovir dipivoxil. Other treatment-emergent adverse reactions reported in >5% of subjects treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash. No significant change in the tolerability profile was observed with continued treatment with VIREAD for up to 240 weeks.

Laboratory Abnormalities: in Studies 0102 and 0103 (0–48 Weeks) laboratory abnormalities (Grades 3–4) reported in ≥1% of subjects treated with Viread (n=426) and adefovir dipivoxil (n=215), respectively, were: any ≥Grade 3 laboratory abnormality (19%, 13%); creatine kinase (M: >990 U/L; F: >845 U/L) (2%, 3%); serum amylase (>175 U/L) (4%, 1%); glycosuria (≥3+) (3%, <1%); AST (M: >180 U/L; F: >170 U/L) (4%, 4%); and ALT (M: >215 U/L; F: >170 U/L) (10%, 6%). Laboratory abnormalities (Grades 3–4) were similar in subjects continuing VIREAD treatment for up to 240 weeks in these trials.

Brief Summary (cont'd)

The overall incidence of on-treatment ALT flares (defined as serum ALT >2 × baseline and >10 × ULN, with or without associated symptoms) was similar between VIREAD (2.6%) and adefovir dipivoxil (2%). ALT flares generally occurred within the first 4-8 weeks of treatment and were accompanied by decreases in HBV DNA levels. No subject had evidence of decompensation. ALT flares typically resolved within 4-8 weeks without changes in study medication. The adverse reactions observed in subjects with chronic hepatitis B and lamivudine resistance who received treatment with VIREAD were consistent with those observed in other hepatitis B clinical trials in adults. *Clinical Trial in Adult Subjects with Chronic Hepatitis B and Decompensated Liver Disease:* In a small randomized, double-blind, active-controlled trial (0108), subjects with CHB and decompensated liver disease received treatment with VIREAD or other antiviral drugs for up to 48 weeks. Among the 45 subjects receiving VIREAD, the most frequently reported treatment-emergent adverse reactions of any severity were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%). Two of 45 (4%) subjects died through Week 48 of the trial due to progression of liver disease. Three of 45 (7%) subjects discontinued treatment due to an adverse event. Four of 45 (9%) subjects experienced a confirmed increase in serum creatinine of 0.5 mg/dL (1 subject also had a confirmed serum phosphorus <2 mg/dL through Week 48). Three of these subjects (each of whom had a Child-Pugh score ≥10 and MELD score ≥14 at entry) developed renal failure. Because both VIREAD and decompensated liver disease may have an impact on renal function, the contribution of VIREAD to renal impairment in this population is difficult to ascertain. One of 45 subjects experienced an on-treatment hepatic flare during the 48 week trial.

Clinical Trials in Pediatric Subjects 12 Years of Age and Older with Chronic Hepatitis B: Assessment of adverse reactions is based on one randomized study (0115) in 106 pediatric subjects (12 to less than 18 years of age) infected with chronic hepatitis B receiving treatment with VIREAD (N = 52) or placebo (N = 54) for 72 weeks. The adverse reactions observed in pediatric subjects who received treatment with VIREAD were consistent with those observed in clinical trials of VIREAD in adults. In this study, both the VIREAD and placebo treatment arms experienced an overall increase in mean lumbar spine BMD over 72 weeks, as expected for an adolescent population. The BMD gains from baseline to Week 72 in lumbar spine and total body BMD in VIREAD-treated subjects (+5% and +3%, respectively) were less than the BMD gains observed in placebo-treated subjects (+8% and +5%, respectively). Three subjects in the VIREAD group and two subjects in the placebo group had significant (greater than 4%) lumbar spine BMD loss at Week 72. At baseline, mean BMD Z-scores in subjects randomized to VIREAD were −0.43 for lumbar spine and −0.20 for total body, and mean BMD Z-scores in subjects randomized to placebo were −0.28 for lumbar spine and −0.26 for total body. In subjects receiving VIREAD for 72 weeks, the mean change in BMD Z-score was −0.05 for lumbar spine and −0.15 for total body compared to +0.07 and +0.06, respectively, in subjects receiving placebo. As observed in pediatric studies of HIV-infected patients, skeletal growth (height) appeared to be unaffected *(See Warnings and Precautions)*.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of VIREAD. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: allergic reaction, including angioedema, lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, abdominal pain, hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT), rash, rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, acute renal failure, renal failure, acute tubular necrosis, Fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases), nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria, polyuria, asthenia. The following adverse reactions listed above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia.

DRUG INTERACTIONS: Didanosine: Coadministration of VIREAD and didanosine should be undertaken with caution and patients receiving this combination should be monitored closely for didanosine-associated adverse reactions. Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. When administered with VIREAD, C_{max} and AUC of didanosine increased significantly. The mechanism of this interaction is unknown. Higher didanosine concentrations could potentiate didanosine-associated adverse reactions, including pancreatitis and neuropathy. Suppression of $CD4^+$ cell counts has been observed in patients receiving VIREAD with didanosine 400 mg daily. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD. In patients weighing <60 kg, the didanosine dose should be reduced to 200 mg once daily when it is coadministered with VIREAD. When coadministered, VIREAD and didanosine EC may be taken under fasted conditions or with a light meal (<400 kcal, 20% fat). For additional information on coadministration of VIREAD and didanosine, please refer to the full Prescribing Information for didanosine.

HIV-1 Protease Inhibitors: VIREAD decreases the AUC and C_{min} of atazanavir. Viread should not be coadministered with atazanavir without ritonavir. Lopinavir/ritonavir, atazanavir coadministered with ritonavir, and darunavir coadministered with ritonavir have been shown to increase tenofovir concentrations. Tenofovir disoproxil fumarate is a substrate of P-glycoprotein (Pgp) and breast cancer resistance protein (BCRP) transporters. When tenofovir disoproxil fumarate is co-administered with an inhibitor of these transporters, an increase in absorption may be observed. Patients receiving VIREAD concomitantly with lopinavir/ritonavir, ritonavir-boosted atazanavir, or ritonavir-boosted darunavir should be monitored for VIREAD-associated adverse reactions. VIREAD should be discontinued in patients who develop VIREAD-associated adverse reactions. **Drugs Affecting Renal Function:** Since tenofovir is primarily eliminated by the kidneys, coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of tenofovir and/or increase the concentrations of other renally eliminated drugs. Some examples include, but are not limited to cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides (e.g., gentamicin), and high-dose or multiple NSAIDs *(See Warnings and Precautions)*. In the treatment of chronic hepatitis B, VIREAD should not be administered in combination with adefovir dipivoxil.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category B:* There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, VIREAD should be used during pregnancy only if clearly needed. *Antiretroviral Pregnancy Registry:* To monitor fetal outcomes of pregnant women exposed to VIREAD, an Antiretroviral Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-258-4263. *Animal Data:* Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to tenofovir. **Nursing Mothers: The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV-1.** Samples of breast milk obtained from five HIV-1 infected mothers in the first post-partum week show that tenofovir is secreted in human milk. The impact of this exposure in breastfed infants is unknown. Because of both the potential for HIV-1 transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breast-feed if they are receiving VIREAD. Geriatric Use:** Clinical studies of VIREAD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for the elderly patient should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Patients with Impaired Renal Function:** It is recommended that the dosing interval for VIREAD be modified in patients with estimated creatinine clearance <50 mL/min or in patients with ESRD who require dialysis *(See Dosage and Administration)*.

For detailed information, please see full Prescribing Information. To learn more call 1-800-GILEAD-5 (1-800-445-3235) or visit www.VIREAD.com.

WHY "NEW STANDARD" READY-TO-USE

INNOVATIONS

+

ADVANTAGES

UK INJECTION KIT(FULL KIT)

State of the art
UK Injection Kit

- ✓CLOSED SYSTEM APPLICABLE FOR USP CHAPTER <797>
- ✓REDUCE THE RISK OF MICROBIAL CONTAMINATION
- ✓FASTER PREPARATION TIME WITH READY TO MIX SYSTEM
- ✓REDUCE THE NEEDLE INJURY AND ANTIBIOTIC ALLERGY OF PRACTITIONER
- ✓WIDE RANGE OF ANTIBIOTIC PRODUCT PORTFOLIO
- ✓AND MORE INNOVATIONS & ADVANTAGES

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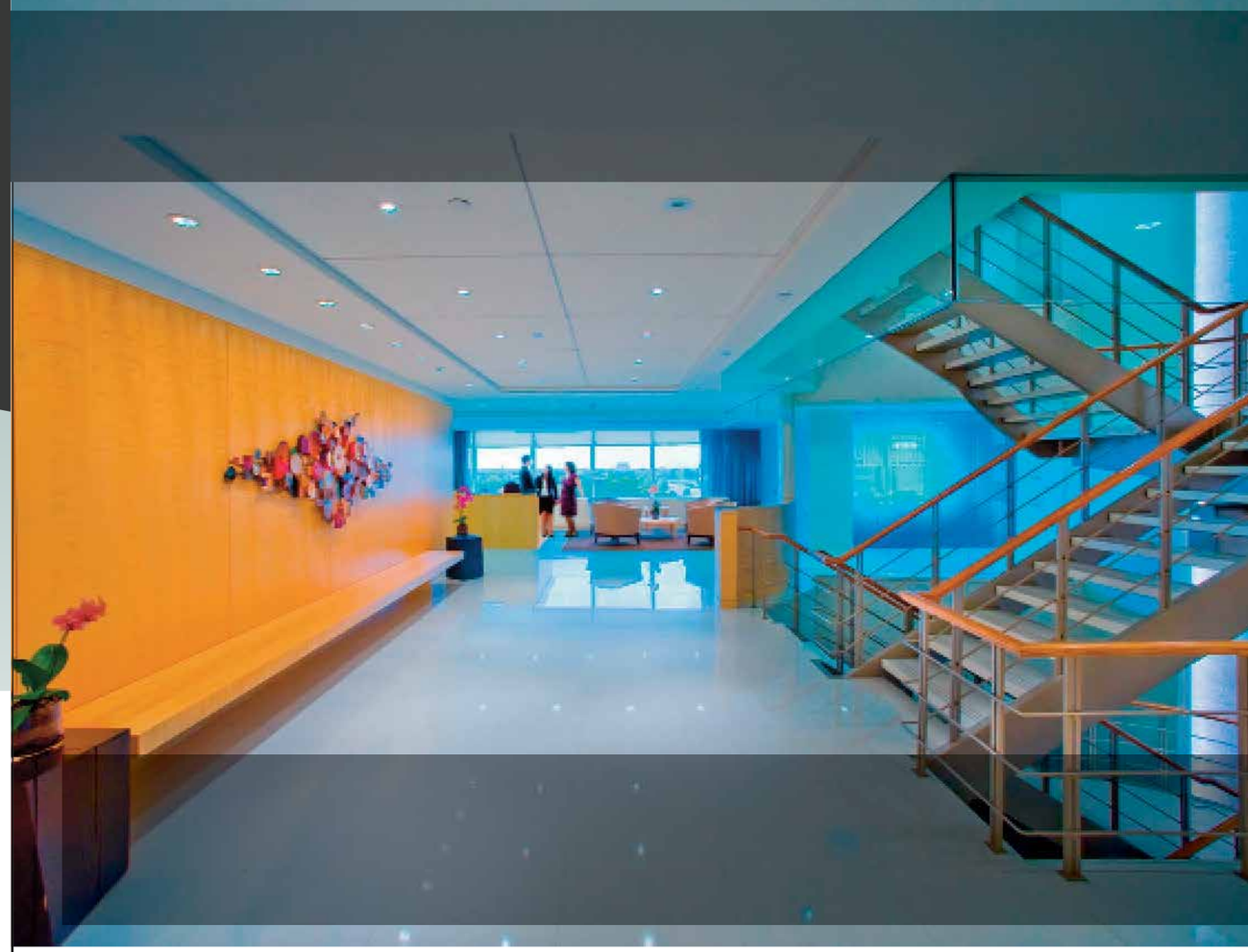
www.ukholdings.co.kr/index_en.html



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Conference Alerts

North America

3rd Innovations in Drug Formulation and Delivery

May 20th to 21st, 2015, San Di, United States

"The 3rd annual Innovations in Drug Formulation & Delivery conference features never-before-heard case studies focusing on the industry's most urgent needs for improving solubility and therapeutic performance.
1.In-depth strategies for designing or transitioning your peptides and biologics into subcutaneous and oral delivery methods
2.Case studies for remaking your bioequivalence and bridging tests to more accurately capture the bioavailability of drugs after a change in delivery method
3.Analysis of the ideal manufacturing and process methods to improve stability, shelf life and bioavailability of amorphous solids
4.Training in the modeling techniques that predict performance of multiple formulations
5.An exclusive interactive workshop devoted to maximizing stability and life cycle access for subcutaneous and oral biologics"
Contact: Evan Ring
Phone: 866-207-6528
Email: info@exlpharma.com
http://atnd.it/20548-0

Neurotherapeutics and Psychosurgery Conference

May 21st to 22nd, 2015, Flint, United States

Conference on ethical and legal issues concerning neuroenhancements and psychosurgery. Submissions from humanities, social and medical sciences, law related disciplines welcome. Revised talks may be published in Journal of Cognition and Neuroethics
Contact: Jami Anderson
Email: anderson@cognethic.org
http://www.cognethic.org/conference_pro_2015a.html

HIV Update: Contemporary Issues in Management

May 28th to 30th, 2015, Boston, United States

Key topics: State-of-the-Art management of HIV-infected patients in both ambulatory and hospitalized settings;
The science of HIV replication and its clinical application;
Comprehensive review of antiretroviral therapy (ART) in the setting of treatment initiation, salvage therapy, and post-exposure prophylaxis;
Diagnosis and management of primary HIV infection;
Detailed discussions of HIV complications, including opportunistic infections, lymphomas, malignancies, and hepatitis B and C co-infections;
Contemporary topics in HIV, including renal disease, endocrine issues, and the management of HPV-related anogenital infection;
Women's health issues in HIV, including management pre and post partum;
Discussions of challenging cases with an expert panel and ample opportunity to ask questions of and interact with the experienced faculty of the Beth Israel Deaconess Medical Center, Harvard Medical School and other prestigious institutions.
Contact: Jennifer Agri
Phone: 617-384-8600
Email: hms-cme@hms.harvard.edu
http://HIVupdateBoston.com

North America

Advances in Cancer Immunotherapy

May 29th to 29th, 2015, Chicago, United States

Specifically designed for clinical oncologists, registered nurses, nurse practitioners, and the entire medical team involved in treating cancer patients with immunotherapy, these introductory, CME- and CNE-certified programs will provide an understanding of basic immunology principles in the clinical application and management of cancer immunotherapy and discuss emerging drugs and concepts in the cancer immunotherapy field
Presented by leading authorities in tumor immunology and cancer immunotherapy, these programs will facilitate understanding of 1) the underlying principles of tumor immunology and immunotherapy, 2) the clinical indications for cancer immunotherapy and appropriate selection of patients, 3) patient management, and 4) the therapeutic effectiveness of immunotherapy to ultimately improve patient outcomes.
Attendees can also take advantage of the opportunity for professional networking that will promote collaboration and scientific exchange with experts, clinical oncologists and other health care providers from the surrounding community.
Contact: Rosanne Stelpflug
Phone: 414-271-2456
Email: education@sitcancer.org
http://www.sitcancer.org/sitc-meetings/aci2015/il

1st International Conference on Medical Ethics, Healthcare Systems & Global Business Issues At Sea

June 6th to 13th, 2015, Miami, United States

The conference will be on a cruise ship. It will have Continuing Education sessions for health professionals as well as Academic Paper Presentation sessions. Papers from the various fields of Business, health, and social sciences are invited
Topics: Patient confidentiality and consent, Medical tourism, Ethics and marketing of health services, Social media and medical ethics , Increasing interference of technology in patient care, Patient data maintenance, Impact of inter-personnel conflict on patient care, Professional behavior and communication by medical office staff, Code of ethics, Gatekeepers for ethical integrity, Legal liabilities and cases pertaining to interns and internships, Legal liabilities and cases pertaining to interns and internships
Contact: Ashish Chandra
Phone: 800-422-0711
Email: Chandra@UHCL.edu
http://www.continuingeducation.net/coursedescription.php?topic=Healthcare_Management_CME_Cruise_Meeting_Caribbean_June_2015

2015 International Conference on Mental Health and Social Work Practice

June 11th to 11th, 2015, Washington DC, United States

The Mental Health and Social Work Practice 2015 International Conference will provide the ideal opportunity to present your projects and experiences to leaders in behavioral health care, physicians and nurse practitioners, psychologists, counselors, therapists, policy analysts, healthcare interior designers, health care clinic owners, project managers, lobbyists, academics, consultants, and researchers. Also, the conference provides an excellent venue for you to present your research and receive quality feedback.
The title and theme of the Mental Health Social Work 2015 Conference is "Mental Disorders, Addictive Diseases, and Culture of Compassion"
Contact: Eric Schwartz
Phone: 240-688-5189
Email: submission@advenaworld.com
http://www.advenaworld.com/speakers--mental-health.html

The International Leadership Development Program for Physicians

June 15th to 26th, 2015, Boston, United States

This program provides training in leadership and management, focused on the clinical and operational challenges senior physicians face as executives. Physicians from around the world will develop skills to be more effective institutional leaders.
At this program, you will build an understanding of your roles and responsibilities as a senior leader while developing practical knowledge about medical center management and operations. You will also learn how to lead teams and motivate others in the context of your personal leadership style. With this knowledge, you will be able to develop and implement strategies to improve health care quality, safety, and patient satisfaction.
Contact: Peter J. Bretton
Phone: 617-432-2100
Email: contedu@hsph.harvard.edu
https://ecpe.sph.harvard.edu/ILD

Europe

10TH PROTEIN KINASES IN DRUG DISCOVERY CONFERENCE
May 7th to 8th, 2015, Berlin, Germany

Over the past decades, protein kinases have proven to be an important class of drug targets for the pharmaceutical industry. This meeting seeks to create a forum for scientists from both industry and academia to gather and discuss the most recent advances in kinase inhibitor research. Leading researchers will present on hot topics such as irreversible inhibitors, allosteric inhibitors, and many more. In addition to scientific talks, dedicated networking sessions will allow attendees to better dialogue on how kinase inhibitor discovery will continue to expand beyond oncology into applications in CNS disorders, inflammation, and more.
Topic included: New Tools and Technologies in Kinase Drug Discovery, The Role of Biomarkers in Kinase Drug Discovery, Novel Approaches in Reversible and Irreversible Kinase Inhibitors, Non-Classical Kinase Inhibitors for Overcoming Challenges in Selectivity, Kinase Inhibitors in Oncology, Kinase Inhibitors: Towards New Therapeutic Areas Beyond Cancer
Contact: Kristen Starkey
Phone: 626-256-6405
Email: infogtcbio@gtcbio.com
https://www.gtcbio.com/conferences/protein-kinases-drug-discovery-overview

21ST COGI CONGRESS: INNOVATION IN REPRODUCTIVE MEDICINE
May 14th to 16th, 2015, Frankfurt, Germany

This Controversies Congress will provide a unique platform for world leaders and international participants to discuss innovation in the field of Reproductive Medicine. Discussions and plenary lectures will facilitate academic dialogue, which will raise the discipline's most dynamic and challenging clinical and technological questions. We have chosen to cover today's most pressing topics, such as new and emerging drugs, stimulation protocols, the use of stem cells in reproductive medicine, biomarkers, New aspects in luteal phase support, live surgery in treating endometriosis, and the evolving role of genetics in RM.
The COGI Congress aims to bridge the gaps between the clinical data available today and newly acquired knowledge, and their application in clinical practice. The program's structure enables international and local experts to share and compare experiences, while allowing ample time for audience/speaker discussion
Contact: ComtecMed
Phone: 972-3-566-6166
Email: cogi@comtecmed.com
http://www.cogi.org/Frankfurt/Default.aspx

3RD WORLD CONGRESS ON TARGETING INFECTIOUS DISEASES:TARGETING EBOLA 2015
May 25th to 29th, 2015, Paris, France

Targeting Ebola 2015 will provide a unique and cutting edge conference to discuss the recent advances, strategies and challenges of all Ebola fields. The keynote lectures given by leading scientists, as well as poster presentations covering various aspects of Ebola infection.
During Ebola 2015 a Practical approach will address and discuss different strategies and challenges (short and long term) across the entire innovation cycle. We will discuss about the vaccine candidates available and the ability to roll out clinical trial vaccination programmes in EU / Africa, and how to conduct studies in areas where Ebola virus disease is endemic. We will highlight how a rapid diagnostics can detect EVD at acceptable costs and with very high sensitivity and specificity. We will invite academics and industrials to discuss strategies to treat Ebola infection by innovative drugs, Immunotherapy and others. We will take en consideration the Ethical and political issues of this strategic problem.
Contact: Céline Mercier
http://www.targeting-ebola.com

Global Cosmetics Compliance Summit
June 8th to 10th, 2015, Amsterdam, Netherlands

The Second Global Cosmetic Compliance Summit will bring together 70+ Directors of Regulatory Affairs, Heads of Compliance & Brand Owners from an international audience to tackle the regulatory challenges across the globe and exploit growth in emerging and existing markets.
- Use real life case studies from Lucy Anabella, Antonia Burrell Holistic Skincare & McBride: SME's that have rapidly expanded in the cosmetic compliance sphere
- Overcome the toughest compliance challenges with expert insight from Avon & La Prairie Group including REACH & The Complexity of Chinese Compliance
- Hear from the Federal Trade Commission & Cosmetics Europe Design with first hand, up to date knowledge of US legislation & ASEAN member states
- Soak up the knowledge from Givaudan & Kimberly Clark's intensive workshops and presentations to shed light on the complexities of product labelling, REACH registration and CLP/classification
- Explore and understand the ambiguity of borderline cosmetics and the intersecting regions with the expertise of Teva"
Contact: Emily Powell
Phone: +44 (0) 20-7368-9300
Email: enquire@iqpc.co.uk
http://www.globalcosmeticcompliance.com/

Sun Protection Conference London
June 9th to 10th, 2015, London, United Kingdom

Can Nature help us to develop future sun protection strategies? The first sunscreens protected against sun burning and were essentially UVB protectants with low factors that allowed easy tanning of the skin.
Modern sunscreen products may still provide highly heterogeneous attenuation of the sun's rays not necessarily consistent with the quality of electromagnetic radiation experienced in Nature. As an industry we have been driven by the quantity of protection as indicated by the SPF and not necessarily the quality of protection. A level of UVA protection is now a requirement for most markets worldwide, but is this sufficient in terms of quality and quantity of broadspectrum protection? Are there other wavelengths that we should consider in our protection strategies? What does natural protection tell us about the biological need?
Following the theme of the conference this year, we will explore and re-examine sun product development strategies in terms of quality of protection, natural substances and human behaviour. In addition, internationally renowned expert speakers have been invited to give an update on sun care technology, testing and worldwide regulations affecting the development, testing, and promotion of sun products.
Contact: Julia Thatcher
Phone: +44 207-828-2278
Email: info@summit-events.com
http://atnd.it/21620-2

CONNECTED HEALTH DEVICES
June 15th to 17th, 2015, Berlin, Germany

Key topics:
- Benefit out of visionary perspectives on medical device connectivity presented by the most advanced medical device, medtech companies and healthcare providers
- Invest successfully in connected medical devices and gain strategic insights how to overcome security and data privacy challenges
- Analysing ROI when investing in wireless medical devices connected to healthcare network platform
- Apply innovative features into design of the device and useful product add-ons to improve competitive advantage
- Improve analytics and big data management capabilities to maximise reliability and efficiency of patient monitoring and clinical trials
Contact: Kristiyan Sokolov
Phone: 357 22 849 408
Email: KristiyanS@marcusevansuk.com
http://www.marcusevans-conferences-paneuropean.com/marcusevans-conferences-event-details.asp?EventID=22037&SectorID=27#.VTfs2iFVhBc

2015 IIER THE 2ND INTERNATIONAL CONFERENCE ON RECENT ADVANCES IN MEDICAL SCIENCE (ICRAMS-2015)
June 20th to 20th, 2015, Paris, France

the Conference of 2nd ICRAMS 2015 is sponsored by International Institute of Engineers and Researchers (IIER). It aims to be one of the leading international conferences for presenting novel and fundamental advances in the fields of Medical Science. It also serves to foster communication among researchers and practitioners working in a wide variety of scientific areas with a common interest in improving Medical Science related techniques.
2014 is the first year of ICRAMS, This is going to be the Second ICRAMS it will be held every year since 2014, the conference will be a international forum for the presentation of technological advances and research results in the fields of Medical Science. The conference will bring together leading researchers, engineers and scientists in the domain of Medical Science interest from around
Phone: +85 259198048
Email: info@theiier.org
http://theiier.org/Conference/France/4/ICRAMS/index.php

Europe

15TH ISANH ANTIOXIDANTS WORLD CONGRESS
June 22nd to 23rd, 2015, Paris, France

The originality of this international conference is to be divided on three days. The first day will be dedicated to the workshop on oxidative stress evaulation and biomarkers. The second and third days will be dedicated the plenary sessions.
The Scientific Committee invited Pr Miroslav Radman to provide his vision about the science of Oxidative Stress & Redox Medicine. He will introduce and conclude the two-days conference and will discuss about Is Oxidative Protein Damage as the Root Cause of Aging and Age-Related Diseases?
Four sessions will be discussed by major and short oral presentations and will highlight hot topics such as:
Positive vs Negative Effects of ROS and Antioxidants
All controversies and contradictions will be discussed by inviting different speakers to underline the subtility of ROS vs antioxidants effects (P. Calderon, P. Lindhal, M. Nikiforov).
Peroxisome and redox homeostasis will be presented by Pr. S. Savary.
Dr Ben Schöttker will present some clinical studies about oxidative stress serum markers and mortality.
Dr M. Ricchetti will highlight a novel paradigm for oxidative and nitrosative stress in ageing.
Different speakers will highlight the impact of oxidative stress in different diseases (liver, renal, neurodegenerative, heart, ocular diseases)
Few industrials will present their innovative researches related to oxidative stress & antioxidants such as:
- L'Oréal: New study about Nrf2 Activation by Resveratrol & skin protection
- Nestlé: Role of Mitochondrial Activation
- BASF: Antioxidant Activity of Cocoa Stem Cells Extract for Extrinsic and Intrinsec Cytoprotection
Contact: Céline Mercier
http://www.isanh.net

Asia

BIOSIMILARS ASIA 2015
May 19th to 22nd, 2015, Shanghai, China

At IBC's Biosimilars Asia Conference, top industry players will explore practical strategies for gaining access to emerging markets, clarifying regulatory pathways and clinical approvals, evaluating business models, risks and investment opportunities, pricing and commercialization strategies and successful case studies.
- Gain in-depth content from leading biosimilars companies and case studies on market access and commercialization strategies
- Understand the latest development in regulations and Government pricing plans in China, EU, US, Korea and India, how to access these markets and gain approvals
- Insights on key success factors for entering the biosimilars investment space with different business models as well as developing win-win partnerships
- Learn innovative and cost effective approaches in biosimilars production and development
- Gather the latest market intelligence and analysis and identify new trends and opportunities in Biosimilars R&D, contract manufacturing and commercialization in Asia
Contact: Rita Parasurum
Phone: +65 6508 2482
Email: Rita.Parasurum@ibcasia.com.sg
http://www.biosimilarsasia.com

World Vaccine Congress Asia 2015
June 3rd to 4th, 2015, Singapore

"Sustainable innovation in Asia's vaccine industry. Year on year the event delivers an impeccable speaking faculty & a top tier conference delegation made up of senior decision makers & industry figureheads. Meet & learn from key vaccine stakeholders.
Learn from Asia's top 10 public health leaders on Asia's most pressing unmet medical needs, Explore reimbursement policies and foster key partnerships with Asian pharmas, biotechs and research institutes, Develop cross regional strategies for emerging markets, Learn how to outsource vaccine manufacturing while maintaining quality, Discover strategies in conducting vaccine clinical trials that are cost effective in Asia "
Contact: Justine Williams
Phone: +44 (0)20-7608-7029
Email: justine.williams@terrapinn.com
http://www.terrapinn.com/conference/vaccine-congress-asia/index.stm

3rd International Conference on Healthcare and Life Science Research (ICHLSR)
June 12th to 13th, 2015, Singapore

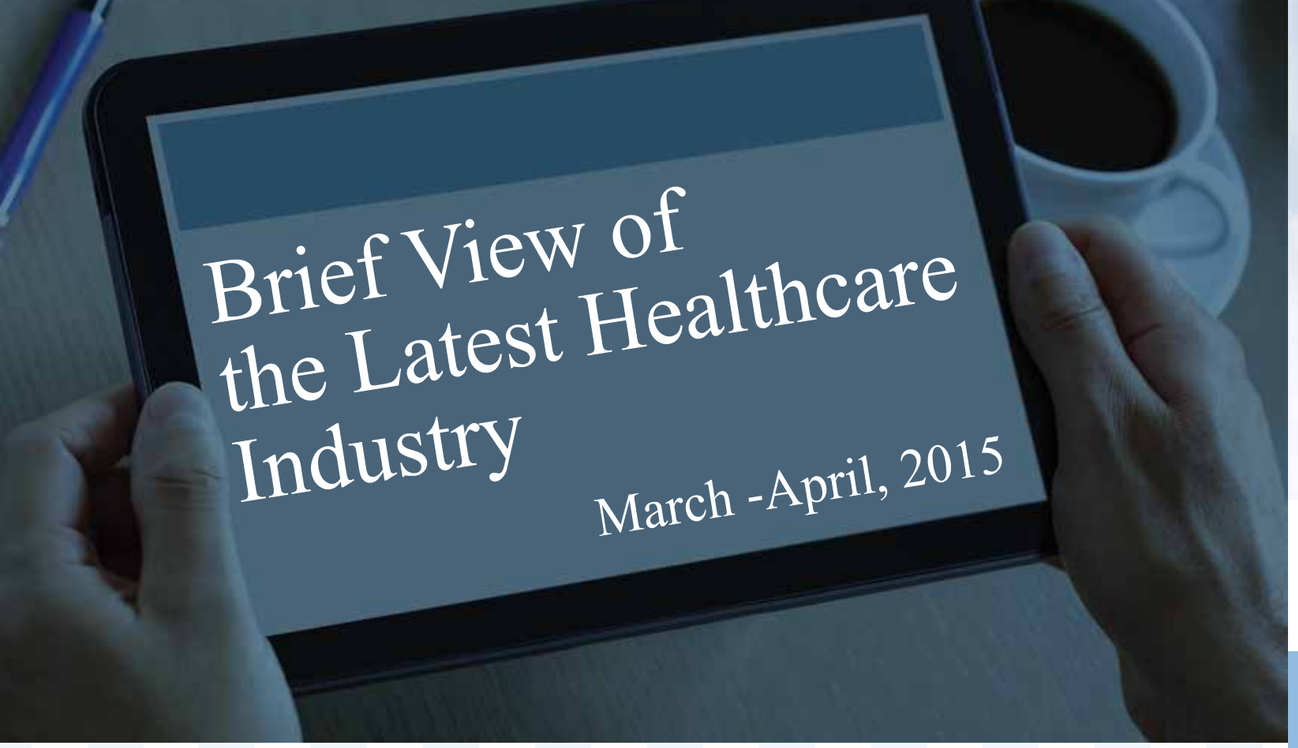
Conference Issues
Recent research trends in life-sciences and healthcare for development of:
- Understanding of life-processes for possible academic, therapeutic or commercial applications
- Solutions for challenges in academics and practice
- Technologies for cleaner, healthier and sustainable environment
- Advanced technologies, devices, protocols and best practices
- Techniques for addressing sustainable food and energy challenges
- Innovations and ideas for improving the quality of health-care and the quality of life
- Novel therapeutic techniques
- Understanding of challenging diseases, epidemics and their management
- New imaging techniques and rapid diagnostics systems
- Innovative digital healthcare systems
- Management practices, operations and Logistics innovations for health and pharma industry
- Medical tourism
- Green and sustainable hospitals and rehabilitation centers
- Effective public health and sanitation models
- Alternative medicine and therapies
- Affordable medical care systems and estimation of economic impact on end-users
- Technological, Social, Economic and Psychological challenges on Health Industry
- Novel rehabilitation techniques
- Innovation in Medical Education
- Disease modeling techniques
- Drug discovery, trials and development
- Other issues of interest related to healthcare and life-sciences
Contact: Dr. Krishna
Phone: +91 94628 32013
Email: info@grdsweb.org
http://ichlsr3.weebly.com/

2ND ANNUAL MICROBIOLOGY AND INFECTIOUS DISEASES ASIA CONGRESS
June 23rd to 24th, 2015, Singapore

In keeping with Oxford Global's highly successful life science congress series, an expert panel of 40 speakers will present a full conference programme covering the topics outlined below. These topics have been compiled as a result of a comprehensive research process undertaken with our advisory board members including Professors, Senior Research Fellows and Directors from leading academic and research institutions.
Cutting Edge Detection Technologies And Molecular Diagnostics, Novel Insights Into Clinical Microbiology, Advances In Microbial Genomics And Genome Sequencing, Recent Breakthroughs In Infectious Diseases
Contact: Steph Punfield
Phone: +65 63455770
Email: s.punfield@oxfordglobal.co.uk
http://www.microbiology-asia.com/download-agenda-marketing-2/

2015 4TH INTERNATIONAL CONFERENCE ON NUTRITION AND FOOD SCIENCES (ICNFS 2015)
June 25th to 26th, 2015, Bangkok, Thailand

The primary goal of the conference is to promote research and developmental activities in Nutrition and Food Sciences. Another goal is to promote scientific information interchange between researchers, developers, engineers, students, and practitioners working in Thailand and abroad. The conference will be held every year to make it an ideal platform for people to share views and experiences in Nutrition and Food Sciences and related areas
Contact: Ms. Eve Li
Phone: +852-3500-0137
Email: icnfs@cbees.org
http://www.icnfs.org/



March

1. New compound may lead to development of cheaper anti-cancer drugs 03/02/2015

A new compound developed at the University of Toronto Scarborough could play an important role in developing cheaper anti-cancer drugs.
Professor Bernie Kraatz, chair of the Department of Physical and Environmental Sciences at U of T Scarborough, has developed a new compound that can be used to monitor the biochemical processes involved with a group of enzymes called protein kinases.
The prevailing form of monitoring kinase activity involves the use of radioactive isotopes, which is costly because the isotopes are expensive to use and have a short shelf life. They are also difficult to work with because of the regulations associated with their handling and disposal.
http://www.medicalnewstoday.com/releases/290030.php

2. Synthetic biology breakthrough leads to cheaper statin production 03/03/2015

University of Manchester researchers, together with industrial partner DSM, have developed a single-step fermentative method for the production of leading cholesterol-lowering drug, pravastatin, which will facilitate industrial-scale statin drug production.
In a study published in Proceedings of the National Academy of Sciences, the researchers have devised a single-step fermentative method for the industrial production of the active drug pravastatin that previously involved a costly dual-step fermentation and biotransformation process.
http://www.medicalnewstoday.com/releases/290116.php

March

3. FDA approves first biosimilar product Zarxio 03/09/2015

The U.S. Food and Drug Administration has approved Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States.
Sandoz, Inc.'s Zarxio is biosimilar to Amgen Inc.'s Neupogen (filgrastim), which was originally licensed in 1991. Zarxio is approved for the same indications as Neupogen, and can be prescribed by a health care professional for:
- patients with cancer receiving myelosuppressive chemotherapy;
- patients with acute myeloid leukemia receiving induction or consolidation chemotherapy;
- patients with cancer undergoing bone marrow transplantation;
- patients undergoing autologous peripheral blood progenitor cell collection and therapy; and
- patients with severe chronic neutropenia.

http://www.medicalnewstoday.com/releases/290537.php

4. FDA involved in case after approving psych meds that cause boys to grow breasts 03/10/2015

It's not often that the FDA gets sued for anything, but a powerful Philadelphia legal firm that handles whistleblower and class action cases throughout the nation, Sheller, P.C., has petitioned the Federal Court to demand the FDA follow through with black box warnings for Johnson & Johnson's drug Risperdal or remove its pediatric approval.
The FDA had ignored Sheller's requests to allow the legal firm to release documents held by drug company Johnson & Johnson and its subsidiary Janssen that would prove the necessity of withdrawing the FDA's 2006 approval of Risperdal for pediatric prescriptions or at least demand black box warnings.
By November 2014, the FDA simply denied all legal actions from Sheller and dismissed their motions to proceed toward a black box warning or remove the drug's pediatric prescription classification. So Sheller has filed a suit which would insist that a federal judge issue an injunction to the FDA for either issuing a black box warning or removing the drugs from pediatric use.
The law under which Sheller is suing the FDA is the Administrative Procedures Act (APA). According to Epic.org: ""The APA serves to police improper agency behavior, protect public safety, and secure proper entitlements. The APA governs all three main agency functions: rulemakings, adjudications, and licensing.
http://www.naturalnews.com/048936_psych_meds_sexual_development_FDA.html

5. Remsima (infliximab) accepted for restricted use in NHS Scotland by the Scottish Medicines Consortium 03/11/2015

Patients in Scotland suffering from inflammatory conditions including rheumatoid arthritis (RA), Crohn's Disease (CD), ulcerative colitis (UC), and psoriasis will now have access to a new wave of biological medicines. Remsima® (infliximab) is a new biosimilar medicine which has the potential to bring significant savings to the NHS without compromising patient care. Patient access follows a review of Remsima by the SMC, which has accepted Remsima for restricted use in line with SMC and Health Improvement Scotland (HIS) advice for the originator medicine Remicade® (infliximab), in RA, UC (adults and paediatric), CD (adults and paediatric), psoriasis and psoriatic arthritis.
http://www.medicalnewstoday.com/releases/290661.php

6. New test uses human stem cells to identify dangerous side effects of drugs 03/11/2015

Scientists at Imperial College London have developed a test that uses combinations of cells from a single donor's blood to predict whether a new drug will cause a severe immune reaction in humans.
The test could avert disasters like the 2006 trial of the drug TGN1412, which led to six healthy young men being admitted to intensive care with multiple organ failure. The volunteers receiving TGN1412 experienced a catastrophic inflammatory reaction called a cytokine storm.
http://www.medicalnewstoday.com/releases/290646.php

7. New Rules Are Issued for Testing of Medical Devices 03/12/2015

FDA has released a new guidelines for testing procedures of reusable medical devices. It issued the new requirements in the wake of news that two people in a Los Angeles hospital had died from a deadly bacteria traced to medical scopes. The changes will apply to new devices that the F.D.A. approves, not to the ones on the market that have led to the infections. The F.D.A. has said it received 75 reports from January 2013 to December 2014 of bacterial infections across the country believed to be linked to duodenoscopes. See the new guideline: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf
http://www.nytimes.com/2015/03/13/health/policy/new-rules-are-issued-for-testing-of-medical-devices.html

8. #BeCrueltyFree South Korea campaign welcomes cosmetics bill requiring mandatory use of alternatives, but loopholes must be closed 03/12/2015

Humane Society International's #BeCrueltyFree South Korea campaign joined Congresswoman Moon Jeong-Lim and officials on 11 March at the National Assembly to witness the launch of a Korean bill that marks an initial milestone towards ending animal testing of cosmetics in the country. The #BeCrueltyFree campaign has been working with the Congresswoman over the past two years, including intensive discussions last week regarding bill language. Most recently, the campaigners also held a public event with TV star Sam Hammington and LUSH Cosmetics to call for the bill to be an effective ban on cosmetics cruelty.
http://www.medicalnewstoday.com/releases/290767.php

9. Teva to Buy Auspex, an American Drug Developer, for $3.2 Billion 03/30/2015

Teva Pharmaceutical had agreed to acquire Auspex Pharmaceuticals, a developer of drugs that treat people with movement disorders, for about $3.2 billion in cash. Teva will pay $101 a share for Auspex. Including debt, the deal is worth $3.5 billion, and the boards of both companies have approved it.
http://www.nytimes.com/2015/03/31/business/dealbook/teva-to-buy-auspex-an-american-drug-developer-for-3-2-billion.html

April

10. More research needed on use of 'smart drugs' by healthy people 04/01/2015

Rearchers have called for the pharmaceutical industry, governments and medical organizations to work together to investigate the consequences of long-term use of cognitive-enhancing drugs by healthy individuals.
http://www.medicalnewstoday.com/articles/291757.php

11. FDA issues final guidance on the evaluation and labeling of abuse-deterrent opioids 04/03/2015

The U.S. Food and Drug Administration has issued a final guidance to assist industry in developing opioid drug products with potentially abuse-deterrent properties.
Opioid drugs provide significant benefit for patients when used properly; however opioids also carry a risk of misuse, abuse and death. To combat opioid misuse and abuse, the FDA is encouraging manufacturers to develop abuse-deterrent drugs that work correctly when taken as prescribed, but, for example, may be formulated in such a way that deters misuse and abuse, including making it difficult to snort or inject the drug for a more intense high. While drugs with abuse-deterrent properties are not "abuse-proof," the FDA sees this guidance as an important step toward balancing appropriate access to opioids for patients with pain with the importance of reducing opioid misuse and abuse.
* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf
http://www.medicalnewstoday.com/releases/291920.php

12. Amphetamine-like stimulant remains in dietary supplements 2 years after FDA discovery 04/08/2015

The 2014 study from the Food and Drug Administration (FDA), published in the Journal of Pharmaceutical and Biomedical Analysis, revealed that nine of the tested 21 dietary supplements marketed for weight loss, improved cognitive function or enhanced athletic performance containing a plant extract called Acacia rigidula also contained beta-methylphenylethylamine (BMPEA).
BMPEA is a synthetic compound closely related to amphetamine. Though the safety of the substance has not been tested in humans, studies in cats and dogs have shown it to increase blood pressure and heart rate - conditions known to raise the risk of heart attack and stroke in humans.
But despite the FDA's findings, it seems the organization has taken no action to enforce the removal of BMPEA from dietary supplements or warn consumers about the potential risks.
*http://www.ncbi.nlm.nih.gov/pubmed/24176750 J Pharm Biomed Anal. 2014 Jan;88:457-66. doi: 10.1016/j.jpba.2013.09.012. Epub 2013 Oct 5.
http://www.medicalnewstoday.com/articles/292100.php

13. Making food more 'porous' could reduce its salt content 04/13/2015

Scientists from the University of Illinois have found that manipulating the porosity of food during manufacturing can affect its health benefits.
Much of the salt that is added to food for flavoring is not released into our mouths, which means that a lot of salt content is wasted. The Illinois researchers wanted to see if they could release more salt during chewing. The implications of this would be no difference in terms of taste to the consumer, but food manufacturers would not have to add as much salt as before.

They attempted to do this by targeting a certain fat-protein emulsion structure to increase the porosity of the food. When the porosity of the food was increased, the researchers found that the foods broke apart differently when chewed, which exposed more surface area and increased the saltiness.
http://www.medicalnewstoday.com/articles/292276.php

14. L'Oreal says demand slowed in Europe for mass beauty 04/20/2015

The market for mass beauty products in western Europe had slowed in the early part of the year but was still growing moderately in North America as it posted a 14.1 percent rise in first-quarter sales according to L'Oreal. Looking forward, L'Oreal forecast sales growth in the first quarter would be below its average for the year due to an improvement in demand for mass market consumer beauty products later in the year.
http://www.reuters.com/article/2015/04/20/us-l-oreal-sales-idUSKBN0NB1XD20150420

15. FDA: Medtronic Must Stop Most Sales of Synchromed Drug Pumps 04/27/2015

The Food and Drug Administration says Medtronic must stop most sales of its implantable drug pumps after years of uncorrected problems. The FDA has filed a court order against Medtronic that says the medical device giant must halt most production and distribution of its Synchromed II drug pumps, which are implanted devices used to treat patients with cancer, chronic pain and severe muscle spasms. Medtronic will be legally required to hire an outside expert to help correct the problems. The FDA issued the company three warning letters about quality control and manufacturing problems at its drug pump facility in Columbia Heights, Minnesota between 2006 and 2013. FDA inspectors visited the plant five times over that period, the agency said in a Monday statement.
http://abcnews.go.com/Health/wireStory/fda-moves-halt-medtronics-production-drug-pump-30623194

16. Mylan Rejects Teva's $40 Billion Takeover Offer 04/27/2015

Mylan rejected a $40 billion takeover bid from an Israeli competitor, Teva. Mylan firmly and sharply rejected Teva's bid to become the industry's biggest generic drug company, deriding its unwanted suitor as a tangle of flawed corporate culture and mismanaged operations. Mylan will not begin negotiating unless a bid surpasses $100 a share, while Teva is offering about $82 a share.
http://www.nytimes.com/2015/04/28/business/dealbook/mylan-rejects-tevas-40-billion-takeover-offer.html

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