February 2015 - ISSUE 5

WKMJ

World Korean Medical Journal

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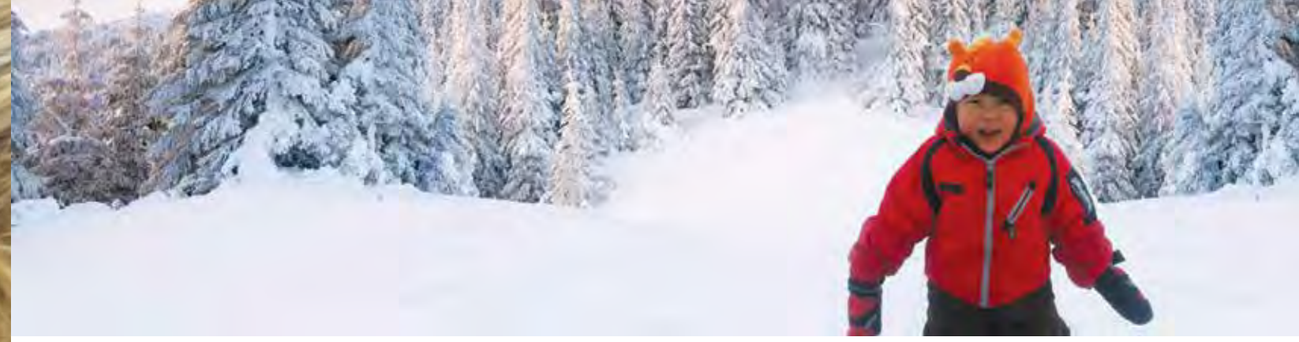

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MAIN OFFICE 210B Sylvan Ave., Englewood Cliffs NJ 07632
Email. info@wmedicalstrategy.org
Tel. 201.402.1400
Fax. 201.430.2472

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FROM THE PUBLISHER

Dear Readers,

The number of Koreans living overseas has been rising consistently since 1990, and now, exceeds 7.2 million. Human resources of the Korean Diaspora are enormous, and are well demonstrated in many fields. World Korean Medical Organization (WKMO) alone has 30,000 physicians of Korean heritage scattered throughout the world, outside of the Korean peninsula. In the face of globalization and trans-nationalism, WKMO promotes building a network, linking physicians of one country to another, creating platforms for collaboration.

The upcoming WKMO European Forum in London on March 21, 2015, exemplifies this network building. Colleagues from Asia, South and North America, Middle East, and Europe will gather to discuss trans-cultural healthcare and global initiatives. We hope to enhance the value and the need of networking and increase productivity of our vast human resources.

In this issue of WKMJ, we feature Dr. Philip Jaisohn(Jae-Pil Seo) and his work. As one of the most distinguished men in the history of Modern Korea, he was the first naturalized Korean American and the first Korean to obtain an MD degree and practice medicine in the United States. His tumultuous life of 87 years was filled with challenges and hardships. Through it, we witness amazing dedication and pursuit towards humanity and a peaceful world. As you read his story, I hope you will be inspired by Dr. Jaisohn's visionary life, as he had embodied the best values from both Korean and American roots.

The entrepreneur interview is Dr. B.G. Rhee President of Green Cross Holdings, the maker of one of the world's most sold hepatitis B vaccines and leading manufacturer of blood plasma derived products. Dr. Rhee also serves as the chairman of Korea Biotechnology Industry Organization since 2013. In the interview, Dr. Rhee shares his philosophy and principles of biopharmaceutical leadership in Korea.

You will also find other interesting articles in the current issue, including biopharmaceutical reports on biosimilar reference products and diabetic neuropathy patient stratification.

I hope you will find WKMJ to be a community through which you can bring positive impacts on healthcare and its industry. This magazine is for you. Thanks for reading!

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

FROM THE EDITOR IN CHIEF

Dear Colleagues,

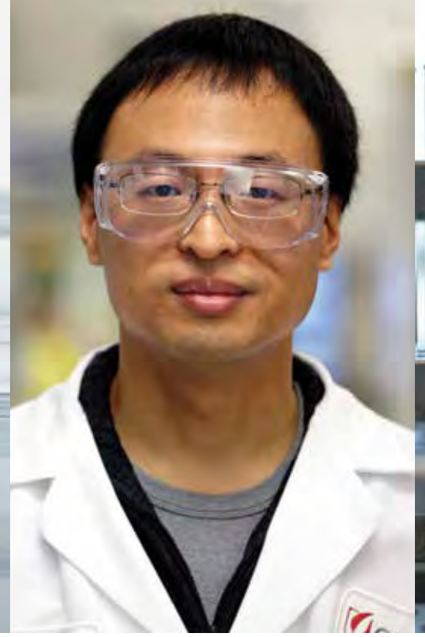
Happy New Year, the year of the Ram. It is hard to believe it already has been a year since the WKMJ started publishing.

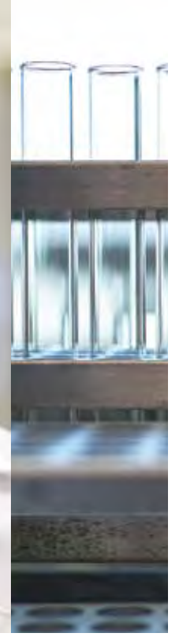
We highlight a very special Korean medical figure, Dr. Philip Jaisohn(Jae-Pil Seo) who has many firsts but was also a pioneering activist. Dr. Jaisohn is prominent Korean being the first naturalized American citizen in 1890. He is also the first Korean American physician in 1892 graduating from George Washington University. He practiced pathology and microbiology as a medical doctor but he so much more being was an activist in promoting Korean civil rights, modernization and independence when Korea was ruled by an emperor and then was annexed by Japan. He returned to Korea in 1894 and founded a Korean newspaper aptly named Independent News using Korean instead of Chinese allowing more widespread readership. On returning to the US he published Korean Review journal and convened the Korean Independence League to promote Korean affairs. Not only was he first in many ways but he fought and sustained efforts on Korea's behalf from both Korea and America and there is appropriately a statue of him at the Korean Embassy in DC. He did so much in difficult times for Korea in the late 19th century entering the 20th century but was able to return as an advisor and see Korea's independence.

The entrepreneur interview is Dr. B.G. Rhee President of Green Cross Holdings, a Korean biotechnology company with a growing global outreach. Green Cross has large portfolio of broad range of products for many medical conditions. The portfolio includes many cutting edge therapeutics, including important vaccines like hepatitis B and plasma derived products which are high end therapeutics including cell therapy, recombinant products and stem cell. The expansion to many global markets doesn't happen without great planning and vision which Dr. Rhee has, and wish the company much success in bringing affordable therapeutics to the world.

As 2015 is well underway we look forward to a productive year starting with the WKMO regional forum in London in March and the annual WKMO Convention in Los Angeles in July. Hope you can make one or both meetings as WKMO is reaching out and network the modern international Korean medical community.

David Y. Ko, MD
Editor in Chief
Board Director of WKMO
Keck School of Medicine of USC





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WKMJ RECAP OF NOVEMBER ISSUE

Cover Story
Inspirational Korean Healthcare Leader: “1st Korean Physician in Brazil, Pioneer Story of Dr. Yung Man Lee”

Dr. Yung Man Lee is the first Korean physician in Brazil. Cover story reveals Dr. Lee’s immigration journey from Korea to Brazil and becoming a doctor from nothing. Now he is recognized as Honorary Sao Paulo Citizen and future doctors admire him as a role model. Read our Issue 4 to find out more about Dr. Lee’s journey.

Entrepreneur Interview
Next Generation Medical Device Company, Socrates CEO, Scott J. Smith

Socrates is a rapidly growing medical device company that integrates innovative technologies into a product. Socrates is delivering an innovative diabetic monitoring experience through painless, accurate and truly non-invasive blood glucose monitoring device, Socrates Companion. CEO Scott J. Smith talks about his motivation and inspiration behind developing innovative technology. Read our Issue 4 to find out more about background story of Socrates.

Medical Institute Report
City of Hope National Medical Center

City of Hope is a new model of cancer center, focused on rapidly transforming scientific discoveries into better treatments and better prevention strategies for cancer, as well as diabetes, HIV and other life-threatening diseases. The Medical Institute report shows the unique features of medical institutes around the world. To read more about City of Hope, please read out Issue 4 to find out more stories.

WKMO Report
1st Inaugural KUMA Conference

On November 15, 2014, Korean UK Medical Association (KUMA) opened an anniversary conference for the first time at Sir Alexander Fleming Building, Imperial College London, UK. The conference focused about UK healthcare system and ways to draw up a plan to enhance medical network globally. About 100 people from medical and research institutions, and universities attended KUMA conference.

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INSPIRATIONAL KOREAN HEALTHCARE LEADER

"CEO of Green Cross Holdings, Dr. B.G. Rhee"

1. We understand that Green Cross is one of the top leading pharmaceutical companies in Korea, and we admire the efficient and proactive expansion. What are the major business philosophies or strategies of Green Cross?

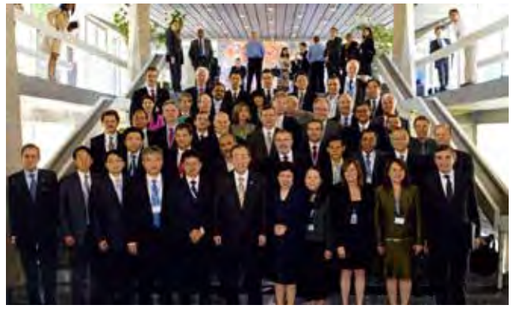
- Green Cross Holdings always focuses on patients' needs and the healthier global society. Our main business portfolio is plasma derived products, vaccines, recombinant products and cell therapy products.

For *plasma derived products,* we are building new facility in Montreal, Canada for North America market and expanding plasma collection centers in the US and China.
For *vaccines,* we have developed hepatitis B vaccine in early 1980's, and our vaccine still is one of the most sold hepatitis B vaccine in the world. Influenza vaccine and varicella vaccine were approved for WHO PQ (Pre Qualification), requirement for tender business in South America through PAHO. These two vaccines have more than 50% market share in this business.

ENTREPRENEUR INTERVIEW

For *recombinant products,* we have developed GreenGene F, a recombinant Factor VIII for hemophilia A patients as 4th product in the world, Neulapeg, once a week formulation of G-CSF for neutropenia and Hunterase for very rare hunter syndrome patients as 2nd in the world. There are approximately 2,000 hunter syndrome patients worldwide and annual treatment cost is more than $300,000 per patient.
For *cell therapy products,* we are currently marketing Immuncell LC, autologous T cell for hepato cellular carcinoma and developing allogenic NK cell and CAR-NK. We are also collaborating with US companies for dendritic cell and stem cell.

We will continue to focus our research on great future impacts for healthier life of human beings.



Attending WHO Meeting: Byung-Geon Rhee attending 2009 WHO meeting when A(H1N1) flu epidemic occured, with WHO Director-General Marget Chan, UN Secretary-General Ki-moon Ban, and many vaccine experts

Dr. B.G. Rhee

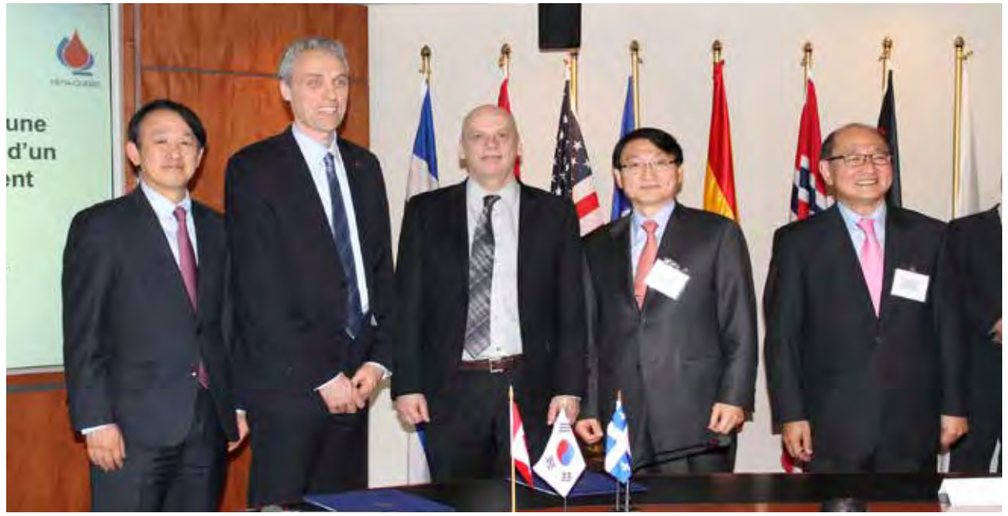
2. Green Cross Holdings recently has been gradually expanding through M&As and focused investments in new drug development. These factors have been strengthening Green Cross Holdings' global competitiveness. What does 'globalization' mean to Green Cross Holdings?

-Compare to any other industry in Korea, the most Korean pharmaceutical companies have little experiences in global market. Only 20 percent of our sales come from the overseas businesses. Our goal is to increase it up to 50 percent.

Green Cross China is growing rapidly with excellent reputation for plasma derived products, and we will add recombinant and cell therapy products for Chinese market. Green Cross BioTherapeutics which is newly established in Canada will be the base camp for North American market.

We already have several strategic partners in the US for monoclonal antibody and cell therapy, and we continue to search for more investment and partnership opportunities with US/EU companies.

3. You have a science background and still, you had been recognized as one of the most successful CEOs in Korean pharmaceutical industry. What are the pros and cons of being a scientist trained CEO in the pharmaceutical and healthcare company?



Canadian Blood Fractionation Preparation Plant construction contract: Byung-Geon Rhee at signing ceremony at Investissement Quebec's HQ in Motreal, Quebec

-The pharmaceutical and healthcare industry is very unique and science background CEO has some advantages to make business decisions based on scientific confidence and principles. As a chemical engineer and biomedical engineer by training, I may have weakness in financials and other general business issues but could overcome by education and experiences. This was great experience for me to combine science and business.

4. Healthcare industry is one of the most unique fields where collaboration of service providers, researchers, and technology providers is essential. How are you dealing with managing your business networks successfully?

-Just like any other industries, networking is one of the key elements for business success. Since healthcare industry is so diverse, we need more collaboration from many different fields. Geographically, the major market of healthcare industry is still concentrated in western countries and we must work with them. Because of various cultural differences between Asian and western countries, I try to understand these cultural differences in business and adapt to global standard. This is how I manage my business network.

Thailand Princess visiting Korea: Byung-Geon Rhee with Thailand princess when visiting Oh-Chang Factory in Korea to discuss about Green Cross exporting Blood Fractionation Preparation Plant in Thailand

5. As an entrepreneur, what would you say are the top three priority assets or skill sets needed to be success in the global healthcare industry?

- Passion, Trust and Attention to others. These are the top three priority assets I may say that apply to have the successful life, not just limited to be successful in the global healthcare industry. Doing a good business and living a good life must be the same.

6. You have been serving as a chairman of Korea Biotechnology Industry Organization (Korea BIO) since 2013. As one of the significant KOLs in Korea's healthcare industry, how do you forecast global and Korean biotech industry in 2015?

- I have attended JP Morgan Conference in January 2015 and felt global biotech industry is booming. Cancer immunotherapy is one of the hot areas and the trend will persist.

Korea has many world class industries like semiconductors, smart phone, shipbuilding, automobile, home appliances, etc. However, biotech industry is far below compare to the global level. Korean government has set biotech industry as one of the next generation growth engine. Cell therapy will be one of the areas we are moving aggressively towards, and mobile healthcare/ wearable device is another area of interest by combining our strong IT and BT.

B.G. (Byung Geon) Rhee, Ph.D.

President, Green Cross Holdings Corp.

Dr. Rhee is a President of Green Cross Holdings Corp and Chairman of Korea Bio Industry Organization. Dr. BG Rhee has more than 25 years of experience in various positions within the pharmaceutical industry. Before joining Green Cross, Dr. Rhee was a President and CEO of Expression Genetics, Inc., a bio-venture company in the US. Dr. Rhee has a particular interest in developing innovative ways for Green Cross to become a global leader in the healthcare industry. Dr. Rhee obtained his B.S./M.S. degree in Chemical Engineering from Seoul National University and Ph.D. degree in Chemical Engineering and Biomedical Engineering at Rice University, Houston, TX.

The Mogam Biotechnology Institute(MOGAM)

KOREAN MEDICAL PIONEER

Dr. Philip Jaisohn's Legacy of Humanism (1864-1951)

Born Seo Jae-pil in Korea's Bosung county in Jeolla province in 1864, his journey through political turmoil of Korea to the United States and back left an indelible legacy of dedication, service and activism. Supporting the ideals of independence and democracy for Korea, his life became an extraordinary story of many 'firsts.'

He became the first naturalized Korean American, the first Korean American medical doctor and the first publisher to use Han'gul, the native Korean script invented by King Sejong, for the newspaper The Independence, the first bilingual newspaper in Korea. The Independence, first published in April 7, 1896, broke with then Korean tradition of publishing in only Chinese letters and paved a way for the modern Korean journalism. Printed in both Korean and English, the newspaper informed ordinary Koreans and the world of the news and events from Korea. Furthermore, He was the first person on record for an interracial matrimony between a Korean and an American, having married in 1894 to Muriel Armstrong, a socialite and niece of the 15th President of the United States James Buchanan, Jr. The couple later had two daughters.


독립신문 THE INDEPENDENT.

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So, what drove this man beyond these illustrious achievements? Dr. Jaisohn was a man deeply concerned with the cause of humanity and freedom, especially with Korea's independence from Japan and progress toward modernization. Never losing his sight on this mission, he worked tireless until his death at age 87 in 1951. At the Rose Tree Park in Media, PA, a monument stands today as a tribute to his humanitarian spirit and dedication.

Dr. Jaisohn's beloved Korea was a reclusive Confucius society under the influence of China's Qing Dynasty in the 1800s. In this environment, precocious young Jae-pil stood out as an early adopter of modern political principles who believed in equality among Koreans.

Young Seo Jae-pil

Excelled as a student, he was sent to Japan in the early 1880s as part of the first group of Korean students to study at the Youth Military Academy in Tokyo. Once returned to his homeland at age 21, Jae-pil was full of hopes and eagerness to establish a modern foundation for Korea. He joined Gapsin coup led by Kim Okgyun, a radical revolt against its feudalistic government, which unfortunately failed in three days with China's intervention. Convicted of treason, Jae-pil lost his family and property and saw the only way to save his life was to become an exile. He found his way to San Francisco via Japan.

Gapsin coup key members; Jae-pil is third from left

Around this time of the late 18th to 19th centuries, Asia was engulfed in protectorate expansion fervor by competing Western governments seeking political and economic gain in the region. Japan, the first Asian nation to be modernized, was no exception to this expansion effort as the sole military power emerged from the Far East. In spite of the peace treaty signed with Korea in 1882, the United States made a secret deal with Japan over Korea in favor of protecting the Philippines from Japan's further aggression. Korea was annexed by Japan in 1910.

Gapsin coup key members; Jae-pil is third from left

During this time of drastic political upheaval and changes in Korea and the Far East, Jae-pil arrived in the United States and took his Americanized name Philip Jaisohn. Jaisohn continued his studies with the support of various sponsors, including American industrialist John W. Hollenback, and pursued a medical degree at George Washington University, formerly known as Columbian Medical College, inspired by Dr. Walter Reed. He became the first Korean American medical doctor in 1892, two years after he had become a naturalized U.S. citizen.

At the time, Japan's imperialistic Meiji government was campaigning hard to annex Korea following its victories over the Sino-Japanese War and Russo-Japanese War. Realizing Korea's vulnerability to colonizing efforts by the powers surrounding the peninsula, Dr. Jaisohn returned to Korea in 1896 and initiated several reform movements in social, political, economic and educational domains, including medical and health care initiatives.

From establishing the Independence Gate in Korea to the historic First Korean Congress in Philadelphia, Dr. Jaisohn organized and supported numerous entities and political activities for Korea's political sovereignty and democracy, including the Korean Information Bureau, the League of Friends of Korea, and the monthly journal Korean Review, until he exhausted his own finances to bankruptcy in 1925.

Independence Gate, Seoul, Korea

Faithful and loyal to both his native and adopted countries, Dr. Jaisohn not only spent his life defending the freedom of those oppressed but also promoted equality among all people. From 1927 and on, he focused his work as a medical doctor in the United States serving as a pathologist and also as Chief Advisor for the U.S. Military government in South Korea at the end of World War II. His lifetime of devotion as a diplomat and medical officer in three U.S. Wars earned him high commendations from Presidents Franklin D. Roosevelt and Harry Truman, and the U.S. Congress in 1946.

This statue of Philip Jaisohn stands outside the South Korean Embassy in Washington, D.C.

Having witnessed the end of Japan's occupation in Korea in 1945, Dr. Jaisohn returned to the United States in 1948 and died in 1951 after suffering from a heart attack during the Korean War. His remains were repatriated to South Korea and interred at the Korean National Cemetery in 1994.

Without a doubt, Dr. Philip Jaisohn was America's greatest gift to Korea in the first half of the 20th century – as a founding father of Korea's modernization and democracy, its future. For Korean Americans, he set an example to follow for generations to be conscientious of both Korean and American roots; embody the very best values they have inherited; and contribute to the betterment of both societies and the world at large by overcoming prejudice and striving to be of service for fellowmen. He was a true pioneer and patriot whose love of his countries, near and far, and dedication to humanitarian causes never waned. W

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

Biopharmaceutical Report I

Diabetic Neuropathy Patient Stratification, Chances Boosted

- Phase II signals encouraging for positive Phase III translation
- Capsaicin as stratification tool shows promise for responder selection
- Topical application to reduce side effects compared to oral treatments

BioDelivery Sciences International's [NASDAQ:BDSI] topical clonidine gel has pain experts optimistic on Phase III painful diabetic neuropathy (DN) trial outcome thanks to its strategic inclusion criteria.

BDSI did not respond to a request for comment.

Clonidine is a α2 adrenergic agonist and imidazoline receptor agonist that has been in clinical use for over 40 years in a number of conditions, such as high blood pressure, anxiety disorders and attention-deficit/hyperactivity disorder, amongst others.

Topical clonidine gel is under investigation in a 140-patient Phase III trial investigating its efficacy and safety in the treatment of pain associated with DN, according to ClinicalTrials.gov. The primary outcome measures are a change in average pain score over time and a change from baseline in the numeric pain-rating scales score assessing the average pain in the past 24 hours, according to the site.

On 8 December the company announced randomisation of patients had been completed and noted it expects the trial to report results at the end of March 2015. BDSI plans to begin a second pivotal Phase III study during 1Q15, according the company press release.

Phase II results and patient stratification provides optimism

In the Phase II trial there was no statistically significant difference between clonidine gel and placebo (p=0.07), however in any subjects who felt any level of pain after being exposed to capsaicin, clonidine was superior to placebo (pless than0.05). In subjects with a capsaicin-induced pain rating of two or more, the mean decrease in foot pain was 2.6 for active compared to 1.4 for placebo (p=0.01) [Campbell CM et al. Pain (2012); 153(9):1815-1823].

Capsaicin is the active component of chilli peppers and is an irritant which causes the sensation of burning; it is often used as topical cream to relieve pain in a number of indications including diabetic neuropathy.

In the Phase II trial, capsaicin was used to test whether the pain nerves in patients were functioning, a higher pain score indicated functioning neurons, noted Dr Aristidis Veves, professor of Surgery, Beth Israel Deaconess Medical Cente, Boston, Massachusetts.

In the Phase III trial the inclusion criteria notes that the subject must have a pain score of at least two on the 11-point Numeric Pain Rating Scale, within 30 minutes following topical 0.1% capsaicin application, according to ClinicalTrials.gov.

By using capsaicin, there is a higher likelihood of identifying clonidine gel responders for a better chance at Phase III success, noted Veves and Dr David Armstrong, professor of Surgery, University of Arizona College of Medicine, Tuscon.

The argument is that if you have pain receptors present and responding to capsaicin then clonidine gel will work on these abnormally functioning receptors, noted Dr Rayaz Malik, professor of Medicine and consultant physician, Division of Cardiovascular Medicine, Manchester Royal Infirmary, UK.

Pain can be caused by a number of mechanisms, in some cases pain from neuropathy could be caused by factors other than dysfunctional neurons, such as cross talk from other neurons or gating issues in the spine, and those patients would not be helped by clonidine gel, said Veves. Thus it is important to stratify patients and a capsaicin test provides a useful way to do this, he added.

The overall result in the Phase II trial was not far from statistical significance in the overall population and likely failed as it included an unselected population including those that could not benefit as they did not have intact cutaneous or epidermal nerve fibres, said Charles Ponte, professor of Clinical Pharmacy and Family Medicine, West Virginia University School of Pharmacy. The fact that the Phase III trial is stratified for patients responding to capsaicin means there is a better chance of success because patients are selected with intact nerves, he added.

There is a definite signal in the Phase II study that shows performing a capsaicin test to check nerve function is a good way to stratify patients for this treatment in clinical trials, noted Malik.

It is a really "elegant idea" to stratify patients according to how their pain receptors respond, it is like the equivalent of performing a biopsy, said Armstrong. What is also encouraging about this medication is that it appears to be effective in the patients with pain receptors that are still functioning and these are the ones that have the biggest need for treatment, he added.

Topical clonidine gel is under investigation in a 140-patient Phase III trial investigating its efficacy and safety

Strong tolerability data expected

Currently there are a number of options for painful DN including pregablin and duloxetine, both of which are oral treatments, noted Veves. However, many patients cannot tolerate the side effects of these oral treatments, noted Veves and Malik. Topical gel should limit the side-effect profile and there are not likely to be systemic effects, noted all of the experts interviewed. The side-effect profile was virtually non-existent in the Phase II trial, it was an extremely clean drug, they added.

From the point of view of a patient, this is a favourable treatment as the patient has more control over the application of the drug as compared to an oral treatment, noted Armstrong. It is also favourable from the point of view of a doctor as the patient must apply the treatment to their feet which means they are more likely to be made aware of any developing complications, he added.

BDSI's market cap is USD 771m.

Hamish McDougall
Reporter, BioPharm Insight

Hamish has a BSc in Neuroscience from the University of Sussex and is primarily covering the neuroscience indications for BioPharm Insight. Prior to joining us he was assistant commissioning editor for a well-known collection of biomedical journals at Expert Reviews, including Expert Review of Gastroenterology & Hepatology, Expert Review of Clinical Pharmacology and Expert Review of Respiratory Medicine.

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Biopharmaceutical Report II

Biosimilar Reference Products Expected to Grow

- Logistic complications create high demand for the expertise of comparator suppliers
- Reference batches can be sourced from manufacturers but more often from authorized distributors

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, experts said. They noted the regulatory and logistical capabilities of product sourcing are a time-consuming process and the pharma focus on biosimilar development has increased demand.

The higher demand in the past two or three years has been in anticipation of forthcoming patent expirations of blockbuster biologics such as Johnson & Johnson's (NYSE:JNJ) Remicade (infliximab), said Daniel Galbraith, chief science officer of Scotland-based BioOutsource. He added that he expects the demand for outsourcing to continue especially as the FDA and other regulators clarify their requirements for biosimilar development.

In the past few years sourcing innovator medications for biosimilar trials has been an increasing business model, said Michael Cohen, managing director of the Pennsylvania- and UK-based Myoderm and Steve Glass, head of Clinigen Group's (AIM:CLIN) Clinical Trials Supply division. From pharma companies to CROs such as PPD (NASDAQ:PPDI), customers need help in early stage planning of biosimilar trials, from analytical testing to Phase III trials, Glass said.

Outsourcing the procurement of biosimilar reference products are growing, a source from a diagnostics and laboratory service provider said. The field is a niche specialty so even a CRO would probably further subcontract outsourcing to drug and biologic development, delivery technologies and supply solution providers like Somerset, New Jersey-based Catalent Pharma Solutions, he added.

The higher demand in the past two or three years has been in anticipation of forthcoming patent expirations of blockbuster biologics

Otherwise, formulation or chemistry providers could also pick up subcontracted business for biosimilar reference drug outsourcing, he said. Patheon (TSE:PTI), Boonton, New Jersey-based Enteris BioPharma, and San Diego, California-based Latitude Pharmaceuticals are examples of formulation service providers whilst companies including SAFC (NASDAQ:SIAL), BASF (ETR:BAS) and Dow (TYO:4850) are all chemical companies.

Supply chain providers, including California and New York-based GT Nexus, are also considering how they could fit into the biosimilar paradigm. Possible routes may include sourcing reference product, GT Nexus Vice President of Manufacturing Industry Solutions Diane Palmquist added, noting providers are focusing on ways to differentiate them from their competition.

In general, the complication of cold-chain logistics, ensuring authenticity of products purchased and providing regulatory documents - such as certificates of analysis - has CROs and companies developing biologics, including biosimilars, turning to specialty suppliers of comparators for their expertise, Cohen said. As an example, Ukraine, which is a hotbed of biosimilar trial development, has very detailed regulations on importation of biologics, he noted, including batch specific regulations, Glass said.

Services offered by outsourcing players

For biosimilars, it is important to build up an analytical reference library as multiple reference lots for biosimilar trials, to ensure that the product in biosimilar development is identical to the innovator products, Cohen added. He noted that building such a library can take months or

years as it can often include sourcing drugs for different markets such as the US, EU, Asia, and Latin America.

It usually takes nine to 12 months to have a reference library prepared and have analytical testing complete before Phase I trials can begin, Galbraith noted. The library can help a biosimilar developer understand the degree of variability between the reference product batches and to the biosimilar, he explained.

Products have to be sourced from a variety of regions depending on regulations on where the biosimilar intends to be marketed, experts agreed.

About five to 10 batches of reference material are typically purchased, Galbraith said. For now, both the EU and US require batches from the country of origin; thus, batches cannot be taken from European markets for the US market, he explained. Head-to-head analytical testing is then done between a batch of a reference product and a biosimilar, he said. EU regulations require that biosimilar makers have a reference library to understand the molecule and the US has similar language in its draft biosimilar guidances, he said.

Outsourcing the procurement of biosimilar reference products are growing

Challenges involved in sourcing products

Getting hold of a reference product can be particularly difficult for biosimilar makers, Warwick Smith, director general, British Generic Manufacturers Association said, though he noted it could become easier in the EU with the EMA's new guidance allowing the use of none-European Economic Area authorised comparator (reference product) in biosimilar clinical trials, set to come into force 30 April 2015. The guidance means biosimilar developers no longer have to unnecessarily repeat trials in three or four different geographic jurisdictions, Smith noted. The comparator needs to be authorised by a regulatory authority with similar rigorous scientific and regulatory standards to those of EMA trials, the EMA's website states.

One major consideration in sourcing innovator products is whether a manufacturer is willing to supply product or not, Cohen said, adding the catch is that some manufacturers may be willing to supply medications if information about trials are supplied. Galbraith noted that under US biosimilar regulations, a biosimilar maker is required to inform the innovator company that trials will be done but the EU does not have that stipulation. If they decline, it may not just be about trying to stifle biosimilar development but also about ensuring they have enough drug supply for their current and future patients, especially when there is a limited market, he noted. If manufacturers decline to supply products, other sources include distributors authorized by manufacturers to sell product, he said.

Since biological products do not have a long shelf life, obtaining large batches can be difficult, not to mention expensive, Galbraith said. For example, sourcing Bristol-Myers Squibb's (NYSE:BMY) chemotherapy drug Yervoy (ipilumumab) costs about GBP 15,000-20,000 a batch, he said. Even beyond analytical testing,

Phase I biosimilar studies are much larger than new molecule Phase I studies, with several arms, so there is a need for initial large batch sizes, he said. In a batch or lot, there could be 10,000 vials and a subset will be used for testing, depending on how many assays a customer wishes to run, Galbraith said.

Jennifer C. Smith-Parker

Reporter, BioPharm Insight

Jennifer is an award-winning biopharmaceutical industry journalist. Prior to joining BioPharm Insight Jennifer was Associate News Editor at FDA Week, covering FDA regulatory policy for all FDA-regulated product areas. She also worked at The Monitor, where she covered health, environment and science issues and conducted a year-long project on indigent healthcare services. She was awarded the Texas Medical Association's Anson Jones journalism award for an article on breast cancer. Jennifer graduated from New York University with a Bachelor's with Honors in History and Journalism.
Follow her on Twitter @JsmithParker

Natalie Morrison

Reporter, BioPharm Insight

Natalie covers the contract services sector for Biopharm Insight. She was previously a journalist for Outsourcing-Pharma.com, breaking the latest contract research and manufacturing news to the pharmaceutical industry. She has a BA Hons in English Language with Creative Writing from Lancaster University, and holds a National Council for the Training of Journalists accreditation. Before joining the world of B2B journalism, Natalie was a tabloid reporter in the UK.
Follow her on Twitter @Morrison_Pharma

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

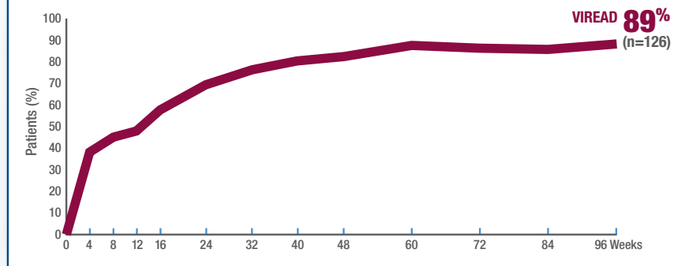
Adverse Reactions

- **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

+

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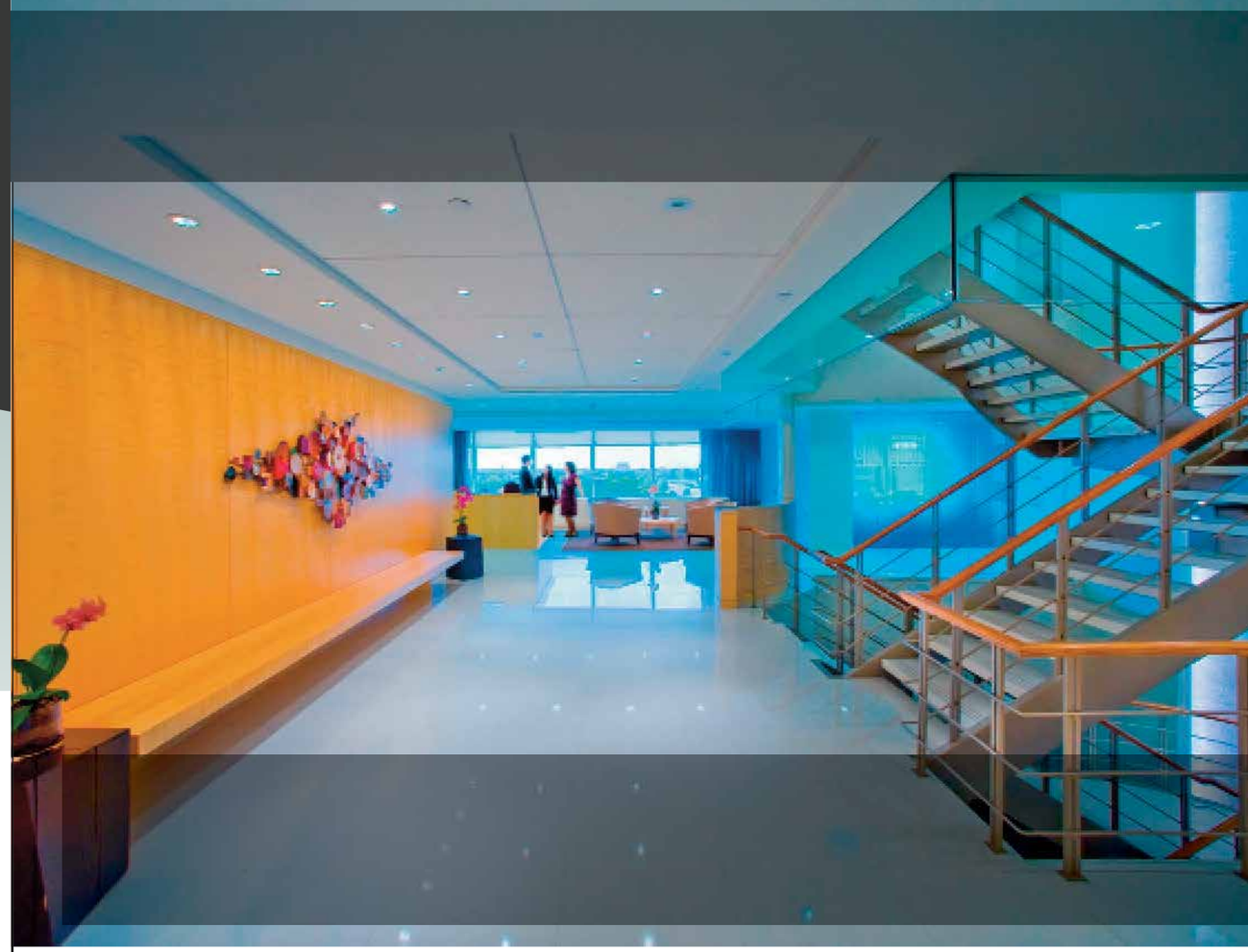

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Conference Alerts

North America

MISS – 15th Annual Minimally Invasive Surgery Symposiums
February 25th to 28th 2015, Las Vegas, United States

The Annual Minimally Invasive Surgery Symposium (MISS) is the premier meeting of thought leaders in minimally invasive surgery for metabolic/bariatric disorders, hernia, foregut, and diseases of the colon. The conference is led by Executive Director Philip R. Schauer, MD, Cleveland Clinic, along with a faculty of internationally known advanced laparoscopic surgeons and bariatric specialists. In addition to general didactic sessions, the conference will offer optional hands-on workshops in laparoscopic suturing and endoscopic interventions.
Contact: Kathleen Wenzler
Phone: 973-206-8092
Email: k.wenzler@globalacademycme.com
http://www.miss-cme.org

Keystone Symposia – Heart Disease and Regeneration: Insights from Development
March 1st to 6th, 2015, Copper Mountain, CO, United States

This meeting highlights new concepts in cardiovascular development, regeneration, and repair and emphasizes common molecular mechanisms with therapeutic potential for cardiovascular regeneration. Emerging technologies for genome editing and imaging will be discussed with the aim of facilitating new research directions and translational approaches. This meeting brings researchers with expertise in cardiac development, molecular biology, stem cell biology, genetics, and epigenetics to facilitate our understanding of heart development and homeostasis and to explore scientific directions and therapeutic approaches for the treatment of heart disease in children and adults. The conference will be held jointly with Cell Biology of the Heart: Beyond the Myocyte-Centric View.
Contact: Attendee Services
Phone: 970 262 1230/800 253 0865
Email: info@keystonesymposia.org
http://www.keystonesymposia.org/15X1

WSPC 2015 – 16th World Congress of Pain Clinicians
March 5th to 7th, 2015, Miami Beach, United States

WSPC 2015 will attract some of the world's top pain experts. By focusing on participant-friendly educational activities together with hands-on courses, WSPC 2015 will facilitate an important discussion regarding interventional techniques for pain management.
Topics: Pain, palliative, opioid, anesthesia, anaesthesia, intensive care, Acupuncture, acupressure, Epiduroscopy, pidural adhesiolysis, Fibromyalgia, Headache, Osteoporoses, kyphoplasty, pain medicine, migraine, neuropathic pain
Contact: Vanessa Fisher
Phone: +41 22 908 0488
Email: wspc@kenes.com
http://www.kenes.com/wspc

North America

PDC – Pacific Dental Conference
March 5th to 7th, 2015, Vancouver, BC, Canada

The Pacific Dental Conference is one of the largest dental conferences in North America offering a varied and contemporary selection of continuing education programs. With over 150 open sessions and hands-on courses and over 300 exhibiting companies occupying 600 booths — we have you and your entire dental team covered. Join us under the roof of the Vancouver Convention Centre, West Building next March for Canada's premier dental conference!
Phone: 604 736 3781
Email: info@pdconf.com
http://www.pdconf.com

NCBC – 25th Annual Interdisciplinary Breast Center Conference
March 14th to 18th, 2015, Las Vegas, United States

The 25th Annual Interdisciplinary Breast Center Conference is an opportunity for breast health professionals in all fields to earn CME credits, certifications and gather valuable information on the latest technologies while networking with hundreds of peers from around the world. Over the course of the weekend, the general sessions provide learning opportunities for doctors, nurses, surgeons, radiologists, administrators, patient navigators, and anyone else on the breast center team. Our 11 post-conference workshops offer specialized training and skill validation for every member of the breast center team. Finally, a dedicated exhibit hall offers 100+ vendor displays and abstract posters, which allows participants a view of the very latest technologies and techniques in a professional yet relaxing environment.
Contact: Jennifer Hayes
Phone: 574-267-8058
Email: Jennifer@breastcare.org
http://www2.breastcare.org/

Course – Hands-On Cardiac Ultrasound Imaging & Doppler 2015
March 16th to 21st, 2015, Irving, Texas, United States

The most effective week in echocardiography you'll ever spend. This course will establish the complete transthoracic echocardiographic protocol: 2-D, M-mode, color and spectral Doppler, tissue velocity, and diastolic dysfunction. Each step and every measurement will be carefully laid out and completely explained. The majority of our time will be spent in the scan lab practicing the full echo protocol to completion. Scan Lab open 24 hours for independent practice. Classroom sessions will drive home every point in a supportive dialog fashion. You'll feel comfortable asking any question, as many time as it takes to understand. After regular hours, the scan lab will be open around the clock for you to practice independently with classmates. And after the course is complete, you'll become a permanent part of our Community, with forever Q & A support.
Contact: Amy Donaldson
Phone: 972 353 3200/800 845 3484
Email: infor@kmaultrasound.com
http://www.kmaultrasound.com

The 4th WKMO Annual Convention
July 2-4, 2015, Los Angeles, USA

World Korean Medical Organization will be hosting the 4th World Korean Medical Organization Annual Convention at Intercontinental Los Angeles Century City . The general theme of the convention is "Trans-cultural healthcare and Global Initiatives". Annually, 200 international physicians who share Korean heritage gather to discuss better health.
Contact: Suki Lee
Phone: 201 402 1400 ext. 503
www.wkmonet.org

Europe

Precision Medicine for Cancer
March 1st to 4th 2015, Luxembourg, Luxembourg

Recent advances in technology have provided an unprecedented opportunity to develop platforms for implementing precision/ personalised medicine in cancer. This conference will discuss the challenges that face us in implementing these approaches. Although our understanding of the pathogenesis of cancer has advanced enormously in recent years, we have only just begun to successfully translate this into improvements in the clinical management of patients. A significant opportunity is offered by the knowledge that cancer cells are 'addicted' to certain altered genes, a vulnerability that can be exploited therapeutically. A number of cancer-causing genes have been identified that are recurrently altered and stimulate tumour growth. These 'driver genes' correspond to oncogenes (or tumour suppressor genes) that are mutated or deregulated (e.g., amplified), causing the tumour to become dependent on the lesion(s) for survival and/or proliferation.
Contact: Kathryn Wass
Email: Kathryn.Wass@nottingham.ac.uk
http://www.eacr.org/precisionmedicine2015/index.php

HPV 2015 – XII INTERNATIONAL WORKSHOP OF LOWER GENITAL TRACT PATHOLOGY
March 5th to 7th 2015, Rome, Italy

HPV infection and cervical cancer, Cervical cancer screening around the world, HPV vaccination, Challenges in colposcopy, Molecular tests in cytopathology lab, LBC & Automation, Cervical cytopathology : the old and the new, Low genital tract infections and cervical cancer screening, Contraceptives and cervical cancer, The great debates: clinical and pathology perspective, Management of CIN, Issues in colposcopy, Multifocal disease, Classification and quality control in cervical cytopathology, Diagnosis in cytopathology, Legal questions, Training course in colposcopy, Training course in cytopathology, Posters & Communications.
Contact: Organizing Secretariat – triumph C.&C. Srl
Phone: +39 06 35530382
Email: hpv2015rome@thetriumph.com
http://www.hpv2015rome.com

AD/PD 2015 – THE 12TH INTERNATIONAL CONFERENCE ON ALZHEIMER'S AND PARKINSON'S DISEASES
March 18th to 22nd, 2015, Nice, France

AD/PD will build on its well-earned reputation for unravelling the mechanisms and improving the treatment of Alzheimer's, Parkinson's and other related neurodegenerative diseases.
Topics: Degenerative Disorders, Movement disorder, alzheimer's, parkinson's , dementia, lewy bodies, lobar degeneration, huntington's
Contact: Rachel Zablow
Phone: +41 22 908 0488
Email: adpd@kenes.com
http://www.kenes.com/adpd

CIP 2015 – THE 4TH GLOBAL CONGRESS FOR CONSENSUS IN PEDIATRICS AND CHILD HEALTH
March 19th to 22nd, 2015, Budapest, Hungary

CIP Congress brings an innovative and stimulating global academic debate platform searching for consensus and agreements on main child health pathologies, difficulties and controversies. The concept for the CIP congress and program was developed for Pediatricians working in Primary and Secondary Care, as well as for specialists in the diverse areas of Pediatrics, Pediatric Surgeons, Family Medicine Doctors, General Practitioners, Researchers and Policy Makers. The outstanding scientific program will feature distinguished keynote addresses, cutting edge state-of-the-science lectures, controversial debates, and compelling presentations by main leaders in Pediatrics.
Contact: Karen Davidson
Phone: 41 22 5330 948
Email: cip@cipediatrics.org
http://2015.cipediatrics.org

Global Leadership Series 2015 WKMO Regional Forum-Global Collaboration & Initiatives
March 20th to 21st, 2015, London, United Kingdom

The World Korean Medical Organization (WKMO) will gather in London, UK, on March 20-21, 2015 focusing on a general theme of "Global Initiatives and Collaboration" and will have discussions on WKMO Global Initiatives, London Research Innovation in 2015, and Trans-Cultural Health by internationally renowned physicians. As a result, we hope to facilitate academic and bio-health industrial collaborations and exchanges amongst all health care professionals.
Contact: Suki Lee
Phone: 1 201 402 1400
Email: wkmosecretariat@gmail.com
http:// www.wkmonet.org/

Asia

AACNS 2015 – The 14th Asian Australasian Congress of Neurological Surgeons
April 15th to 18th, Jeju, South Korea

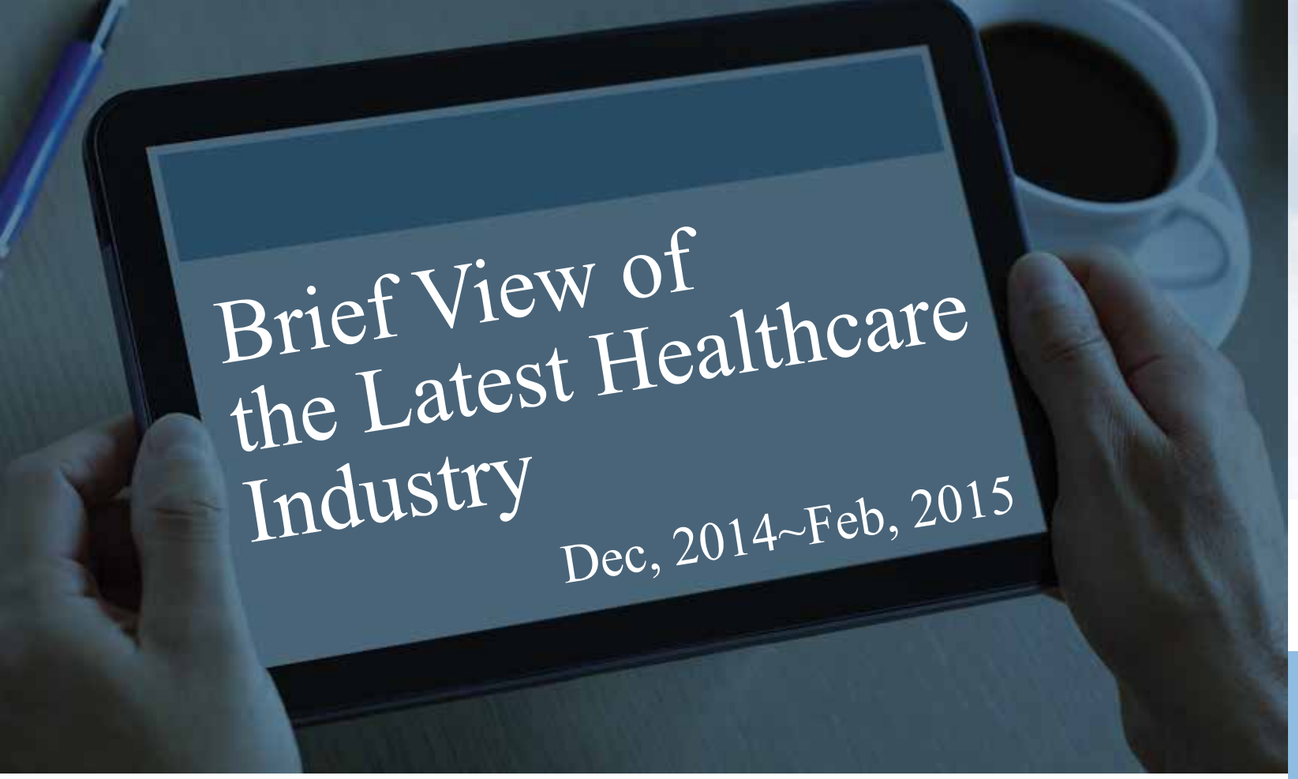
The four-day congress will feature an exciting line-up of expert speakers including top practitioners, opinion leaders and researchers. Delegates can look forward to an intensive knowledge-sharing event comprising plenary sessions, oral presentations and video screenings. There will be a host of networking opportunities for delegates to rub shoulders with top experts and opinion leaders.
Topics: Glial tumors, metastatic tumors, Spinal cord tumors, spinal column tumors, Tumors of peripheral nerves, Medulloblastoma, Craniopharyngioma, sellar lesions, Acoustic tumors, Skull-base lesions, Pediatric low-grade gliomas, Germ-cell tumors, Moder imaging techniques, Chemotherapy for brain and spinal cord tumors, Radiotherapy, Proton Beam debate, Neurofibromatosis, CNS neoplasms
Contact: Gabriel Heng
Phone: +65 295 6984
Email: info@aacns2015.com
http://aacns2015.com

5TH INTERNATIONAL NEONATOLOGY CONFERENCE ON "HOTTEST TOPICS IN NEONATAL MEDICINE"
March 12th to 14th, 2015, Abu Dhabi, United Arab Emirates

Following the four previous successful conferences from 2010 to 2014, this year 3-day intensive conference will review the recent developments and up-to-date levels of evidence and practice in the area of neonatal-perinatal medicine. There will be renowned lecturers from the USA, Europe and our region. The program will include talks and discussions on the newest research in the diagnosis, prevention and treatment of health problems in the neonates. Educational sessions will also be presented by many of world leading neonatologists. The conference aims at improving new born survival and helps improve standards of education in the field of neonatology. It will also promote high standards of neonatal care, enhance quality of care for patients and families, decreasing health disparities and improving health care outcomes.
Contact: Afsal Ahmad
Phone: 0097124919888
Email: afsal.ahmad@menaconf.com
http://www.menaconf.com

HKSTENT-CICF 2015 – CARDIOVASCULAR INTERVENTION COMPLICATION FORUM 2015
March 13th to 15th 2015, Hong Kong, China

HKSTENT-CICF 2015 is the first-of-its-kind meeting held in Hong Kong and around the region with focus on the management of cardiovascular intervention complication. Unique to the program is a series of case based lectures on tips & tricks in managing complication, interactive case studies with experts and case competition.
Topics: cardiology, cardiovascular, intervention, complication, heart, heart disease, stenting, stent
Contact: MCI Hong Kong
Phone: 852 2911 -7932/2911 7915
Email: hkstent@mci-group.com
http://hkstent.org/



December

1. Smoking linked to loss of Y chromosome in males 12/5/14

Only men have the Y chromosome, which "may in part explain why men in general have a shorter life span than women, and why smoking is more dangerous for men," says lead researcher Prof. Jan Dumanski, of Uppsala University in Sweden. Researchers have already shown that male smokers are more likely to develop cancer outside of the respiratory tract than female smokers. In the new study, the discovery of a potential link between smoking and genetic damage that only affects men could account for this difference.
http://www.medicalnewstoday.com/articles/286474.php

2. Researchers link vitamin D deficiency to seasonal affective disorder 12/7/14

Seasonal affective disorder (SAD) - a form of depression that usually begins in the fall, continuing throughout the winter months. Symptoms include feeling sad or anxious, fatigue, concentration problems, irritability and feelings of guilt and hopelessness. In this latest study, Stewart and colleagues present the idea that vitamin D deficiency may be behind all of the aforementioned theories related to SAD.
http://www.medicalnewstoday.com/articles/286496.php

3. More than salt, sugars may contribute to high blood pressure 12/11/14

Cardiovascular disease is the number one cause of premature mortality in the developed world, and hypertension is its most important risk factor. The researchers indicate "sugar may be much more meaningfully related to blood pressure than sodium, as suggested by a greater magnitude of effect with dietary manipulation."
http://www.medicalnewstoday.com/articles/286795.php

December

4. Alcohol disrupts body's sleep regulator 12/11/14

Around 20% of adult Americans use alcohol-known to be a powerful sleep inducer to help them fall asleep. However, new research shows that while alcohol may bring on sleepiness, it can disrupt sleep and, over time, cause insomnia by interfering with the body's system for regulating sleep.
http://www.medicalnewstoday.com/articles/286827.php

5. Endurance training alters skeletal muscle 'at an epigenic level' 12/13/14

Long-term endurance training alters the epigenetic pattern of the human skeletal muscle, according to new research from the Karolinska Institutet in Sweden, published in the journal Epigenetics. A key finding of the study was that the majority of epigenetic changes occurred in "enhancers," which are regulatory regions of the genome.
http://www.medicalnewstoday.com/articles/286929.php

6. A year in medicine: review of 2014 12/19/14

Looking back on 2014, perhaps two medical stories stick most in the memory-one because of its popularity in social media, the other because of its newsworthiness. Stem cells, dementia and Alzheimer's disease, Ebola, E-cigarettes, health policy, innovative technology, paralysis, and personal health tracking.
http://www.medicalnewstoday.com/articles/285692.php

7. Eat more whole grains to reduce CVD, total mortality risk 1/6/15

Whole grains form a part of many diets deemed to be beneficial for health – such as the Mediterranean diet. But what health benefits do whole grains offer in their own right? According to a new study, eating more of them may reduce mortality, particularly deaths resulting from cardiovascular disease.
http://www.medicalnewstoday.com/articles/287573.php

8. Most physicians in Asia 'withhold life-sustaining treatment for terminally ill patients' 1/14/15

According to the study researchers, including Jason Phua of the National University Hospital in Singapore, more than half of all cases of critical illness, mechanical ventilation and deaths in intensive care units occur in Asia. Over 70% of physicians in Asia would withhold life-sustaining treatments.
http://www.medicalnewstoday.com/articles/287897.php

January

9. First lab-grown contracting human muscle 1/14/15

In a new study, researchers from Duke University in Durham, NC, reveal they have grown the first ever human skeletal muscle that contracts in response to external stimuli, such as electrical impulses and pharmaceuticals, The team says their creation paves the way for testing of new drugs and the study of diseases without having to put a patient's health at risk.
http://www.medicalnewstoday.com/articles/288012.php

10. Video-based treatment may improve autism-related behavior in at-risk infants 1/25/15

A new study published in The Lancet Psychiatry suggests video-based therapy may improve the engagement, attention and social behavior of infants at risk of autism and reduce their risk of developing the condition. Compared with the infants who did not receive the iBASIS-VIPP therapy, those who did showed significant improvements in engagement, attention and social behavior. On the AOSI scale, infants who received the intervention had lower scores for autism-related behavior than those who did not receive the treatment.
http://www.medicalnewstoday.com/articles/288450.php

11. Pluripotent stem cells used to generate hair growth 1/28/15

Though common, hair loss is a distressing disorder. It can dent a person's confidence and provoke feelings of depression. Now, researchers from Sanford-Burnham Medical Research Institute in La Jolla, Ca, say they are one step closer to a new treatment for the condition; they have found a way to generate new hair using human pluripotent stem cells.
http://www.medicalnewstoday.com/articles/288657.php

12. Organ transplants in the US 'have saved almost 2.,3 million years of life' 1/31/15

Little more than 50 years ago, the world's first successful kidney transplant took place. Now, more than 16,000 kidney transplants take place each year in the US alone, indicative of just how far organ transplantation has come. Now, researchers have analyzed 25 years of transplant data to determine how many years of life have been saved by the procedure.
http://www.medicalnewstoday.com/articles/288673.php

February

13. Antibiotic use has more unwanted effects than previously thought 2/11/15

Scientists are beginning to discover that antibiotic use - and overuse especially - is associated with a range of problems that affect, among other things, glucose metabolism, the immune system, food digestion and behavior. They also suspect it is linked to obesity and stress. Disruption in host-microbe dialog can not only disrupt digestion, cause diarrhea and ulcerative colitis, but new research is also linking it to immune function, obesity, food absorption, depression, sepsis, asthma and allergies.The team also found that the antibiotics and bacteria that have developed resistance to them cause significant changes to mitochondria, leading to more cell death.
http://www.medicalnewstoday.com/articles/289259.php

14. Designer protein 'blocks all known strains of HIV' 2/18/15

The results of the study, which are published in the journal Nature, demonstrate how the new drug candidate blocked every strain of HIV-1, HIV-2 and SIV (simian immunodeficiency virus), including the variants that are most difficult to block. Studies like this support the idea that killing bad bacteria with antibiotics is perhaps not a good way to deal with infection - given the increasing list of side-effects and problems they cause. Prof. Morgun suggests boosting the healthy bacteria so they outcompete the unwanted ones might be a better approach.
http://www.medicalnewstoday.com/articles/289611.php

15. Daily antiretroviral medication 'highly protective' against HIV infection 2/25/15

Pre-exposure prophylaxis (PrEP) was found to reduce the risk of infection by 86% for this group during the PROUD study (Pre-exposure Option for reducing HIV in the UK: immediate or Deferred). The effects were so pronounced that a group of participants who had been deferred access to PrEP were offered the treatment ahead of schedule. A total of 22 HIV infections occurred among the participants during the first year of the study. Of these, 3 were in the group receiving PrEP and 19 were in the group whose access to PrEP was deferred. The researchers calculate that this gave the PrEP group an HIV incidence of 1.3 per 100 person-years, compared with 8.9 per 100 person-years in the deferred group.
http://www.medicalnewstoday.com/articles/289949.php

16. Could too much sleep increase the risk of stroke? 2/26/15

According to the National Sleep Foundation, adults aged 18-64 should get 7-9 hours of sleep each night. But this latest study, involving more than 9,000 people with an average age of 62, found that getting more than 8 hours sleep each night was associated with a 46% increased risk of stroke. What is more, the researchers found that people who increased their amount of sleep from 6-8 hours each night to more than 8 hours during follow-up were four times more likely to have a stroke, compared with those who consistently slept for 6-8 hours a night.
http://www.medicalnewstoday.com/articles/289876.php

Global Leadership Series 2015

WKMO Regional Forum

Global Collaboration & Initiatives

London | March 21, 2015

- WKMO Global Initiatives
- London Health Forum
- Research Innovation in 2015
- Trans-Cultural Health

PROGRAM

Mar 21, 2015: WKMO Executive Meeting	
9:00-12:00 PM	WKMO Executive Board Meeting
Mar 21, 2015: WKMO Regional Forum in London Global Leadership Series, "Global Collaboration and Initiatives"	
5:00-6:00 PM	Networking
6:00-6:15 PM	Welcoming Remarks
6:15-6:45 PM	WKMO Global Initiatives
6:45-7:30 PM	London Health Forum
7:30 PM	Dinner will be served
7:45-8:30 PM	Research Innovation in 2015
8:30-9:15 PM	Trans-Cultural Health

**For Registration, contact WKMO office, ✉ wkmosecretariat@gmail.com / ☎+1 201 402 1400

KHIDI Korea Health Industry Development Institute

WKMO WORLD KOREAN MEDICAL ORGANIZATION

KOREAN UK MEDICAL ASSOCIATION KUMA

New Jersey Anesthesia Group
North American Partners in Anesthesia

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Michael Umanoff, M.D.

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