May 2014 - ISSUE 2

WKMJ

World Korean Medical Journal

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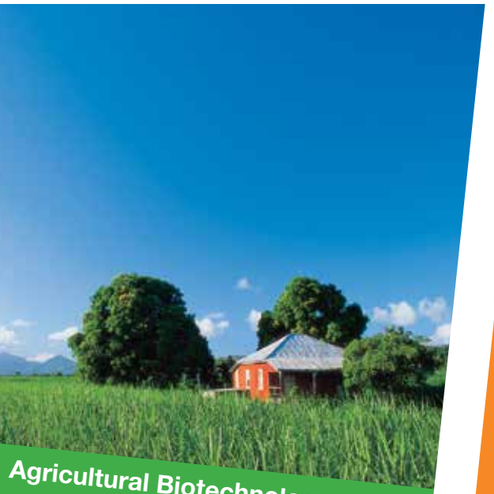

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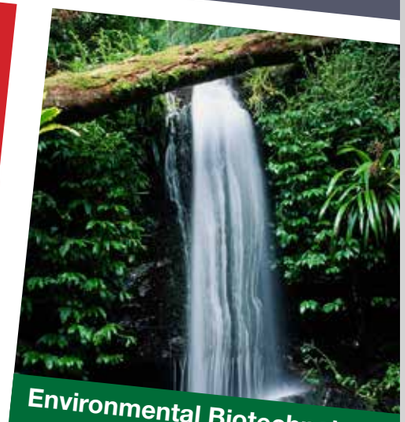

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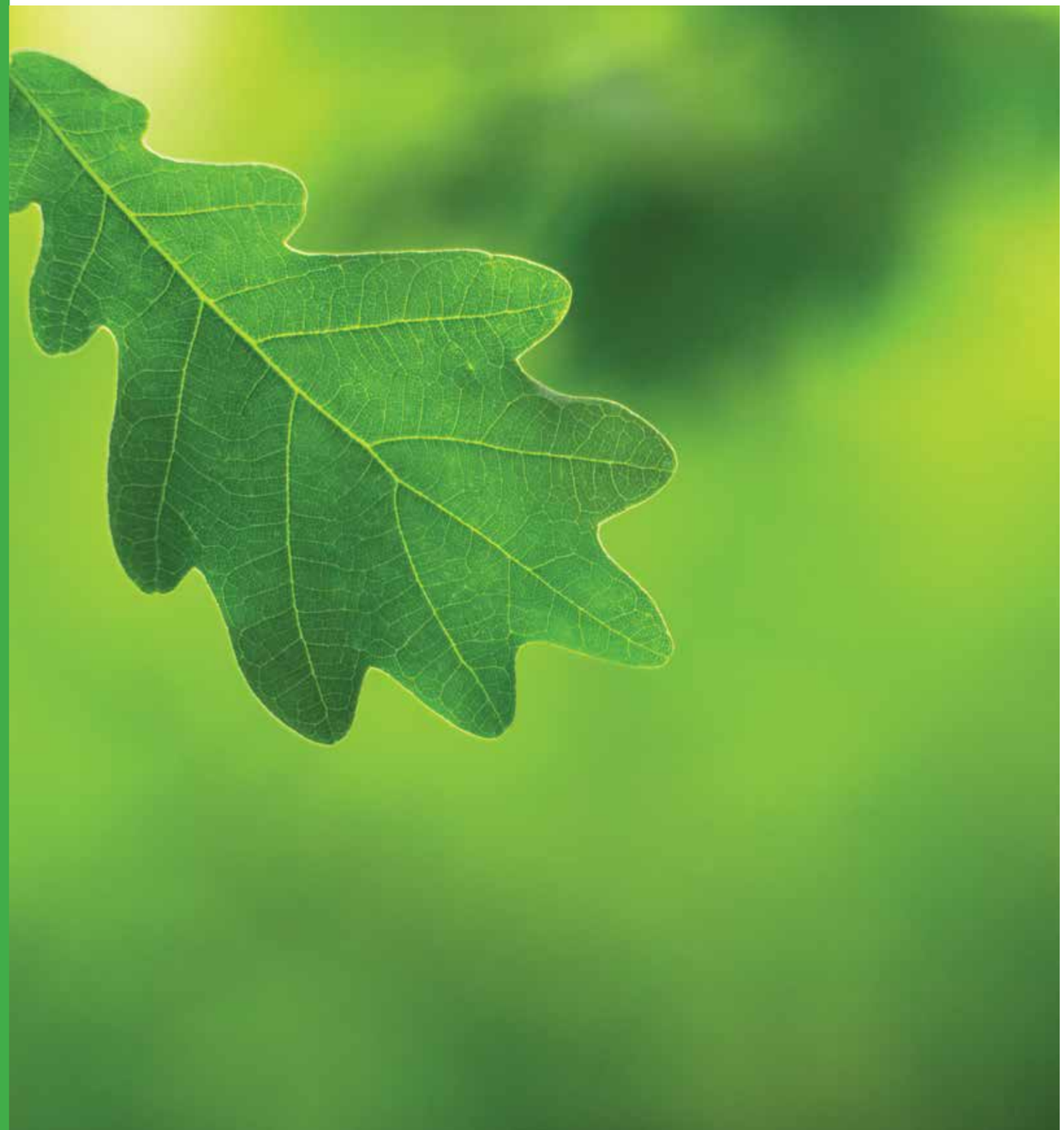

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"WKMJ WILL CONTINUE TO PROVIDE A PLATFORM FOR ALL HEALTHCARE PROFESSIONALS TO EXPLORE, INTERACT, AND ESTABLISH A WHOLESOME NETWORKING."

Two months ago we launched the first issue of WKMJ, and it was met with positive emails and phone calls about the ways the WKMJ will nurture WKMO and Korean American medical community. Needless to say, our goal is to connect with one another, and provide a forum for readers to develop an integrative perspective in healthcare.

In this issue, we feature Dr. Jong-Wook Lee, a world leader in public health who served as a director general of World Health Organization from 2003-2006. He was a man of conviction and passion, and an inspiration to the global community. His achievements in the areas of tuberculosis and vaccine preventable diseases of children in needed communities are noteworthy. His insights into how we can better serve the communities as physicians, and his visions on global health will always remain as a living legacy inspiring and motivating the young generation.

Our aim is to fill every issue with a variety of information from technology, pharmaceuticals, and health care policy. In our Entrepreneur Interview, we meet Dr. Phillip Frost of OPKO Health Inc. A physician, a CEO, and a leader in healthcare arena, Dr. Frost advises young physicians to be entrepreneurial and to embrace change as new business models are being developed to treat the aging population. We also have a new section called <Conference Alerts> where the readers are regularly updated on the upcoming conferences and symposia on medicine, healthcare and bio-health industry.

WKMJ will continue to provide a platform for all healthcare professionals to explore, interact, and establish a wholesome networking. In the face of healthcare reform, industry trends are challenging physicians to go beyond the usual boundary of medicine, and to apply our expertise into various related and sometimes complicated fields. We need to adjust accordingly in our varying roles. Through this publication, it is my hope that we can assist in this ever-changing field.

Chul S. Hyun, MD, PhD
Publisher
President of WKMO

"COMPASSION OF KOREAN PEOPLE AS PHYSICIAN; THERE IS VERY LITTLE OUTSIDE PRESENCE BUT THERE ARE SIGNS OF WHO(WORLD HEALTH ORGANIZATION) AND UN(UNITED NATIONS) ACTIVITIES IN NORTH KOREA"

Hope you enjoyed the first issue. There were two quotes that stood out from that issue: First was of Dr. Sammy Lee about the "compassion of Korean people" as physicians. Second was Dr. Ui-Hwa Chung, a neurosurgeon who is now the honorable speaker of the Korea National Assembly, who said reunification of Korea is "the greatest mission of all Koreans around the globe."

In this issue, we feature Dr. Lee Jong-wook who was the Director General for the World Health Organization (WHO), a specialized agency of the UN that is concerned with international public health. WHO has the herculean task of improving health and healthcare throughout the world with limited resources. As the top physician at WHO, Dr. Lee did great things particularly focusing on universal access to TB prevention, which is a major issue in North Korea. I made my first visit to North Korea recently and noticed that there is very little outside presence but there were signs of WHO and UN personnel and activities there, so his influence is still felt to this day. He met an untimely passing but accomplished a lot in 3 years as Director General. The UN and WHO can only do so much in each country, but in North Korea there is reason for hope as I was there for a momentous occasion, groundbreaking for a new private medical school called Pyongyang University Medical School (PUMS).

On the July 4th weekend, WKMO is hosting the "The 3rd WHO Annual Convention" focusing on the theme of 'Cultural Barriers and Ethnic Disparities in Healthcare.' August 7-9 the 40th Anniversary meeting of KAMA will be in Hawaii with special keynote speaker, the President of the AMA, as well as forums on North Korea healthcare including PUMS. Both are great educational and networking opportunities not to be missed.

David Y. Ko, MD
Editor in Chief
Board Director of WKMO
President of KAMA

WKMJ RECAP OF MARCH ISSUE

Cover Story
Overcoming the odds: Dr. Sammy Lee's journey to the American Dream

"The first man to win back-to-back gold medals in Olympic platform diving", "the first Asian American to win an Olympic gold medal of the U.S.", "member of the US Olympic Hall of Fame" are just a few of titles Lee has received in his lifetime, as his accomplishments were not limited to the athletic field. Dr. Sammy Lee received his M.D. at University of Southern California School of Medicine in 1947, specializing in the diseases of ear, nose and throat. He went on to serve in the U.S. Army Medical Corps in Korea, where he won the James E. Sullivan Award. This is the inspirational true story of Sammy Lee, a Korean American who overcame discrimination to realize his dream of becoming an Olympic champion diver and becoming a doctor.

Entrepreneur Interview
John Martin, CEO of Gilead Sciences, Inc.

Dr. John Martin quoted "Gilead's decision-making is guided by science and by the needs of patients that we are able to identify the most important projects with the greatest likelihood of success, and those that will have the greatest future impact on patients' health. And while simplifying treatment has significantly benefited millions of patients worldwide, we continue to look at how we can improve on existing treatment options. "

Special Report I
"WKMO Global Leadership Series 2014" in Sao Paulo, Brazil on Feb. 6th"

World Korean Medical Organization (WKMO)hosted an International Forum to discuss Korea-Brazil medical collaboration. Attended by more than 100 physicians, including Dr. Chul Soo Hyun, President ofWKMO, Dr. David Ko, president of KAMA (Korean American Medical Association), Dr. Heejung Kang, president of AMCO (Korean Paraguay Medical Association) and other WKMO board member physicians from Korea, U.S., Brazil UK and Australia. Hon. Bonwoo Koo, Ambassador of Brazil, Dr. Claudio Lottenbert, the Chairman of 'Sociedade Benficente Israelita Brasileira Hospital Albert Einstein' had given congratulatory remarks, and Brazilian physician representatives, Dr. Sangchoon and Dr. Andre Dongwon Lee had given presentations on current medical status of Brazil. This event was organized by W Medical Strategy Group.

Special Report II
'W Medical Strategy Group' Launched!

W Medical Strategy Group, a medical consulting subsidiary firm of WKMO was officially launched on Feb. 11th at the Yale Club in New York, NY. Many executives from top pharmaceutical and medical device companies, American Corporations and finance consulting firms, including Merrill Lynch and PWC, attended the event showing much interest in the launch.

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A Public Health Advocate for the Poor: Dr. Jong-wook Lee (1945-2006), WHO Director-General

Four years before Ban Ki-moon made headlines around the world as the eighth Secretary-General of the United Nations (UN), Dr. Lee Jong-wook – known to his friends and colleagues as JW; as the Schweitzer of Asia to others –became the first Korean national to head a United Nations agency, the World Health Organization (WHO).

For 23 years with WHO, he set about improving the health of the poor on the international stage, eventually ascending to the role of director-general. Just three years into his appointment as the organization's sixth director-general, he would meet his untimely death in Geneva on May 22, 2006 in the midst of preparing for the annual World Health Assembly, a meeting of the 192 Member States. A life of hard work and dedication cut short too soon, he was only 61 years old.

COVER STORY

[photo: WHO/P.Virot]
Dr. Lee Jong-wook at his first staff meeting at WHO on July 21, 2003 as he took his post as director-general. Dr. Jim Yong Kim is sitting behind him.

Dr. Lee's work and vision as a world leader in public health were well reflected upon his death by then United Nations Secretary General Kofi Annan in a statement: he was "a strong voice for the right of every man, woman and child to health prevention and care, and advocated on behalf of the very poorest people."

True to this remark, Dr. Lee pledged to help the poorest and most marginalized people in the world. He tirelessly visited 60 countries in the three years of his Generalship; traveled to nearly every Member State in his career spent with WHO believing health interventions are a must to reduce poverty. He was convinced that disease risk was directly linked to a nation's poverty level and focused on dealing with healthcare problems in poor countries.

According to Paul Benkimoun who wrote in his article, How Lee Jong-wook Changes WHO, for the Lancet in 2006, Dr. Lee was among the least likely to be elected director-general in 2003 of a six-name shortlist that included UNAIDS Executive Director Peter Piot.

Nonetheless, his experience spanning for more than 20 years at all levels, including technical, managerial and policy positions, proved to be his key strength coming into the top position at a time of global public health crisis, including the severe acute respiratory syndrome (SARS) epidemic, the emergence of H5N1 avian influenza virus and the highly politicized H.I.V. and AIDS treatment.

He knew the ins and outs of WHO better than most. Once elected, Dr. Lee tackled every challenge bravely, listened intently and grasped both the political and technical issues in public health. However, his tenure was not without difficulties and failures.

For instance, "3 by 5," the AIDS treatment program targeting to deliver antiretroviral (ARV) therapy to 3 million people in developing countries, fell short of its goal and was widely criticized.

[Photo: WHO/Christine McNab]
Dr. Lee on one of his first country visits as Director-General, outside the community health clinic in KwaMlanga, South Africa. He was warmly greeted by children.

However, some saw his firm commitment to the program differently: Dr. William Foege, an international health leader at the Bill and Melinda Gates Foundation, regarded the program's failure as "insignificant compared to the courage to promote a vision of what the world should be doing."

Also speaking of Dr. Lee's willingness to take responsibility for failure, Dr. Jim Yong Kim, Dr. Lee's close friend and one-time aide who now heads the World Bank Group as its 12th president, said that his leadership in a way "fundamentally changed people's attitude to the possibility of treatment for a chronic disease in settings of poverty."

[photo: WHO/K. Bernard]
Dr. Lee reading Shakespeare to staff. He never forgot how to relax and laugh.

From leading an effort to eradicate polio in the Western Pacific to implementing GDF to ensure access to tuberculosis medicines to his very last day working as director-general, he strived to make a difference in every program he managed and every life he touched, while maintaining a sense of purpose and his humor.

Survived by his wife and son, Dr. Lee's legacy continues today, largely through the enduring mission of WHO. And in a more personal way, his wife Reiko is also carrying out his mission through her own work with non-governmental organization Mujeres Unidas (Women Together), a Partners In Health project in Peru, in the shantytown of Carabayllo. Dr. Lee Jong-wook was selected by Time Magazine in 2004 as one of the world's 100 most influential people who shaped our lives.

[Photo: WHO/Christine McNab]
Dr Lee worked for 23 years at the World Health Organization, and was the first person from the Republic of Korea to lead a United Nations agency.

Established in 2008, the Dr. Lee Jong-wook Memorial Prize for Public Health awards a person or persons, an institution or institutions, a governmental or non-governmental organization or organizations that have made an outstanding contribution to public health. Awarded once a year, the prize consists of a plaque from the founder and a sum of money, which will not exceed US$

100,000. The Prize aims at rewarding work that has extended far beyond the call of normal duties, and it is not intended as a reward for excellent performance of duties normally expected of an official occupying a government position or of a governmental or intergovernmental institution. The 2014 Dr. Lee Jong-wook Memorial Prize for Public Health was awarded to the Czech Society of Cardiology, together with Professor Sinata Koulla-Shiro of Cameroon.

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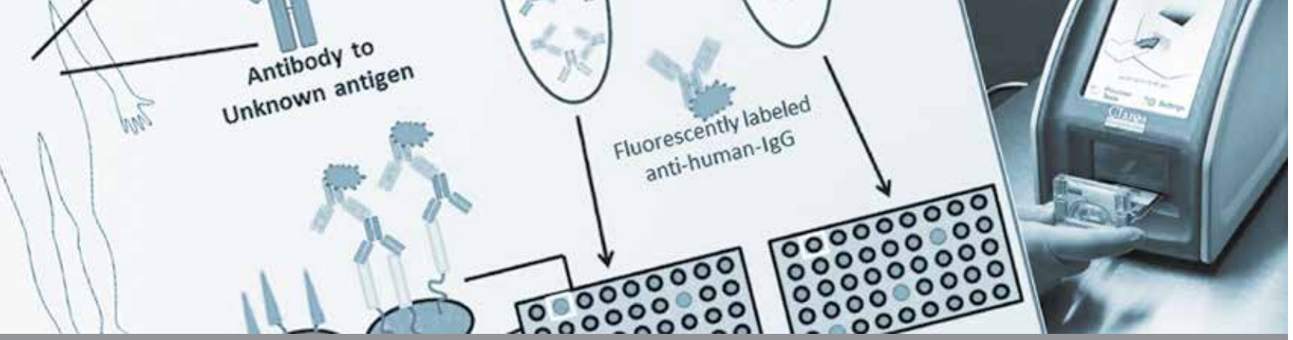


Entrepreneur Interview

Dr. Phillip Frost, CEO and Chairman, OPKO Health Inc.

1. We understand that OPKO Health, Inc. is a rapidly growing multi-national pharmaceutical and diagnostics company, and we admire the efficient and proactive expansion of OPKO. What are major business philosophies or strategies of OPKO?

“OPKO is focused on tackling some of the biggest problems in healthcare. Our first marketed product, the 4Kscore, is a test to better asses a man’s chance of developing high-grade prostate cancer. As your readers are well aware the traditional PSA test has significant limitations leading many men to have needless and painful prostate biopsies and unnecessary cancer treatments. Currently, about 80 percent of prostate biopsies ultimately prove to be unnecessary because they are either negative for cancer or show a low-grade disease that is no threat to health. Besides being painful, biopsies carry a significant risk of bleeding and infection. Our clinical data demonstrated that the 4Kscore could help to reduce unnecessary biopsies by providing more accurate information on the probability of high grade prostate cancer, offering both the urologist and the patient better information to make a more informed decision.

Our lead therapeutic product is Rayaldee, a first-in-class oral vitamin D prohormone, for the treatment of secondary hyperparathyroidism (SPHT) associated with chronic kidney disease and vitamin D insufficiency. Chronic kidney disease (CKD) is a growing problem worldwide and the co-morbidities are putting tremendous pressure on the healthcare system. Rayaldee is designed to safely and effectively treat patients with stage 3 and 4 CKD without the complications found in other treatments including hypercalcimia. The compound is completing Phase III trials with data expected by the middle of the summer.

We also continue our long tradition of allocating capital to projects we think have significant upside potential. OPKO’s lead biologic product is hGH-CTP, a once weekly recombinant human growth hormone product under development for treatment of growth hormone deficiency, a pituitary disorder resulting in short stature in children and other physical ailments in children and adults. A pivotal Phase III trial in adults with growth hormone deficiency is under way and Phase II trial in children with growth hormone deficiency is expected to be completed in the coming months. hGH-CTP, which is injected once weekly, could be a promising alternative to the current standard of care for growth hormone deficiency which requires daily injection of hormones. By reducing the burden of daily injection therapy, we believe our product could improve compliance and therefore yield better treatment outcomes.”

2. You’ve had significant roles and footsteps in biopharmaceutical industry, including establishment of IVAX and serving as the board chairman of Teva pharmaceuticals. As one of the industry’s renowned key opinion leaders, where do you think the pharmaceutical industry is headed? What do you think is the most important issue in the industry?

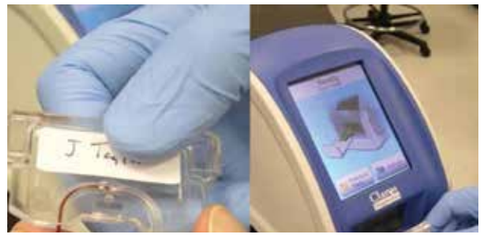
“The most important activity any pharmaceutical company can engage in is to help patients. We live in an era when economic pressures are becoming more acute, so it is incumbent on pharmaceutical companies to articulate their value proposition to both payors and increasingly directly to patients. The trend looks as though it is to continue - that is why we at OPKO strive every day to find new and interesting ways to help patients. At OPKO, we decided to focus on both diagnostics and pharmaceuticals because in the future we see a more aligned relationship between tests and drugs.”

3. OPKO seems to focus on European and Latin American countries. What are OPKO’s business strategies in Asian region including Korea?

“We have been very impressed with the growth in Asia and are contemplating strategies to address the market on the continent. I suspect you will see us become more active in the area in the near future.”

4. The World Korean Medical Organization(WKMO) recently established a consulting subsidiary named W Medical Strategy Group to maximize utilization of knowledge and expertise of our member physicians in achieving our goals of enhancing quality of human life. What do you think the role of physicians and also the role of firms like ours should be in developing new therapeutics?

“Physicians serve an integral role in the development of new therapeutics. Of course Physicians assist us with clinical trials which are essential to getting therapeutics and diagnostics approved and available for reimbursement. Once a therapeutic is marketed, physicians provide us with valuable feedback on our products as they, along with the patients, are our customers.”



5. As a physician, a CEO, and a leader in the healthcare arena, what would be your advice to medical students who are expected to be physicians in few years?

“Be entrepreneurial. New physicians are very well placed to find solutions to problems in the industry. It is a very exciting time to enter medicine given the new technology and new communication mechanisms that are now available. Also be willing to embrace change as new business models are being developed to treat the aging population.”

6. WKMO is a global organization of physicians with Korean heritage. Do you have any personal memories or relationships with Korea or Koreans?

“It has been gratifying to see the tremendous contributions that Korean-Americans have made to the healthcare system both in the U.S. and worldwide. Given our interest in the region we are frequently in contact with Koreans and Korean-American’s to make sure we are addressing their medical needs.”

Bio

Phillip Frost, Chairman & CEO OPKO of Health, Inc.

Dr. Phillip Frost is Chairman and CEO of OPKO Health, Inc., a multinational biopharmaceutical and diagnostics company headquartered in Miami, Florida. He is also Chairman of the Board of Directors of Teva Pharmaceutical Industries Ltd., an international pharmaceutical company based in Petah Tikva, Israel, specializing in generic and proprietary pharmaceuticals and active pharmaceutical ingredients.

Phillip Frost was born in Philadelphia, Pennsylvania where he attended public schools. Dr. Frost earned his B.A. in French Literature from the University of Pennsylvania in 1957, and his M.D. from the Albert Einstein College of Medicine in 1961. He served as a Lieutenant Commander, U.S. Public Health Service at the National Cancer Institute from 1963 to 1965, after which he joined the Dermatology faculty at the School of Medicine, of the University of Miami. Dr. Frost then served as Chairman of the Department of Dermatology at Mount Sinai Medical Center of Greater Miami from 1970 through 1990.

From 1987 to 2006, Dr. Frost served as Chairman of the Board of Directors and Chief Executive Officer of IVAX Corporation, a global pharmaceutical company. When IVAX merged with Teva Pharmaceutical Industries Ltd, he went on to serve as Vice Chairman of the Board until assuming his role as Chairman in 2010. Dr. Frost was also Chairman of the Board of Directors of Key Pharmaceuticals, Inc., from 1972 until it was acquired by Schering Plough Corporation in 1986.

Phillip Frost was Co-Vice Chairman of the Board of Governors of the American Stock Exchange from 2005 - 2008, and is Chairman of the Board of Ladenburg Thalmann Financial Services.

Dr. Frost was a former Chairman of the Board of Trustees of the University of Miami where he still serves as a Trustee, and he is also a Trustee of the Mount Sinai Medical Center. Phillip Frost was a Trustee of The Scripps Research Institute from 2004 to 2012, and a Regent of the Smithsonian Institution from 2006 until 2010. In 2010, Dr. Frost was nominated as a member of the Scientific Advisory Council of the Foundation for Development of the Center of Research and Commercializing of New Technologies in Russia. Most recently, Dr. Frost was appointed as a Founding Member of the Scientific Governance Board of the Shanghai Institute for Advanced Immunochemical Studies (SIAIS).

Dr. Frost was appointed by President Ronald Reagan to the National Cancer Advisory Board and by President Bill Clinton to the National Museum Service Board. He was named National Entrepreneur of the Year by Ernst & Young in 2001. Dr. Phillip Frost is a recipient of the 2014 Ellis Island Medal of Honor.
Dr. Frost is a generous supporter of education, science and technology and the arts. After his gift in 2003, the largest ever given to a university-based music school, the University of Miami named the school the Phillip and Patricia Frost School of Music. Also in 2003, after his gift to the Art Museum at Florida International University, the museum was named The Patricia & Phillip Frost Art Museum. Most recently, he provided a major gift for the construction of the new Miami Science Museum, which will be named the Patricia & Phillip Frost Science Museum. He and his wife, Patricia, are renowned collectors who gave their 113-piece collection of American abstract art to the Smithsonian Institution in 1986.

THE BIOTECHNOLOGY INDUSTRY IN KOREA: RIPE FOR INVESTMENT

TRACKING THE AFFORDABLE CARE ACT

Special Report I

The Biotechnology Industry in Korea:
Ripe for Investment

Korea has emerged over the past decade as one of the major industrial markets in the Asia-Pacific region, which accounts for 24% of the world's population, 19% of global production, and 13% of international trade volume, making it a clear hub in the global economy. Asia's share of global GDP, measured in purchasing power, has increased from 26.8% in 2001 to 33.8% in 2010 and is expected to rise to 38.9% by 2016. Pharmaceutical sales in Asia have more than doubled from USD97 billion in 2001 to USD214 billion in 2010 and are expected to reach USD386 billion by 2016. Korea is favorably located at the center of the Asia-Pacific region, which is a geographic advantage for Korean and locally-based foreign companies serving the major East Asian markets such as China, Japan and the ASEAN countries, which together account for 31% of global international trade demand. Korea's strong economic growth, increasingly favorable environment for foreign direct investment, and rapid transformation into a knowledge-based information society have resulted in a growing number of attractive investment opportunities for both domestic and international institutional investors.

Currently, there are hundreds of companies that make up Korea's biotechnology industry. As the health profile of South Koreans is already on par with their counterparts in industrial countries, the domestic demand for health-care and biotechnology products is primarily due to increasing household resources available for higher-cost medical treatments. The expansionary pressures of the domestic drug market are also driving demand for newer and better therapies, which is a reflection of South Korea's public healthcare system that features universal access and relatively low out-of-pocket payments. This has fueled significant growth in recent years for the biotechnology and broader healthcare sector in Korea. In fact, Korea's health care sector is one of only a few sectors whose collective market capitalization has continued to grow after 2010 with a current market cap of approximately W35 trillion compared to W21 trillion in 2010 and W12.5 trillion in 2005 (Figure 1).

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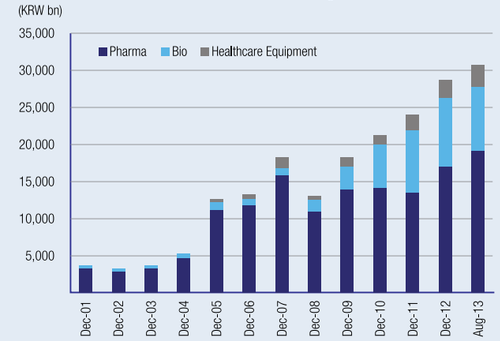
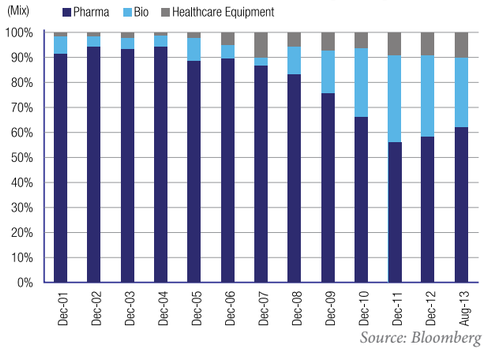
Figure 1
Korean Health Care Sector Market Capitalization Trends



Source: Bloomberg

Furthermore, Korea's biotechnology sector has been experiencing significantly faster growth than its pharmaceutical and medical technology sector peers (Figure 2).

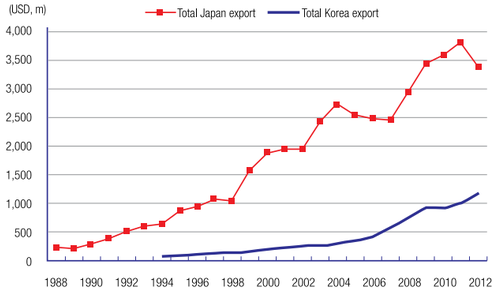
Figure 2
Korean Health Care Sector Market Cap Composition



Source: Bloomberg

In many ways, the Korean pharmaceutical and biotechnology sectors appear to be on the verge of an upward re-rating similar to the re-rating that occurred with Japanese pharmaceutical companies in the 1990s. The rapid growth of Japanese pharmaceutical companies two decades ago was the result of several factors. First, the 1990s was an era of innovation for drugs to treat chronic conditions such as hypercholesterolemia, hypertension, and diabetes with many new drugs gaining widespread use globally. It is well known that Takeda led diabetes drug development by launching Actos, but less well known is that Takeda's proton pump inhibitor, Prevacid, for peptic ulcer disease was launched not long after AstraZeneca's omeprazole. Although Takeda was an innovator in diabetes, it was more of a fast-follower in peptic ulcer disease. Japanese companies sent researchers to universities in the United States and Europe to study the most recent advances in disease biology and then took these new findings and developed better drugs in the same mechanistic class through innovative medicinal chemistry, which allowed them to be successful fast-followers. Second, the pharmaceutical market in the United States was growing at double digits in the 1990s, and the U.S. Food & Drug Administration approved many drugs quickly. Since the U.S. pharmaceutical market was growing fast, if Japanese companies were able to form partnerships with U.S.-based companies that allowed them to build their own U.S.-based commercial subsidiaries, these companies gained deep access into the fast-growing U.S. market. Notable alliances during this time period included Takeda with Abbott, Takeda with Lilly, Astellas with Abbott, Daiichi Sankyo with Johnson & Johnson, and Eisai with Pfizer. Similarly, Korean pharmaceutical exports have also been steadily growing over the past decade, albeit at a lower overall rate but at a similar trajectory to Japanese pharmaceutical exports, which also indicates that Korea is moving in the right direction (Figure 3).

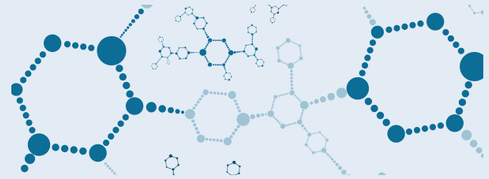
Figure 3
Korean and Japanese Pharmaceutical Exports



Source: OECD, Citigroup Research

The impetus for Korean pharmaceutical and biotechnology companies to expand into Western markets is high given the current state of the domestic pharmaceutical market in Korea. Pharmaceutical sales in Korea are expected to grow <6% per annum in the next three years, which is below the historical average of 9%. This slow domestic sales growth is a function of three structural factors: (1) new regulation of drug promotion and rebates; (2) likely implementation of a regular price cut system; and (3) doctors' behavioral changes in writing fewer prescriptions. These negative drivers are overshadowing growth related to Korea's aging population. New laws in Korea have been enacted recently that place unfavorable taxation on sales promotion expenses. Specifically, Korean tax regulators have started applying stricter guidelines on entertainment expenses, imposing additional taxes on several pharmaceutical companies including Dong-A ST (W84 billion), Kyungdong (W9 billion), and Samjin (W13 billion). In addition to these new taxes, the Korean government has implemented a dual punishment system that penalizes rebate payers such as pharmaceutical companies and their beneficiaries including doctors. So far hundreds of doctors have been charged and penalties have been assigned including fines and suspensions of medical licenses. Also in 2011, a compulsory drug price cut related to illegal rebates was implemented as a powerful regulatory tool to reduce illegal rebates. More recently in November 2013, the Korean government also implemented a sales-volume-based price cut system that targets drugs with strong sales (+10% YoY or +W5 billion YoY). If a drug meets these criteria, the government can negotiate with the manufacturer for as much as a 10% price cut. Finally, because the Japanese government recently stated that it is targeting a 20% ceiling on pharmaceuticals as a percentage of total healthcare spending, the Korean government is also considering a similar move to reduce pharmaceutical spending to 24% of all healthcare spending from its current 26.6%. All these measures indicate that Korean pharmaceutical and biotechnology companies will have to look abroad for growth.

Accordingly, the next step is for Korean pharmaceutical and biotechnology companies to build sustainable businesses from their own discoveries through direct revenue recognition of their products rather than a royalty stream. The first step in this process however requires significant capital, which is where the investment opportunities arise. Conducting successful clinical trials is the single most important step to developing and launching new drugs in any market. Thus, completion of late-stage clinical trials overseas would increase license-fee income with higher royalty streams. However, Korean pharmaceutical and biotechnology companies have historically not had sufficient capital to conduct overseas clinical trials. In the prior two decades, blockbuster drugs were broadly-used primary care products whose commercial potential was primarily based on broad adoption and enormous sales volume. This represented a significant barrier for Korean pharmaceutical and biotechnology companies because compared with their average W700 billion equity base, the cost to run one Phase 3 trial in the U.S. for a primary care product could be as high as USD200 million. Note that this compares with a W17 billion (USD15 million) clinical trial cost in Korea according to KDRA. For example, Celltrion, a Korean biotechnology company, spent USD200 million to conduct their clinical trials for a biosimilar Remicade, which recently gained regulatory approval in Europe. Not many Korean companies are able to fund clinical trials of this magnitude themselves. In recent years, however, many U.S. and European biotechnology companies have seen tremendous success developing targeted drugs for orphan diseases and cancers that are refractory to current treatments with very small clinical trials that have average costs on par with the costs of running a clinical trial in Korea. Furthermore, there is an industry-wide transition to using contract research organizations to run clinical trials for pharmaceutical and biotechnology companies with all the requisite regulatory and clinical development expertise residing within these contract research organizations. This represents a tremendous opportunity for Korean pharmaceutical and biotechnology companies to run their own clinical trials for their own products to become commercial entities in Western markets.



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. Relying on licensees to commercialize their drugs for them in foreign markets greatly limits the upside potential from such blockbuster therapies. The case of Dong-A ST's Tedizolid is an example of the limitations of these out-licensing business models. Dong-A ST is a Korean pharmaceutical company that currently receives only 7% of total Tedizolid global sales, which are approximately USD1 billion whereas its commercial partners take

93% of the USD1 billion because they market the drug for Dong-A ST. Therefore, the next logical step in the evolution of Korean pharmaceutical and biotechnology companies is to establish joint ventures overseas that will allow them to build their own overseas subsidiaries, vertically integrate them with R&D centers abroad, and commercialize their products themselves. The Korea Drug Research Association highlights that 29 Korean pharmaceutical companies have signed out-licensing contracts for 91 drugs in the past three decades, which has given credibility to Korea's R&D efforts. In addition, several Korean pharmaceutical and biotechnology companies have recently forged significant strategic alliances with global partners, which has given credibility to the entire sector (Figure 4).

Figure 4

Medytox
ALLERGAN

- Next generation Botox global licensing deal with Allergan (September 2013)
- USD65 million upfront with USD370 million total milestone payments.

HANDOK
TEVA
TEVA PHARMACEUTICALS

- Joint venture to develop novel therapeutics and generics in Asia

CELLTRION
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Remsima – World's first biosimilar monoclonal antibody approved by European Medicines Agency (August 2013)
- Approved in 31 European countries

Source: Medivate Partners, Company Reports

In the near-to-intermediate term, Korean biotechnology companies have a clear edge over their pharmaceutical peers in terms of revenue growth. For the major pharmaceutical companies such as Dong-A ST, Green Cross, Yuhan, and LG Life Sciences, the average projected revenue growth forecast is +13% for this year, slowing to +8% next year due to low domestic pharmaceutical market growth. In contrast, biosimilar-maker, Celltrion, stands out with an expected +45% growth in revenues this year while stem cell companies such as Medipost and Pharmicell are also expected to see higher top line growth as recent launches gain traction. Earnings growth for the larger pharmaceutical companies should also be solid as exports and increasing royalty revenues allow for better leverage in their income statements. Celltrion, Dong-A ST, and Green Cross are all set to deliver mid-to-high-teens earnings growth this year while Yuhan is forecasted to grow earnings +40% this year albeit from a low base. For Korean biotechnology companies in general, earnings growth this year will be higher on a relative basis than many of their peers by market-capitalization in the United States, which also argues for greater money inflows from growth investors (Figure 5).

Figure 4

	Mkt Cap (USDm)	Stock currency	3 Months	6 Months	12 Months	3 Years	5 Years	10 Years
Celltrion Incorporated	4,943	KRW	14%	4%	30%	145%	1612%	1612%
Yuhan Corp.	1,805	KRW	7%	32%	56%	12%	13%	13%
LG Life Sciences Ltd.	927	KRW	45%	49%	70%	8%	19%	19%
Dong-A Pharm.Co.Ltd.	1,266	KRW	22%	29%	49%	14%	10%	10%
Green Cross Corporation	1,445	KRW	12%	2%	24%	32%	102%	102%
Green Cross Hdg.Corp.	660	KRW	0%	10%	7%	83%	86%	86%
Pharmicell Company Ltd.	186	KRW	2%	-29%	-43%	54%	316%	316%
Medipost Company Ltd.	635	KRW	29%	-9%	2%	296%	505%	505%
Hanmi Pharm Ctd.	1,193	KRW	41%	87%	192%	NA	NA	NA
Seegene Inco.	950	KRW	18%	29%	14%	NA	NA	NA
Daewoong Pharm.Co.Ltd.	587	KRW	33%	108%	107%	25%	-34%	-34%
M/CAP WA			**19%**	**24%**	**49%**	**74%**		
ex-biotechs			**25%**	**48%**	**73%**	**18%**		

Source: Thomson Reuters Datastream

So in overview, the Korean pharmaceutical and biotechnology sectors have seen some promising developments that are becoming increasingly investable. In particular, immuno-oncology and stem cell therapies are well-developed, with many late-stage pipelines nearing approval or already approved. Indeed, stem cell treatments have reached clinical maturity for acute heart attack, degenerative cartilage disease, and Crohn's Disease with patients now having access to approved stem cell treatments. Company pipelines on established platforms include treatments for stroke, spinal cord injuries, and Alzheimer's disease, some of which are in late-stage trials. All of these developments represent significant opportunities for investors to capitalize on the enormous potential within the pharmaceutical and biotechnology sectors in Korea. W

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Special Report II

Tracking the Affordable care

Tracking the Affordable Care Act

Author: Laura Carabello, Principal, CPR Strategic Marketing Communications

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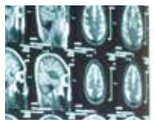
Now that the first open enrollment period for health insurance under the Affordable Care Act (ACA) has ended, consumers, insurers and federal officials must now tackle the next phase of challenges that could potentially impact the law's effectiveness.

According to the White House, 7.1 million Americans have signed up for health insurance but, more than numbers, success will hinge on the mix of enrollees – requiring enough healthy people to compensate for the costs of sicker individuals. The law's impact will vary from state to state, depending on demographics and political stance toward the law.

One unknown factor to keep in mind is that millions of the newly insured have gone uncounted because they did not utilize the state or federal exchanges -- but will nevertheless influence the risk pool.



Cost Issues

Lingering issues related to cost will persist:

Premiums -- A number of insurers have stated that they will seek double-digit increases in premiums next year, although certain factors could mitigate this possibility, including:

- competition as more insurers enter the market in some states
- Federal and state officials' ability to negotiate with insurers in the face of excessive pricing
- ACA mechanisms designed to stabilize premiums, i.e. if one insurer enrolls a disproportionate number of sick people, the government and other insurers will help defray the costs

In general, if policy changes encourage fewer younger and healthier people to purchase coverage in the exchange, premiums will increase in the marketplace and lead to fewer options for consumers.

Extension -- The grace period extended to those unable to complete enrollment before the March 31 deadline has raised some flags. Moody's Investor Services states that the extension is "credit negative" for carriers because it increases the risk of anti-selection and will likely lead to higher premiums in 2015, further discouraging enrollment.

Tax -- The law's health insurance tax is slated to increase 40 percent next year, adding almost $400 to an average family's healthcare costs.

ACA Impact on Physicianse Act

The ACA has shifted greater financial responsibility onto the patient, sparking a higher level of consumer expectation. Health insurance plans include substantial annual deductibles—between $1,500 and $10,000 for a family, and co-payment amounts have increased, particularly for labs test and imaging.

In response, many physicians have shifted their revenue model from dependence on insurance reimbursement to aggressively collecting out-of-pocket patient payments, adding greater levels of accountability, operational challenges and reporting requirements.

Another issue of concern to physicians, the Senate recently passed the temporary fix to the sustainable growth rate (SGR) that delays (to October 2015) the implementation of ICD-10, the process of converting medical documentation practices, billing procedures, payment structures, and health IT infrastructure to accept ICD-10 codes. This delay will now serve as a major distraction to providers, as well as require massive additional investments of time and money.

Possibly the most daunting issue related to ACA centers around its impact on healthcare infrastructure and the physician shortage. Without more graduates from nursing and medical schools and increased innovation in shared roles and responsibilities among doctors, nurses, and other medical professionals, individuals and families will face longer wait times, greater difficulty accessing providers, shortened time with providers, increased costs and growing frustration with care delivery. It's possible that this issue alone could negatively affect healthcare workers and their ability to provide care, given increased regulatory burdens, heavier workloads and reduced payments.

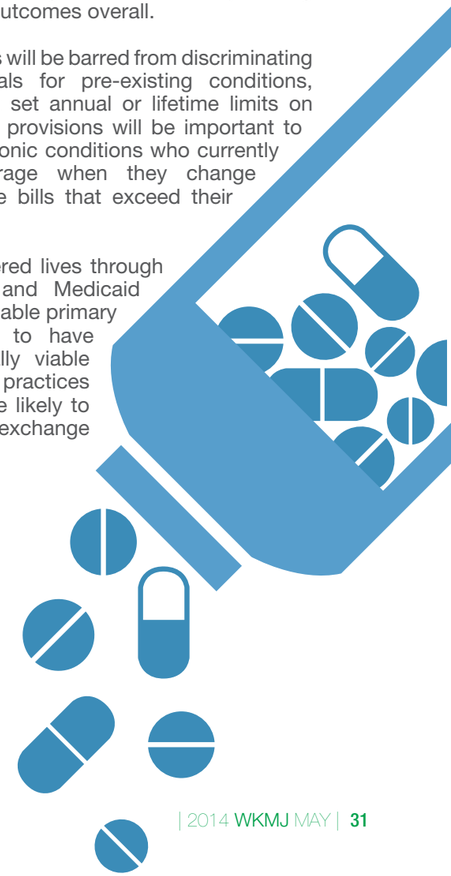
The current U.S. population is more than 315 million and growing. By 2030, 72 million Americans will be 65 or older, a 50 percent shift in age demographics since 2000. The shift is mostly due to aging Baby Boomers. Seniors currently account for 12 percent of the population but will account for 21 percent by 2050. This growing, aging population will ensure more chronic disease and additional stress on the healthcare workforce.

Rural populations are poorer and more likely to rely on government assistance, creating the potential for high demand due to the Medicaid expansion in 26 states. As it is, rural Americans face longer wait times, difficulty accessing care, long-distance travel and limited resources.

That said, the new law removes some major impediments in insurance coverage for patients, and mandates extra services previously not covered, such as maternity care, mental health services, medications, rehabilitation services, and chronic disease management – potentially leading to better health outcomes overall.

Also, health plans will be barred from discriminating against individuals for pre-existing conditions, and they cannot set annual or lifetime limits on coverage. These provisions will be important to patients with chronic conditions who currently can lose coverage when they change jobs and/or have bills that exceed their insurance limits.

While more covered lives through the exchanges and Medicaid expansion will enable primary care physicians to have a more financially viable practice, many practices at full volume are likely to refuse to join exchange plans.



Key Challenges Ahead

It remains unclear as to whether employers will cut employee insurance or not. Under the ACA, large employers are generally required to offer coverage to full-time employees -- defined as those who work at least 30 hours a week -- or pay penalties. The administration has delayed the requirement, but it will hit many employers in 2015 or 2016.

Some employers say this mandate incentivizes them to reduce work hours for some employees, but the White House claims there's no supporting evidence of such a trend, and promises that small businesses will have an opportunity to buy insurance online for their employees through the federal marketplace in the fall.

For now, the full impact of the ACA remains a question mark as evidence of its influence continues to emerge and as key mandates kick in over the next couple of years.

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Principal
CPR Strategic Marketing Communications

LAURA CARABELLO has been an entrepreneur and a strategy consultant in both domestic and international businesses related to healthcare and technology since 1985. Her fields of experience span from healthcare and healthcare information technology to hard core technology disciplines and related infrastructure. She has a particular interest in medical travel, healthcare/healthcare information technology, telehealth/telemedicine, managed care and employee benefits, life sciences (pharmaceuticals and medical devices), and other business-to-business and direct-to-consumer healthcare and technology companies. She has been instrumental in the growth and development of companies worldwide and has orchestrated their transition to a Web-centric world.

Founder and principal owner of CPR Strategic Marketing and Communications, (www.cpronline.com), Carabello has more than 25 years' experience in business development, marketing, and corporate positioning. As strategy consultant, she has worked with over 1,000 companies, including public and private organizations. She also serves as a strategic advisor to public, private and not-for-profit entities, and has been invited by the US Federal Trade Commission to testify on healthcare advertising and marketing ethics.

Bio Pharmaceutical Report I

AstraZeneca's pipeline projections a tough sell, Pfizer will struggle to drive combined value

- Valuations unreliable given large timeframe to market
- Likely EU/US pricing pressures to impact revenue forecasting
- Combined Pfizer-AZ pipeline unlikely to create industry leader

AstraZeneca's (LON:AZN) own pipeline valuations up to 2023 are overinflated given the uncertainties in R&D execution and the future commercial landscape, industry experts said. Pfizer's (NYSE:PFE) poor track record in the clinic raises doubts on converting any potential synergies to a successful combined pipeline in the long term, they added.

On Tuesday (13 May), AZ issued a statement that its board believes Pfizer's attempt to acquire AZ does not reflect the value of its pipeline. On 6 May, AstraZeneca issued an update to shareholders on its strategy to deliver annual revenues of greater than USD 45bn by 2023.

AstraZeneca's pipeline valuations on individual candidates are based on loose analyst forecasts and optimistic assumptions on success, noted an industry consultant. These numbers hold little weight in accurately predicting market reality, particularly the further they are away from the market, he said.

The projections are "very bullish", particularly as AZ had a poor drug development record under its previous management, said an industry advisor and former global healthcare banker. The valuations are a standard defence, but these numbers would have been slightly more credible from players like Novartis (VTX:NOVN), Roche (VTX:ROG) or Bristol-Myers Squibb (NYSE:BMY) who have had more R&D success, he added.

The rapidly changing landscape for launching new drugs is becoming increasing difficult to secure premium pricing for ROI (particularly in oncology) which puts a spin on accurately predicting AZ's commercial potential nine years from now, with little data generated on its early-stage pipeline, said a drug reimbursement consultant.

AZ has "taken exaggeration to the limit" on projected revenues, and it's questionable whether AZ itself believes its own numbers

AZ has now decided to focus on its three core areas: oncology, respiratory and cardiovascular, according to AZ's CEO Pascal Soriot in a 24 April conference call.

AZ has valued key pipeline assets and non risk-adjusted peak year sales estimates were given for MEDI4736 (USD 6.5bn) and AZD9291 (USD 3bn) for lung cancer and olaparib for ovarian cancer (USD 2bn). The Immuno-oncology assets are generating the most interest in AZ's pipeline, but AZ is lagging behind in the race to market with big pharma oncology firms including BMS, Merck (NYSE:MRK) and Roche, said a second industry consultant. Ultimate commercial success will depend on comparative effectiveness data, but also power in pricing negotiations in a competitive space which will be a challenge, the two industry consultants and advisor said.

The oncology space is increasingly coming under scrutiny from a price point in Europe, requiring more robust and difficult-to-generate cost-effectiveness data to justify high listed prices, the reimbursement consultant noted. The US has been the preferred launch region, but it is expected that there will soon be downward pricing pressure in the US as charging upwards of USD 100,000 per patient per year for some oncology treatments is becoming less feasible, a second industry consultant added. This could heavily impact AZ's products that are five or six years away from the market, added the first industry consultant.

Lead developments in respiratory -- PT003 and PT001 for chronic obstructive pulmonary disease (COPD) -- have been given a USD 4bn peak sales estimation by AZ, however, the COPD area is a complex and competitive space, said the advisor. Pulmonologists have previously told BioPharm Insight that the LABA/LAMA combinations will be the new mainstay of COPD treatment, though AZ's program (PT003) is well behind in the race as GlaxoSmithKline (LON:GSK) is already leading the market with its imminent EU/US launch of Anoro elipta this year. US R&D hurdles have been encountered by closest competitors Novartis and Forest (NYSE:FRX), though their EU launches are at least three years ahead of AZ, who expects a best case global launch in 2017, he added.

In the cardiovascular (CV) and diabetes arena, AZ's Brilinta (ticagrelor) for acute coronary syndrome (ACS) has the highest sales projection of USD 3.5bn by 2023, driven by its current approval in ACS and expansion into the broader patient population. 2013 sales in ACS were USD 283m and cardiologists have previously told BioPharm Insight that Brilinta would see minimal uptake in a broader secondary care setting. Brilinta has so far not had a successful launch and it will be difficult to meet AZ's projections, said the second industry consultant and advisor. Diabetes does seem to be an area with more growth promise for AZ with its existing product base including Onglyza (saxagliptin), Bydureon (exenatide) and Farxiga (dapagliflozin), with good 1Q14 earnings of USD 347m, noted the second consultant, yet added that a revenue target of USD 8bn for the total franchise by 2023 is also a stretch.

AZ has made a string of pipeline announcements over the last two weeks including a drug approval, trial initiation, trial results and research collaborations, which could be a mixture of defense strategy and coincidence, yet no announcement has made any drastic changes to overall valuations, noted the advisor.

AZ has "taken exaggeration to the limit" on projected revenues, and it's questionable whether AZ itself believes its own numbers, said a former senior Pfizer executive. Pfizer's tax-incentivised GBP 63bn (USD 106bn) offer convincingly exceeds AZ's overinflated pipeline projections, noted the advisor and second industry consultant.

Pfizer's swoop will struggle to combine value

Despite the overly optimistic projections, all experts agreed a merger of Pfizer and AstraZeneca would not likely add great value in a combined pipeline. From an R&D standpoint, AZ and Pfizer are historically two big pharma players infamous for sinking enormous amounts

A merger of Pfizer and AstraZeneca would not likely add great value in a combined pipeline

of money into R&D with a low success rate, said the advisor. Pfizer's major strength areas are CV, immunology, neuroscience, oncology and vaccines, and the biggest value synergies between AZ and Pfizer have been described in oncology, noted the advisor. Yet neither Pfizer nor AstraZeneca are the leaders in oncology, and combining two low-tier players will not leverage a leader in the field like Pfizer is suggesting, he added.

A combined Pfizer-AstraZeneca will never be able to compete with the likes of oncology leaders Roche, Novartis and Celgene (NASDAQ:CELG), the second industry consultant added.

In any merger, pipelines suffer with drug development slashes, and no mergers to date have seen the pure addition of pipelines, said the first industry consultant. There is no rationale on potential synergies and how they will improve innovation and cost-effective healthcare, he said. Pfizer also has a bad track record of acquisitions including Warner-Lambert, Pharmacia and Wyeth, where poor strategic decisions were made on which assets to progress and shelve, noted the second industry consultant. Pfizer could handle the merger, but its statements on commitments to innovation are not substantial enough to convince this can be executed correctly for the long term, added the former Pfizer executive and advisor.

AZ's management has publicly reinforced the fact this merger would cause disruption and distraction to R&D efforts and this is not an exaggeration as mergers of this size can easily cause up to 10 years of R&D disruption, the advisor said. The merger of GlaxoWellcome and SmithKline in 2000 saw a similar disruption that only started to see R&D upside at the latter part of 10 years, the advisor noted.

Pfizer has run out of options from a clinical perspective and is making a short-term financial move, all experts agreed.

There is a short-term financial rationale from a shareholder perspective to go ahead with the deal with a few offer bumps as AZ prepares to lose a disproportionate part of its sales between now and 2018 as blockbusters go off patent, the advisor said, adding, whilst a credible leader, Soriot's execution in driving pipeline assets to the market over the next 10 years becomes a big investment risk.

AstraZeneca has a market cap of GBP 59.6bn. Pfizer has a market cap of USD 185bn.
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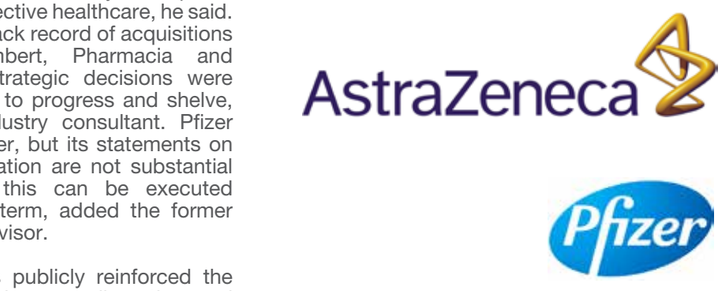

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Merck's Phase III tecemotide vaccine trial in NSCLC in Asian patients could show benefit, but EGFR target is unclear

- Marginal OS benefit found in Asian patients in previous trial lends optimism
- Vaccine combination with PD1/PDL-1 checkpoint inhibitors promising
- Minimal side-effect profile encouraging for patients with Stage III lung cancer

Merck (ETR:MRK) and Oncothyreon's (NASDAQ:ONTY) Phase III tecemotide (L-BLP25 liposome vaccine) has the potential to demonstrate efficacy in an Asian non-small-cell lung cancer (NSCLC) population subset, oncologists said. Concurrent chemotherapy and radiation may contribute to positive outcomes, some noted. However, the justification for specifically testing this population is unclear, they noted.

The 500-patient INSPIRE trial (NCT01015443) is expected to have interim results in 2H14, according to analyst reports. The study compares BLP25 liposome vaccine, formerly known as Stimuvax, plus best supportive care to a placebo IV infusion and best supportive care. Subjects are only East Asian with Stage III, unresectable NSCLC who have demonstrated either stable disease or objective response following primary chemoradiotherapy, according to ClinicalTrials.gov.

There is another Phase III tecemotide trial, START2 (NCT02049151), which began in March 2014 with a recruitment goal of 1,002 patients, according to ClinicalTrials.gov. The inclusion criteria is the same as the INSPIRE trial, with no sites listed in East Asia. The estimated completion date is July 2018.

The sponsors declined to comment.

START data in Asian patients encouraging

A "reasonable chance" exists that INSPIRE will statistically meet the overall survival (OS) primary endpoint, principal investigator Dr Tony Mok said. He pointed to a marginal benefit found in OS for Asian patients from the earlier, Phase III START trial (NCT00409188), which ended in 2012 after it failed to show statistically significant OS in 1,513 patients.

Mok noted that targeting epidermal growth factor receptor (EGFR) mutation, which is found more often in the Asian population, has led to positive outcomes in past NSCLC trials. He cited AstraZeneca's (LON:AZN) IRESSA (gefitinib) as an example.

EGFR mutations are found in about 30% of unselected NSCLCs in East Asian patients and in about 10% of North American and European patients (J Clin Oncol. 2013 Mar 10; 31(8):1070-80).

The START data supports BLP25 liposome vaccine's potential to show benefit in Stage III lung cancer patients and "nothing else out there" has similar strong data, said START investigator Dr Charles Butts, medical oncologist, Cross Cancer Institute, Edmonton, Canada, said. If FDA-approved, the treatment would provide an option for Stage III NSCLC patients where none exists, he added. His caveat though was the INSPIRE trial's sample size seems small.

To his knowledge, previous studies have not shown correlations between EGFR-mutated lung cancer patients and better outcomes with immunotherapy vaccines, said Dr Hak Choy, chair, Department of Radiation Oncology, University of Texas Southwestern Medical Center, Dallas. The rationale behind targeting only Asian patients is unclear, he added, with Bazhenova agreeing it was too early to tell.

Chemotherapy and radiation combination possibly beneficial

The best OS outcome from the START trial appeared to be in a subset of patients who received concurrent chemotherapy and radiation, rather than those who received the treatments sequentially, said lung cancer investigator Dr Lyudmila Bazhenova, medical director, University of California San Diego Moores Cancer Center. Patients who had the concurrent treatment had a median overall survival of 30.8 months compared with 20.6 months in the control arm (Lancet Oncol. 2014 Jan;15(1):59-68).

INSPIRE uses 918 micrograms in eight once-weekly consecutive subQ vaccinations, followed by one vaccination every six weeks until disease progression or if the patient discontinues the trial. START and START2 use 806 micrograms. In all three trials, patients receive one 300mg/m2 infusion of the chemotherapy cyclophophamide three days before the first BLP25 liposome vaccination.

This low chemotherapy dose is thought to stimulate immune cells and growth factor cells, Mok, a professor in the Department of Clinical Oncology, Chinese University of Hong Kong, Prince of Wales Hospital, said. But it is not yet known if this pretreatment makes a difference in clinical outcomes, he added.

The pretreatment administration could be important to help overcome resistance mechanisms that the tumor uses to avoid immune recognition, Butts said. The differences in chemotherapy doses are probably negligible because they are based on how the syringe is filled, he said.

PD1/PDL-1 checkpoint inhibitor drug combos, safety profile hopeful

Even if the INSPIRE trial fails to meet its primary endpoint, the vaccine may still be useful when combined with PD1/PDL-1 checkpoint inhibitor drugs, said lung cancer investigator Dr Karen Reckamp, co-director, Lung Cancer and Thoracic Oncology Program, City of Hope, Duarte, California. Some effector memory T cells may not be activated by the vaccine because the lung tumor has immune checkpoint blockages, for example, she said.

Lung cancer is not one disease and agents like immunotherapy may need "a sort of adjuvant" like checkpoint inhibitors, said Reckamp, who worked as an investigator on GlaxoSmithKline's (LON:GSK) MAGE-A3 vaccine trial in earlier stage, resectable NSCLC. Much interest still exists in combining different immunotherapies with drugs having different mechanisms of action, Bazhenova agreed.

The vaccine's low toxicity is especially important for lung cancer patients who have emerged from highly toxic chemotherapy and radiation treatments, Butts said. So far only minor adverse effects have been seen on the skin at the injection site in the INSPIRE trial, said Mok. In general, the immunotherapy vaccines are very well-tolerated, Bazhenova agreed.

Merck's market cap is EUR 26.8bn (USD 36.7bn). Oncothyreon's market cap is USD 201.6m.

Kathleen Raven
Reporter
BioPharm Insight

Kathleen investigates oncology for BioPharm Insight. She previously worked as a journalist for Reuters Health and has written for Nature Medicine. Kathleen has a BA Honors in journalism, MS in ecology and MA in health and medical journalism, all from the University of Georgia.

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

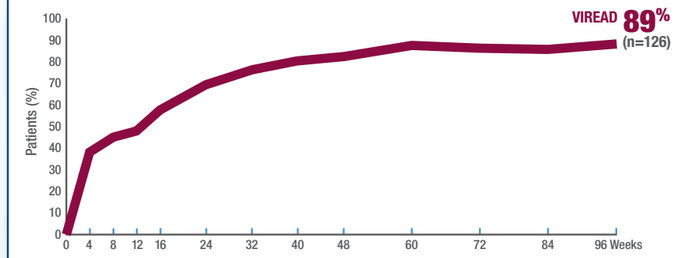
Adverse Reactions

- **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

Brief Summary (cont'd)

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.

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.

WKMO Executives Official Visit to Korea

Photo session for the VIP attendees. In front row, four National Assembly members attended including Jeong Lim Moon, Insook Park, Jaesae Oh, Hong-joon Ahn. Dr. Evelyn Baram-Clothier, Founder and Executive Director of American Medical Foundation also attended. Second and third rows, attended industry leaders including CEOs from Green Cross, DongA, Ahn-Gook, CKD, YuYu, Samsung and etc

WKMO executives including the President Chul S. Hyun, MD, PhD, Vice President(also the President of Korean American Medical Association) David Ko, MD, 2014 Convention Chair and Brazil Executive Hyung Kwon Kim, MD, Outreach Committee Director Kee Park, MD, U.S. Director Mun Hong, MD, W Medical Strategy Group President/CEO Dohyun Cho, PhD, were welcomed and accompanied by the executives from Korea, including Executive Vice President Kyoung Ryul Lee, MD, PhD, Secretary General Kyung Sun, MD, Executive Director Sanghoo Kim, MD, Directors Jongtae Yoon, MD, Kristie Kim, MD and many others. The executives had an official visit to Korea from April 20-24th to explore collaboration opportunities with government officials, physicians and healthcare industry leaders of Korea.

On April 20th, 'Celebration of the Publication of World Korean Medical Journal (WKMJ)' was held at Seoul Club in Seoul to congratulate its first issue release. Over 70 leading minds and eminent figures attended the event, including 5 national congressmen headed by Jaesae Oh, Chairman of National Assembly Committee on Health and Welfare, 30 pharmaceutical and medical device industry executives including Won-bae Kim, CEO of Dong-A ST, BG Rhee, CEO of Green Cross Holdings, Jin Auh, President of Ahn Gook Pharm, Sooin Cho, CEO of Samsung Medison, 50 leader physicians and hospital presidents such as Hee-joong Kim, Vice President of Seoul National University Hospital, and reporters from major Korean newspaper Media such as Chosun Daily and DongA Ilbo.

1. Dr. Chul Soo Hyun, the president of WKMO is introducing mission and functions of WKMO to the audience.
2.. Hon. Hongjoon Ahn, National Assembly Chair of Foreign Affairs and Trade Committee, is delivering his congratulatory remarks
3. Drs. Kyoung-Ryul Lee (Hanaro) and Dohyun Cho (WMSG) signed collaboration MOU to strengthen Hanaro's global operation.

"Readers will find this new publication very informative as WKMJ plans to share scholarly work of member physicians and professionals in the healthcare industry, and provide insights on healthcare industry trends presented from the network of 36,000 member physicians of WKMO across the globe" said President Hyun in his opening remarks.

From April 21-23rd, WKMO executives visited the presidential residence Blue House meeting with senior advisors, and had meetings with Minister of Health and Welfare Ministry, Minister of Food and Drug Safety Ministry, Vice Minister of Finance and Planning Ministry and presidents of governmental organizations such as OKF(Overseas Koreans Foundation), KOICA(Korea International Cooperation Agency) and KHIDI(Korea Health Industry Development Institute). Also, the delegation visited the National Assembly to have detailed discussion with several political leaders.

For the final mission, on April 24th, the delegation visited Hanaro Medical Foundation to witness and congratulate Memorandum of Understanding signing ceremony for Hanaro Foundation and W Medical Strategy Group. Through this MOU, these two organizations agreed to collaborate in enhancing the excellence of preventive healthcare screening programs of Korea to the world. W

Conference Alerts

America

2014 BIO International Convention

June 23-26, 2014 San Diego Convention Center in San Diego, CA

The world's largest biotechnology gathering, the BIO Exhibition allows exhibitors to reach high-level executives and influential decision makers who come to BIO to discover new players in the industry, form partnerships and evaluate emerging technologies. The BIO Exhibition features more than 1,700 exhibitors and covers approximately 180,000 square feet. The exhibition also includes 60+ state, regional and country pavilions who in turn host many companies from their regions.
Conveniently organized by product focus, the exhibition includes companies in the Digital Health Zone, Innovation Zone, BioProcess Zone, Bio IT Zone, Business Services Zone, Contract Services Zone, and Discovery Zone. In 2014 the BIO Exhibition will host thousands of organizations including the leading biotech companies, top 25 pharma companies, top 20 CROs and CMOs, more than 300 academic institutions including the major research labs and government agencies and the leading consultants and service companies.
http://convention.bio.org/2014/

America

22nd Biennial Conference on Diseases of the Vulva and Vagina

September 4-7, 2014 Chicago

This course is an ideal educational program for clinicians who treat patients with persistent or recurrent vulvovaginal conditions. Up-to-date information for providers who work to prevent and treat vulvar condyloma and high-grade squamous intraepithelial lesions of the vulva will be addressed. Providers who are frustrated with persistent or recurrent vulvovaginitis will gain tips on diagnosing and treating these conditions. Some of the rarer conditions, such as Crohn's disease of the vulva hidradenitis suppurativa, and Paget's disease will be explored in detail.
http:// www.issvd.org/

America

2014 Legislative Conference

September 4-9, 2014 Washing-ton DC, Grand Hyatt

Join dermatologists and patient advocates from across the country in Washington, D.C., for the 2014 AADA Legislative Conference and present a united voice to Congress about dermatology's most pressing issues.
http://www.aad.org/members/practice-and-advocacy-resource-center/get-involved/legislative-conference

America

AAO 2014

October 18-21, 2014 McCormick Place, Chicago

Join the Academy in Chicago for AAO 2014, our 118th meeting, in conjunction with the European Society of Ophthalmology (SOE). AAO 2014 is a must-attend week of learning, sharing and networking, not only for ophthalmologists, but also for practice administrators, office managers, billers and coders. Don't miss out on the premier practice management event!
http://www.aao.org/meetings/annual_meeting/program/

America

ACR's 2014 Annual Meeting

November 14-19, 2014 Boston, MassachusettsWashing-ton DC, Grand Hyatt

Join the American College of Rheumatology at the premier meeting in the field of rheumatology, providing you with an environment to see products and services, and the opportunity to build relationships and educate healthcare professionals from around the world.
http://www.acrannualmeeting.org/

America

2014 Annual Clinical Meeting – American Academy of pain management

September 18-21, 2014 JW Marriott Desert Ridge Phoenix, Arizona

Joined by more than 1,000 clinicians, At the 25th Annual Clinical Meeting, you will find information and education you won't find anywhere else. Engaging presentations by top experts in the field of integrative pain management will expand and support the way you think about caring for people in pain. Practical, roll-up your sleeves, hands-on sessions provide you with tools you can use and allow you to network with your peers.
http://www.aapainmanage.org/2014-annual-clinical-meeting/

America

ACG 2014 Annual Scientific Meeting and Postgraudate Course

October 17-22, 2014 Pennsylvania Convention Center Philadelphia, PA

The ACG Annual Scientific Meeting offers you:
· The latest clinical information on key topics for the GI physician
· Plenary sessions and poster sessions that showcase research and provide a wealth of patient-related clinical data and experiences
· Trainees' Forum that allows young physicians to explore career opportunities
· Industry exhibitions featuring the latest advances in gastrointestinal technology and therapeutics
http://gi.org/education-and-meetings/acg-annual-meeting-and-postgraduate-course/

Asia

The 2nd Edition of Medical Asia 2014

November 5-7, 2014 BITEC, Bangkok, Thailnad

The 2nd Edition of MEDICAL ASIA 2014, PHARMA ASIA 2014 And HOSPITAL CONSTRUCTION ASIA 2014 are the only specialized medical, hospital and pharmaceutical events in Thailand that brings together an international congregation of Medical & Healthcare equipment and services, Hospital Construction Technology and Pharmaceutical companies and also its supporting industries gathered in Yangon to showcase the latest developments in the medical, hospital and pharmaceutical industry. Fireworks Exhibitions and Conferences which have organized successful international Medical events such as Medical Asia Thailand, Medical Myanmar and Medical Philippines is the organizer of this premier event in Thailand.

HIGHLIGHTS OF THE EVENT :
· Pharmaceutical Seminars
· Medical Technology Seminars
· International Healthcare Conference
· Hospital Construction Technology Seminars
http://www.thaimedicalexpo.com/

Europe

ESMO World Congress on Gastrointestinal Cancer 2014

June 25-28, 2014 Barcelona, Spain

New findings, new techniques, and recent efforts in research and discovery have changed the way physicians treat their patients — taking a more individualised approach. The ESMO 16th World Congress on Gastrointestinal Cancer will provide important clinical updates in the management of your patients.

With the focus on personalized therapy, multidisciplinary management and unravelling molecular mechanisms, the congress educated and update the broad range of experts who participate in the treatment of gastrointestinal cancers, providing a clear overview for treatment.
http://www.esmo.org/Conferences/World-GI-2014-Gastrointestinal-Cancer

BRIEF SUMMARY

ESOMEPRAZOLE STRONTIUM

delayed-release capsules 49.3 mg

For oral use only

Rx Only

BRIEF SUMMARY of Prescribing Information

INDICATIONS AND USAGE

Treatment of GERD in Adults: Esomeprazole strontium is indicated for the short-term treatment (4 to 8 weeks) for healing and symptomatic resolution and maintenance (controlled studies do not extend beyond 6 months) of confirmed erosive esophagitis (EE), the short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults. **Risk Reduction of NSAID-Associated Gastric Ulcer in Adults, *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults, and Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome in Adults.**

CONTRAINDICATIONS

Esomeprazole strontium is contraindicated in patients with known hypersensitivity to proton pump inhibitors (PPIs). Hypersensitivity reactions, e.g., angioedema and anaphylactic shock, have been reported with esomeprazole use. For information about contraindications of antibacterial agents (clarithromycin and amoxicillin) indicated in combination with esomeprazole strontium, refer to the **CONTRAINDICATIONS** section of their package inserts.

WARNINGS AND PRECAUTIONS

Concurrent Gastric Malignancy: Symptomatic response to therapy with esomeprazole strontium does not preclude the presence of gastric malignancy.

Atrophic Gastritis: Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which esomeprazole is an enantiomer.

***Clostridium difficile* Associated Diarrhea:** Published observational studies suggest that PPI therapy like esomeprazole strontium may be associated with an increased risk of *Clostridium difficile* associated diarrhea. This diagnosis should be considered for diarrhea that does not improve. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents. For more information specific to antibacterial agents (clarithromycin and amoxicillin) indicated for use in combination with esomeprazole strontium, refer to **WARNINGS** and **PRECAUTIONS** sections of those package inserts.

Interaction with Clopidogrel: Avoid concomitant use of esomeprazole strontium with clopidogrel. Clopidogrel is a prodrug. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. The metabolism of clopidogrel to its active metabolite can be impaired by use with concomitant medications, such as esomeprazole, that inhibit CYP2C19 activity. Concomitant use of clopidogrel with 40 mg esomeprazole reduces the pharmacological activity of clopidogrel. When using esomeprazole strontium, consider alternative anti-platelet therapy.

Bone Fracture: Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines.

Hypomagnesemia: Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the PPI. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), health care professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.

Concomitant Use of esomeprazole strontium with St. John's Wort or Rifampin: Drugs which induce CYP2C19 or CYP3A4 (such as St. John's Wort or rifampin) can substantially decrease esomeprazole concentrations. Avoid concomitant use of esomeprazole strontium with St. John's Wort or rifampin.

Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors. Providers should temporarily stop esomeprazole treatment before assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial tests are performed (e.g., for monitoring), the same commercial laboratory should be used for testing, as reference ranges between tests may vary.

Concomitant Use of esomeprazole strontium with Methotrexate: Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration a temporary withdrawal of the PPI may be considered in some patients.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of esomeprazole strontium has been established from adequate and well-controlled studies of esomeprazole magnesium.

Adults: The safety of esomeprazole magnesium was evaluated in over 15,000 patients (aged 18 to 84 years) in clinical trials worldwide including over 8,500 patients in the United States and over 6,500 patients in Europe and Canada. Over 2,900 patients were treated in long-term studies for up to 6-12 months. In general, esomeprazole magnesium was well tolerated in both short and long-term clinical trials.

The safety in the treatment of healing of erosive esophagitis was assessed in 4 randomized comparative clinical trials, which included 1,240 patients on 22.3 mg of esomeprazole magnesium (equivalent to 20 mg of esomeprazole), 2,434 patients on 44.6 mg of esomeprazole magnesium (equivalent to 40 mg of esomeprazole), and 3,008 patients on 20 mg of omeprazole daily. The most frequently occurring adverse reactions (≥1%) in all three groups were headache (5.5%, 5%, and 3.8%, respectively) and diarrhea (no difference among the three groups). Nausea, flatulence, abdominal pain, constipation, and dry mouth occurred at similar rates among patients taking esomeprazole magnesium or omeprazole. Additional adverse reactions that were reported as possibly or probably related to esomeprazole magnesium with an incidence <1% are listed below by body system: **Body as a Whole:** abdomen enlarged, allergic reaction, asthenia, back pain, chest pain, substernal chest pain, facial edema, peripheral edema, hot flushes, fatigue, fever, flu-like disorder, generalized edema, leg edema, malaise, pain, rigors; **Cardiovascular:** flushing, hypertension, tachycardia; **Endocrine:** goiter; **Gastrointestinal:** bowel irregularity, constipation aggravated, dyspepsia, dysphagia, dysplasia GI, epigastric pain, eructation, esophageal disorder, frequent stools, gastroenteritis, GI hemorrhage, GI symptoms not otherwise specified, hiccup, melena, mouth disorder, pharynx disorder, rectal disorder, serum gastrin increased, tongue disorder, tongue edema, ulcerative stomatitis, vomiting; **Hearing:** earache, tinnitus; **Hematologic:** anemia, anemia hypochromic, cervical lymphadenopathy, epistaxis, leukocytosis, leukopenia, thrombocytopenia; **Hepatic:** bilirubinemia, hepatic function abnormal, SGOT increased, SGPT increased; **Metabolic/Nutritional:** glycosuria, hyperuricemia, hyponatremia, increased alkaline phosphatase, thirst, vitamin B12 deficiency, weight increase, weight decrease; **Musculoskeletal:** arthralgia, arthritis aggravated, arthropathy, cramps, fibromyalgia syndrome, hernia, polymyalgia rheumatica; **Nervous System/Psychiatric:** anorexia, apathy, appetite increased, confusion, depression aggravated, dizziness, hypertonia, nervousness, hypoesthesia, impotence, insomnia, migraine, migraine aggravated, paresthesia, sleep disorder, somnolence, tremor, vertigo, visual field defect; **Reproductive:** dysmenorrhea, menstrual disorder, vaginitis; **Respiratory:** asthma aggravated, coughing, dyspnea, larynx edema, pharyngitis, rhinitis, sinusitis; **Skin/Appendages:** acne, angioedema, dermatitis, pruritus, pruritus ani, rash, rash erythematous, rash maculo-papular, skin inflammation, sweating increased, urticaria; **Special Senses:** otitis media, parosmia, taste loss, taste perversion; **Urogenital:** abnormal urine, albuminuria, cystitis, dysuria, fungal infection, hematuria, micturition frequency, moniliasis, genital moniliasis, polyuria; **Visual:** conjunctivitis, vision abnormal.

Endoscopic findings that were reported as adverse reactions include: duodenitis, esophagitis, esophageal stricture, esophageal ulceration, esophageal varices, gastric ulcer, gastritis, hernia, benign polyps or nodules, Barrett's esophagus, and mucosal discoloration.

In two placebo-controlled studies, 710 patients were treated symptomatic GERD and the most common adverse reactions possibly or probably related to esomeprazole magnesium were diarrhea (4.3%), headache (3.8%), and abdominal pain (3.8%). **Combination Treatment with Amoxicillin and Clarithromycin:** In clinical trials using combination therapy with esomeprazole magnesium plus amoxicillin and clarithromycin, no additional adverse reactions specific to these drug combinations were observed. Adverse reactions that occurred were limited to those observed when using esomeprazole magnesium, amoxicillin, or clarithromycin alone. The most frequently reported drug-related adverse reactions for patients who received triple therapy for 10 days were diarrhea (9.2%), taste perversion (6.6%), and abdominal pain (3.7%). No treatment-emergent adverse reactions were observed at higher rates with triple therapy than were observed with esomeprazole magnesium alone. For more information on adverse reactions with amoxicillin or clarithromycin, see their package inserts, refer to **ADVERSE REACTIONS** sections.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of esomeprazole magnesium. Because these 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. These reports are listed below by body system: **Blood and Lymphatic:** agranulocytosis, pancytopenia; **Eye:** blurred vision; **Gastrointestinal:** pancreatitis, stomatitis, microscopic colitis; **Hepatobiliary:** hepatic failure, hepatitis with or without jaundice; **Immune System:** anaphylactic reaction/shock; **Infections and Infestations:** GI candidiasis; *Clostridium difficile* associated diarrhea; **Metabolism and nutritional disorders:** hypomagnesemia; **Musculoskeletal and Connective Tissue:** muscular weakness, myalgia, bone fracture; **Nervous System:** hepatic encephalopathy, taste disturbance; **Psychiatric:** aggression, agitation, depression, hallucination; **Renal and Urinary:** interstitial nephritis; **Reproductive System and Breast:** gynecomastia; **Respiratory, Thoracic, and Mediastinal:** bronchospasm; **Skin and Subcutaneous Tissue:** alopecia, erythema multiforme, hyperhidrosis, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal).

DRUG INTERACTIONS

Interference with Antiretroviral Therapy: Concomitant use of atazanavir and nelfinavir with PPIs is not recommended. Coadministration of atazanavir with PPIs is expected to substantially decrease atazanavir plasma concentrations and may result in a loss of therapeutic effect and the development of drug resistance. Coadministration of saquinavir with PPIs is expected to increase saquinavir concentrations, which may increase toxicity and require dose reduction. Omeprazole, of which esomeprazole is an enantiomer, has been reported to interact with some antiretroviral drugs. The clinical importance and the mechanisms behind these interactions are not always known. Increased gastric pH during omeprazole treatment may change the absorption of the antiretroviral drug. Other possible interaction mechanisms are via CYP2C19. *Reduced concentrations of atazanavir and nelfinavir:* For some antiretroviral drugs, such as atazanavir and nelfinavir, decreased serum levels have been reported when given together with omeprazole. Following multiple doses of nelfinavir (1250 mg, twice daily) and omeprazole (40 mg daily), AUC was decreased by 36% and 92%, C_{max} by 37% and 89% and C_{min} by 39% and 75%, respectively for nelfinavir and M8. Following multiple doses of atazanavir (400 mg, daily) and omeprazole (40 mg, daily, 2 hr before atazanavir), AUC was decreased by 94%, C_{max} by 96%, and C_{min} by 95%. Concomitant administration with omeprazole and drugs such as atazanavir and nelfinavir is therefore not recommended. *Increased concentrations of saquinavir:* For other antiretroviral drugs, such as saquinavir, elevated serum levels have been reported, with an increase in AUC by 82%, in C_{max} by 75%, and in C_{min} by 106%, following multiple dosing of saquinavir/ritonavir (1000/100 mg) twice daily for 15 days with omeprazole 40 mg daily coadministered days 11 to 15. Clinical and laboratory monitoring for saquinavir toxicity is recommended during concurrent use with esomeprazole. Dose reduction of saquinavir should be considered from the safety perspective for individual patients.

Drugs for Which Gastric pH Can Affect Bioavailability: Esomeprazole inhibits gastric acid secretion. Therefore, esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. ketoconazole, atazanavir, iron salts, and erlotinib can decrease, while the absorption of drugs such as digoxin can increase during treatment with esomeprazole. Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10% (30% in two subjects). Esomeprazole is an enantiomer of omeprazole. Coadministration of digoxin with esomeprazole is expected to increase the systemic exposure of digoxin. Patients may need to be monitored when digoxin is taken concomitantly with esomeprazole.

Effects on Hepatic Metabolism/Cytochrome P-450 Pathways: Esomeprazole is extensively metabolized in the liver by CYP2C19 and CYP3A4. *In vitro* and *in vivo* studies have shown that esomeprazole is not likely to inhibit CYPs 1A2, 2A6, 2C9, 2D6, 2E1, and 3A4. No clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that esomeprazole does not have any clinically significant interactions with phenytoin, quinidine, clarithromycin, or amoxicillin. Although drug interaction studies have not shown that esomeprazole has a clinically significant interaction with warfarin, post-marketing reports of changes in prothrombin measures have been received among patients on concomitant warfarin and esomeprazole therapy. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with PPIs and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time. Esomeprazole may potentially interfere with CYP2C19, the major esomeprazole metabolizing enzyme. Coadministration of esomeprazole 30 mg and diazepam, a CYP2C19 substrate, resulted in a 45% decrease in clearance of diazepam. Clopidogrel is metabolized to its active metabolite in part by CYP2C19. Concomitant use of esomeprazole 40 mg results in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition. Avoid concomitant administration of esomeprazole strontium with clopidogrel. When using esomeprazole strontium, consider use of alternative anti-platelet therapy. Omeprazole acts as an inhibitor of CYP2C19. Omeprazole, given in doses of 40 mg daily for one week to 20 healthy subjects in a cross-over study, increased C_{max} and AUC of cilostazol by 18% and 26% respectively. C_{max} and AUC of one of its active metabolites, 3,4-dihydrocilostazol, which has 4-7 times the activity of cilostazol, were increased by 29% and 69% respectively. Coadministration of cilostazol with esomeprazole is expected to increase concentrations of cilostazol and its above mentioned active metabolite. A dose reduction of cilostazol from 100 mg twice daily to 50 mg twice daily should be considered. Concomitant administration of esomeprazole and a combined inhibitor of CYP2C19 and CYP3A4, such as voriconazole, may result in more than doubling of the esomeprazole exposure. Dose adjustment of esomeprazole is not normally required. However, in patients with Zollinger-Ellison's Syndrome, who may require higher doses up to 240 mg/day, dose adjustment may be considered. Drugs known to induce CYP2C19 or CYP3A4 or both (such as rifampin) may lead to decreased esomeprazole serum levels. Omeprazole, of which esomeprazole is an enantiomer, has been reported to interact with St. John's Wort, an inducer of CYP3A4. In a cross-over study in 12 healthy male subjects, St. John's Wort (300 mg three times daily for 14 days) significantly decreased the systemic exposure of omeprazole in CYP2C19 poor metabolisers (C_{max} and AUC decreased by 37.5% and 37.9%, respectively) and extensive metabolisers (C_{max} and AUC decreased by 49.6 % and 43.9%, respectively). Avoid concomitant use of St. John's Wort or rifampin with esomeprazole strontium.

Interactions with Investigations of Neuroendocrine Tumors: Drug-induced decrease in gastric acidity results in enterochromaffin-like cell hyperplasia and increased Chromogranin A levels, which may interfere with investigations for neuroendocrine tumors.

Tacrolimus: Concomitant administration of esomeprazole and tacrolimus may increase the serum levels of tacrolimus.

Combination Therapy with Clarithromycin: Coadministration of esomeprazole, clarithromycin, and amoxicillin has resulted in increases in the plasma levels of esomeprazole and 14-hydroxyclarithromycin. Concomitant administration of clarithromycin with other drugs can lead to serious adverse reactions due to drug interactions [see **WARNINGS** and **PRECAUTIONS** in prescribing information for clarithromycin]. Because of these drug interactions, clarithromycin is contraindicated for coadministration with certain drugs [see **CONTRAINDICATIONS** in prescribing information for clarithromycin].

Methotrexate: Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of PPIs and methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate. However, no formal drug interaction studies of methotrexate with PPIs have been conducted.

SPECIFIC POPULATIONS

Pregnancy: ***Pregnancy Category C:*** There are no adequate and well controlled studies of esomeprazole strontium delayed-release capsules in pregnant women. Teratogenicity was not observed in an embryofetal developmental study in rats with either esomeprazole strontium or esomeprazole magnesium at equimolar oral doses up to 280 mg esomeprazole/kg/day (about 57 times the daily maximum recommended human dose (MRHD) of 40 mg on a body surface area basis). When administered as either the strontium or magnesium salt, changes in bone morphology and physeal dysplasia were observed in pre- and postnatal developmental toxicity studies in rats at doses equal to or greater than 138 mg esomeprazole/kg/day (approximately 33.6 times the daily MRHD of 40 mg on a body surface area basis). Because of the observed effect at the high doses of esomeprazole strontium on developing bone in rat studies, esomeprazole strontium should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Limited published data indicate that esomeprazole and strontium are present in human milk. Because of the effect of esomeprazole strontium observed at high doses on developing bone in rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness of esomeprazole strontium delayed-release capsules have not been established in pediatric patients. Strontium is known to compete with calcium for intestinal absorption and is incorporated into bone. Use in pediatric patients is not recommended because adequate safety studies have not been performed.

Geriatric Use: No overall differences in safety and efficacy were observed between the elderly and younger individuals, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Use in Patients with Renal Impairment: No dosage adjustment is necessary in patients with mild to moderate renal impairment. The pharmacokinetics and safety of strontium in patients with severe renal impairment has not been studied and, therefore, use in this patient population is not recommended.

OVERDOSAGE

A single oral dose of esomeprazole at 510 mg/kg (about 103 times the human dose on a body surface area basis), was lethal to rats. The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor, ataxia, and intermittent clonic convulsions. The symptoms described in connection with deliberate esomeprazole overdose (limited experience of doses in excess of 240 mg/day) are transient. Single doses of 80 mg of esomeprazole were uneventful. Reports of overdosage with omeprazole in humans may also be relevant. Doses ranged up to 2,400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience (see omeprazole package insert - **ADVERSE REACTIONS**). No specific antidote for esomeprazole is known. Since esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of overdosage, treatment should be symptomatic and supportive. As with the management of any overdose, the possibility of multiple drug ingestion should be considered. For current information on treatment of any drug overdose contact a Poison Control Center at 1-800-222-1222.

Please see package insert for full prescribing information.

More detailed information is available upon request.

For more information about esomeprazole strontium contact:
Amneal Pharmaceuticals at 1-877-835-5472.
Date of Issue: December 2013

Licensed from: Hanmi Pharm. Co. Ltd., Seoul, Korea
Distributed by: Amneal Pharmaceuticals, Glasgow, KY 42141

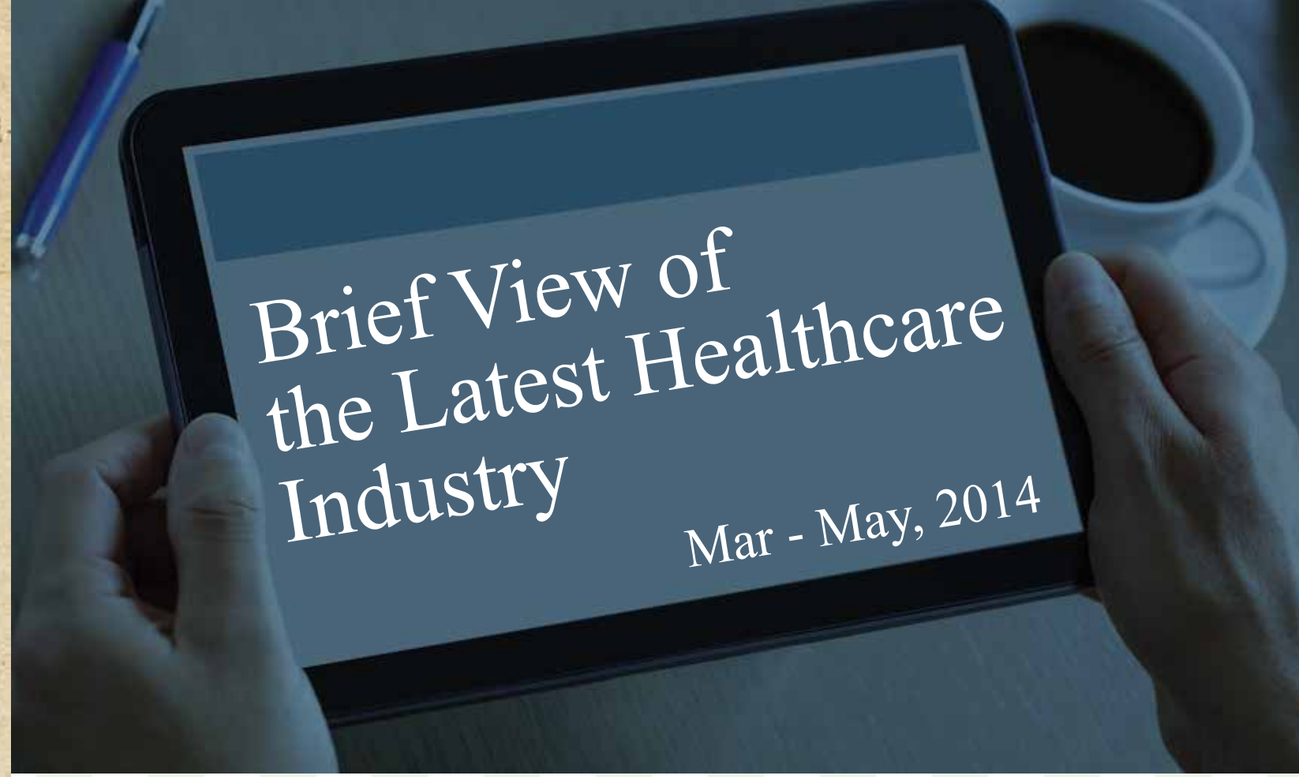
amneal PHARMACEUTICALS

WKMJ

WORLD KOREAN MEDICAL JOURNAL

World Korean Medical Journal (WKMJ) is a bi-monthly journal, which better support the community. WKMJ introduces the emerging issues and new trends of healthcare industry while also providing the best therapeutic products and medical devices available in the US market. WKMJ is delivered throughout 11 countries in the world: Korea, Brazil, China, Japan, Paraguay, Canada, Australia, Singapore, UK, France and Germany

The journal is published by medical consulting & publication arm of WKMO, W Medical Strategy Group.



"The top 10 pharma companies by 2013 revenue"

03/4/2014

After the major patent crashes of 2012, last year was more of a transitional period. Johnson & Johnson, Novartis, Roche, GlaxoSmithKline, Eli Lilly and Bayer saw their revenues rise, although only J&J and Bayer had an appreciable change. Pfizer, Sanofi, Merck & Co. and AstraZeneca were on the revenue eroding spectrum.

"First test to predict Alzheimer's years in advance"

03/10/2014

Howard Federoff at Georgetown University and his colleagues performed the world's first blood test to predict Alzheimer's disease prior to symptom development. The test identifies 10 chemicals in the blood associated with the disease two to three years before symptoms start, but they might be able to predict the disease decades earlier.

"Tamiflu study funded by Roche shows lives saved in pandemic"

03/19/2014

The antivaral drug Tamiflu reduced the risk of death by 25 percent among adults hospitalized during the 2009 H1N1 swine flu pandemic. Although treatment of Tamiflu reduced the risk of death in many groups of adults, it didn't show a significant change in reduction of death risk of pregnant women and severly ill patients.

"Astellas Pharma and Daiichi Sankyo Form Compound Library Sharing Partnership"

03/20/2014

Astellas Pharma and Daiichi Sankyo have unveiled plans for a compound-library sharing partnership, the largest such pact to be formed in Japan. The collaboration involves exchange of some 400,000 selected compounds including a significiant number of proprietary synthetic compounds from the companies' respectie libraries.

"37 new Parkinson's disease medicines now in R&D"

03/27/2014

US biopharmaceutical companies now have 37 new medicines in development for Parkinson's disease – 23 to treat the disease, 11 for related conditions and three diagnostics, according to new industry data. All 23 new products are now either in clinical trials or under by the US Food and Drug Administration (FDA), says the report, from research-based industry group the Pharmaceutical Research and Manufacturers of America (PhRMA). There are around 10 million patients worldwide and approximately 600,000 additional patients are newly diagnosed in each year.

"Antibacterial Drugs Market Expected to Reach USD 45.09 Billion Globally in 2019: Transparency Market Research"

03/28/2014

According to a new market report published by Transparency Market Research, the global antibacterial drugs market will reach an estimated value of $45.09 billion in 2019. Factors such as increasing prevalence of infectious diseases and rising demand for effective as well as affordable antibacterial drugs especially from emerging economies of Asia-Pacific, Latin America, Middle East and Affrica are the major growth drvers for the antibacterial drugs market.

"Pharmacy automation market to grow 8.8 percent annually by 2018"

04/10/2014

Wellesley-based market research firm BCC Research reported Thursday that it expects the global pharmacy automation market to grow to nearly $4.9 billion in 2018, with a five-year compound annual growth rate (CAGR) of 8.8% percent.

"FDA approves Tanzeum to treat type 2 diabetes"

04/16/2014

The U.S. FDA approved GlaxoSmithKline Plc's Tanzeum injection for treating adults with type 2 diabetes, in combination with diet and exercise. Analysts expect the drug to hit $4,430 million in sales by 2018, according to Thomson Reuters data.

"Teva settles patent litigation with Pfizer over generic of Celebrex"

04/18/2014

Teva's U.S. subsidiary has entered into a settlement with Pfizer Inc. over Teva's generic version of Celebrex. Celebrex, a non-steroidal anti-inflammatory, or NSAID medication, typically is used to treat the pain caused by arthritis. Under the terms of the settlement, Teva may launch its generic versions in the U.S. in December 2014, or earlier.

"FDA backs Janssen's Sylvant for rare disease "

04/23/2014

The U.S. FDA approved Johnson & Johnson subsidiary Janssen Biotech's Sylvant (siltuximab) to treat patients with multicentric Castleman's disease (MCD), a rare disorder similar to lymphma (cancer of the lymph nodes).

“Forest Labs to Acquire Furiex Pharmaceutical for Up to $1.5 billion”

04/28/2014

Forest labs agreed to pay $95 a share for the drug development collaboration company, Furex Pharmaceuticals Inc. in a deal worth up to $1.5 billion that would expand Forest Lab’s presence in gastroenterology.

“A First: Lab Grown Epidermis with Funcional Permeability Barrier”

04/30/2014

The first lab-grown epidermis offers an inexpensive alternative lab model for testing drugs and cosmetics. It could also pave a patha for new therapies’ development for uncommon and common skin problems

“Report: Drug prices skyrocketing, with no end in sight. ”

05/01/2014

Despite a wave of M&A deals aimed at increasing efficiency and lowering expenses in the pharmaceutical industry, drug prices continue to rise, with several drug companies nearly doubling the costs of key products over the last 7 years. These companies are Merck, Novartis, Eli Lilly and Pfizer.

“Scientists concern over Pfizer bid for AZ”

05/01/2014

The UK’s medical research collective has come together to warn the government that any deal between US gian Pfizer and Britain-based AstraZeneca, could have far-reaching consequences for R&D in the Country. They are concerned that these consoilidations of large pharmas may reduce R&D investment across the inidustry. Ths scientists are now calling on prime minister David Cameron and the coalition governement to lead the way by setting up a ‘Pharmacuetical Council’ which would bring together medical charities, funding bodies, busiensses academics, the NHS and academic societies to keep Britain at the ‘forefront of drug discovery’.

“Bayer deal to expand consumer business with Merck deal”

05/06/2014

The German drug maker Bayer said on Teusday that it had agreed to acquire Merck’s consumer care business for $14.2 billion, a deal that will make Bayer one of the largest providers of over-the-counter products. This deal would give Bayer control of several well-known brands, incldiung Coppertone, Claritn, and Dr. Scholl’s.

“FDA looks at effectiveness of generic blood pressure drugs”

05/07/2014

Generic drugs make 80% of the prescriptions written in the U.S. saving billions of dollars to payers annually. However, their effectiveness has always been questioned. FDA has been testing

“Sovladi “biggest selling drug” by 2020”

05/14/2014

According to UK market intelligence company, Evaluate, Gilead’s hepatitis C treatment Sovaldi will top the list of biggest selling drugs in 2020.

“Growth foreseen at all levels of the oral solid dosage form excipeints market, according to Kline”

05/15/2014

The oral solid dosage form (OSDF) excipients market is growing sustainably, historically exhibiting a robust increase on a global scale. This market is valued at nearly $2.3 billion in the U.S., Europe, India and China. In the emerging indian and Chinese markets, growth in consumption of excipients is driven by rising incomes and willingness to spend more on healthcare. Key factors driving growth in major markets like the U.S. and Europe include the aging populations and high demand for pharmaceuticals.

The 3rd WKMO ANNUAL CONVENTION

Overcoming barriers and ethnic disparities

Date: July 3-5, 2014
Location: Le Parker Meridien at 57th, New York, USA

World Korean Medical Organization (WKMO) is proud to host its 3rd Annual Convention and Forums in New York City at Le Parker Meridien Hotel, July 3-5, 2014. The convention, which will commence with a reception on the evening of July 3rd, aims to rekindle the spirit of solidarity amongst all the physicians of Korean heritage. As we expect over 400 physicians, medical students and leaders from healthcare industry from all over the world, this Convention will again aim to promote Korean interest and leadership in global medical community. This year's theme is "Cultural Barriers and Ethnic Disparities in Healthcare". It will also feature cutting edge medical and surgical specialty symposia on various topics. In addition, there will be separate sessions on Global Healthcare, Community Outreach and Worldwide Networking for Korean Physicians and Medical Students (WKMSO) with opportunities for exchange of ideas and discussion.

Registration

Your registration package includes access to all education sessions, 'Walk for Korea' marathon (sign up at the registration table is required), continental breakfast, and lunch and the Opening Reception Dinner. For Opening Gala(7/3) and WKMO Gala(7/5), individual tickets must be purchased for attendance. You may find more registration information @ www.Worldkmo.org/2014nyconvention and online registration also available.

- ☐ Physicians : USD 400
- ☐ Fellows/Residents : USD 200
- ☐ Students : USD 150
- ☐ WKMO Gala (July 5, 2014) : USD 300

**Travel and lodging expenses are to be paid by individual attendees.
The convention registration fee DOES NOT include these expenses

WKMO Convention Program

Keynote Speakers

- Dr. Kwang Tae Kim- IHF(International Hospital Federation) President
- Hon. Senator Robert Menendez-Chairman of the Senate Foreign Relations Committee

July 4th

8:00 – 8:30 AM *Breakfast*

Session A- Stomach Cancer: Epidemiology and Treatments

8:30 – 8:35 AM
- Opening Remarks Chul S. Hyun, MD, PhD Weill Cornell Medical College

8:35 – 8:40 AM
- Introductions Yanghee Woo, MD Columbia University

8:40 – 9:05 AM
- The International Disparities of Gastric Cancer Patient Outcomes Compared to Korea Han-Kwon Yang, MD Seoul National University

9:05 – 9:30 AM
- Disparities in gastric cancer diagnosis and treatment in Koreans living in South America Andre Lee, MD Sao Paulo University, Brazil

9:30 – 9:55 AM
- Systemic Treatments in Gastric Cancer –Potential Disparities in Strategies and Outcomes(Korean vs. Others) Yoonmi Lee, MD Columbia University

9:55 – 10:20 AM
- Q & A

10:20 – 10:45 AM
- Innovations in Surgical Treatment of Gastric Cancer and Differences Around the World WJ Hyung, MD Yonsei University

10:45 – 11:10 AM
- Eliminating the National and International Disparities in Gastric Cancer- A Collaborative Multi-national Korean Paradigm Yanghee Woo, MD

11:10 – 11:25 AM
- Q & A

11:25 - 11:30 AM
- Closing Remarks Yanghee Woo, MD Columbia University

11:30 – 12:30 PM **Lunch Session- W Medical Strategy Group Dialog**

Session B-Mental Health issues of Korean Americans

12:30 – 12:40PM
- Introduction Tai P. Yoo MD MSBA UCLA

12:40 – 1:10PM
- "Can't tell anyone about mental illness"
  Su Yeon Lee, PhD The Johns Hopkins University

1:10-1:40PM
- "Prevalence of Depression, Cognitive Impairment and Mental Health Service Utilization among Community Hochang Benjamin Lee, MD Yale University

1:40-2:10PM
- International Adoption of Korean Children; the Trend and Outcome
  Wunjung Kim, MD, MPH Rutgers University

2:10-2:15PM
- Introduction on the keynote speaker David Ko, MD USC

2:15-2:45PM
- History, Culture and Mental Health Issues of Korean Americans
  Tai P Yoo, MD, MSBA UCLA

2:45-3:00PM
- Q & A

3:00 – 3:30 PM *Coffee Break*

Session C - Comparison of Telemedicine Use in Global Leading Nations

3:30 – 6:00 PM Moderator: Joe McMenamin MD, JD
- The potential of telemedicine: Increased access to care (TBC)
  Jay H. Sanders ,MD, FACP, FACAAI The Johns Hopkins University
- Barriers to the success of telemedicine and means to overcome (TBC)
  Joseph McMenamin, MD, JD W Medical Strategy Group
- Experience with telemedicine around the world: Europe case (TBC)
  Laura Ryan, MD NHS 24 Edinburgh
- Mark, : An example of the use of 2D matrix barcodes in medical practice (TBC)
  Mark Paxton, JD "TBD" W Medical Strategy Group

6:00 – 9:30 PM *WKMSO (World Korean Medical Student Organization) Forum and Gala*

July 5th

8:00 – 8:30 AM *Breakfast*

Session D- Models to Improve: Cultural Competence in Healthcare

8:30 – 8:40 AM
- Introduction Dongsoo Kim, PhD

8:40 – 9:10 AM
- "Immigration, social diversity, and health disparity: Cultural and social contingencies of immigration health" Samuel Noh, PhD University of Toronto

9:10 -9:30 AM
- "Health care access model: delivering culturally competent and economically viable services to Korean American population" Kyunghee Choi, VP HNMC

9:30 – 9:50 AM
- "Topic TBD" Nassau University Medical Center

9:50-10:10 AM
- "Cultural competency and psychological implications: A theoretical framework" Dongsoo Kim, PhD Fairleigh Dickinson University

10:10 – 10:30
- Q & A

10:30– 11:30 AM **WKMSO Research Poster Presentation**

11:30 – 12:30 PM **Lunch Session-Hepatitis C**
- Transforming the Treatment Paradigm A Clinical Review of SOVALDI®(sofosbuvir)
  Robert S. Brown, Jr., MD, MPH, Columbia University

Session E-Future of Medical Imaging

12:30 – 12:35 PM
- Introduction Jinha Park, MD, PhD

12:35 - 1:00 PM
- Radiology Screening Tests Save Lives
  Jinha Park, MD, PhD City of Hope Helford Clinical Research Hospital

1:00 -1:25 PM
- Advances in image-guided interventions in oncology
  John Park, MD, PhD City of Hope Helford Clinical Research Hospital

1:25 - 3:00 PM
- "Samsung Imaging Forum"
- 1. Introduction to Samsung's Technology in Elastropgrapy
  Joon Sunwoo, PhD Clinical Research Samsung Medison
- 2. Ultrasound Elastography In Predicting Malignant Thyroid Nodule: Untie A Knot
- Dong-Jun Lim, MD, Assistant Professor, Seoul St. Mary's Hospital, Divison of Endocrinology and Metabolism, Internal Medison
- 3. Clinical Research Plan in Samsung Medical Equipment
  Hyunseung Lee, Clinical Research Samsung Medison
- Contrast-enhanced ultrasound in the abdomen
  Tae Kyoung Kim, MD, PhD University of Toronto.
- "Topic TBD" Ultrasound in Ob/Gyn,
  Sang Choon Cha, MD University of Sao Paulo, Brazil
- Status of Radiology Snapshot
  K. Ty Bae, MD, PhD University of Pittsburgh School of Medicine

3:00 – 3:30 PM *Coffee Break*

Session F-Hepatitis B: Epidemiology and Treatments in Asian Population

3:30 – 3:35 PM
- Introduction: Objective of Symposium and Speakers Chul S. Hyun, MD, PhD

3:35 – 4:15 PM
- Addressing the Challenges of Hepatitis B In Asian Communities
  Chul S. Hyun, MD, PhD Weill Cornell Medical College

4:15 – 4:45 PM
- Coffee Break and Poster Reception

4:45 – 5:25 PM
- Screening and Management of Advanced Liver Disease
  Ray Kim, MD Stanford University

5:25 – 6:00 PM
- CHB Case Study Presentation Joseph Ahn, MD Oregon State University

6:00 – 9:30 PM *WKMO Gala*

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