Clinical Research Newsletter Volume - 9, September 2015

LAMBDA

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## GLOBAL NEWS

**1.1. NICE recommends Daichii Sankyo's Lixiana to prevent stroke and embolism** August 7, 2015

- Daiichi Sankyo Company, Limited announced that NICE has issued its final recommendation for LIXIANA® (edoxaban) for the treatment and prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults. The NICE recommendation comes shortly after edoxaban received European marketing authorization in June 2015 for two indications. The final NICE recommendation states: "Edoxaban is recommended, within its marketing authorisation, as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults."

**1.2. FTA between EU and Vietnam to open up new possibilities for pharma**

August 11, 2015

- EU Trade Commissioner Cecilia Malmström and Vietnamese Minister of Industry and Trade Vu Huy Hoang agreed in principle on a comprehensive and ambitious trade and investment agreement. This Free Trade Agreement (FTA), for which negotiations started in October 2012, is the most ambitious and comprehensive FTA that the EU has ever concluded with a developing country, the second in the ASEAN region after Singapore, and a further building block towards the EU's ultimate objective of an ambitious and comprehensive region-to-region EU-ASEAN FTA. This agreement will allow EU exporters and investors to access a fast-growing market of 90 million people and to consolidate their presence in one of the most dynamic regions in the world.

**1.3. U.S. Biosimilars Market Worth $11Bn by 2020 - 22% CAGR Forecast for Global Biosimilar Industry** August13, 2015

- The Global & USA Biosimilar Market Analysis to 2021 research report indicates a high market potential for biosimilars by 2019 when 50% of the biologics market is forecast to belong to off-patent drugs as there is tremendous interest by big pharma and generics companies in biosimilars industry. The U.S., Europe and Japan are spending the most on biologics and therefore will become the largest biosimilar market hubs.

**1.4. Google launches life science unit as standalone Alphabet company** August 24, 2015

- Google has announced plans to launch its life sciences team as a standalone unit under its new Alphabet structure. The internet search giant established the life science team as part of its X lab research operation, tasking it with finding solutions to global health problems. In January of last year, Google's life sciences unit unveiled a smart contact lens designed to monitor glucose levels in tears, with Novartis' Alcon eye-care unit later in-licensing the smart lens technology for ocular medical uses, with an initial focus on diabetes and presbyopia. Earlier this month, DexCom announced that it entered into an agreement with Google's life sciences division to co-develop a series of next-generation continuous glucose monitoring products.

**1.5. 8.5% CAGR through 2020 forecast for Brazil's pharma market** August 26, 2015

- The Brazilian pharmaceutical market will expand in value from $29.4 billion in 2014 to reach approximately $47.9 billion by 2020, representing a strong Compound Annual Growth Rate (CAGR) of 8.5%, according to research and consulting firm Global Data. The company's latest report states that Brazil's increasingly elderly population, which will lead to a rising incidence of chronic and lifestyle-associated diseases, as well as the country's robust investment in healthcare, will be key drivers of market growth during the forecast period.

## DOMESTIC NEWS

**2.1. India defers EU trade talks over European ban on multiple drugs tested by GVK Biosciences** August 05, 2015

- India's Commerce and Industry Ministry has deferred negotiations with Europe regarding the Broad based Investment and Trade Agreement this month, saying it is "disappointed and concerned" over an EU decision to ban the sale of around 700 pharmaceutical products that had been tested by GVK Biosciences. D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, suggested the commerce ministry's move sends a strong message to European regulators, which he said have "acted unfairly and without any proof." Shah also indicated that the drug inspector who concluded that clinical trial data had been manipulated by GVK Biosciences was not qualified to do so as "only a cardiologist…can verify such data."

**2.2. Government likely to set up think tank to boost pharma exports** August 20,2015

- In order to resolve bottlenecks faced by pharmaceutical companies in the global market, the government is considering setting up a think tank with representatives from the industry, government departments and research bodies. Commerce Minister Nirmala Sitharaman met senior officials from the Ministry of Health, Drugs Controller General of India, Department of Pharmaceuticals, Department of Biotechnology, Department of Commerce and Pharmexcil to take stock of various issues affecting exports of Indian Pharma industry.

## REGULATORY NEWS

**3.1. CT Informed Consent via Audio-Video Recording Added to D&C Rules via Gazette Notification (GSR 611 (E))** August 19, 2015

- DCGI has amended D&C Rules via Gazette Notification (GSR 611 (E)). According to the new rules, An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. In case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

### 3.2. FDA warns of severe adverse events with Picato gel for skin condition

August 22, 2015

- The U.S. Food and Drug Administration (FDA) is warning about reports of severe allergic reactions and herpes zoster (shingles) associated with the use of Picato gel (ingenol mebutate). Picato is used to treat actinic keratosis, a scaly, crusty lesion on the skin that may be red or yellow in colour. USFDA has also received reports of cases involving severe eye injuries and skin reactions associated with the application of Picato gel.

### 3.3. UK to bring in Sunshine Act of its own to curb health service 'bribery'

August 24, 2015

- British Health Secretary Jeremy Hunt announced that all National Health Service hospitals and General Practitioner groups will be required to keep a list of every gift and payment from pharmaceutical companies to health service staff. Under the new "Sunshine Rule," NHS personnel who receive such benefits from drug companies will have to declare them or face dismissal and potentially jail time. The British Health Secretary's decision was spurred by a recent Telegraph investigation which found evidence of senior NHS directors soliciting thousands of pounds for consulting work, and other officials speaking about company-sponsored advisory board meetings held in luxurious hotels.

## DRUG APPROVALS AND LAUNCHES

### 4.1. Aprecia's Spritam is first 3D-printed drug product approved by FDA

August 03, 2015

- Aprecia Pharmaceuticals Company announced that the U.S. Food and Drug Administration (FDA) has approved SPRITAM® levetiracetam for oral use as a prescription adjunctive therapy in the treatment of partial onset seizures, myoclonic seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy. SPRITAM utilizes Aprecia's proprietary ZipDose® Technology platform, a groundbreaking advance that uses three-dimensional printing (3DP) to produce a porous formulation that rapidly disintegrates with a sip of liquid. While 3DP has been used previously to manufacture medical devices, this approval marks the first time a drug product manufactured with this technology has been approved by the FDA.

### 4.2. US FDA approves Bayer's Finacea for inflammatory Papules and Pustules of Mild to Moderate Rosacea

August 04, 2015

- Bayer HealthCare announced that the U.S. Food and Drug Administration (FDA) has approved Finacea® (azelaic acid) Foam, 15% for the topical treatment of the inflammatory papules and pustules of mild to moderate rosacea. The approval is based on results from two pivotal clinical trials examining the efficacy and safety of Finacea® Foam compared to its foam vehicle (without the drug azelaic acid) in the topical treatment of papulopustular rosacea. Papulopustular rosacea is a skin disease causing inflammatory lesions (papules and pustules) on the nose, cheeks, chin and forehead.

### 4.3. US FDA Approves Taro's Keveyis™ (dichlorphenamide) 50 mg Tablets for Primary Hyperkalemic and Hypokalemic Periodic Paralysis

August 10, 2015

- Taro Pharmaceutical Industries Ltd announced that the U.S. Food and Drug Administration (FDA) has approved Keveyis™ (dichlorphenamide) 50 mg Tablets for the treatment of primary hyperkalemic and hypokalemic periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis is the first medicine approved by the FDA for the treatment of primary periodic paralysis, which is estimated to affect approximately 5,000 people in the United States.

### 4.4. US FDA approves Sun Pharma's Ximino

August 20, 2015

- Sun Pharmaceutical Industries Ltd. announced that the U.S. Food and Drug Administration (FDA) has approved its Supplemental New Drug Application (sNDA) for XiminoTM (Minocycline HCl) extended-release capsules 45 mg, 90 mg and 135 mg. XiminoTM extended-release capsules are indicated for inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

## DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

### 5.1. Merck & Co., NewLink Genetics' Ebola vaccine candidate shows 100 percent protection in Guinea trial

August 01, 2015

- An analysis of interim data published in The Lancet on Friday suggests Merck & Co. and NewLink Genetics' investigational Ebola vaccine candidate rVSV-ZEBOV demonstrated 100 percent efficacy in an ongoing Phase III ring vaccination trial in Guinea. According to Merck, "it appeared that all vaccinated individuals were protected against Ebola virus infection within six to 10 days of vaccination."

### 5.2. Clovis Oncology files for rociletinib approval in USA and Europe

August 03, 2015

- Clovis Oncology, Inc. announced that it has submitted its New Drug Application (NDA) regulatory filing to the USFDA for rociletinib for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test. Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA in May 2014. In addition, Clovis has also submitted its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) through the centralized procedure.

### 5.3. US FDA accepts Teva's NDA for SD-809 for Huntington disease

August 13, 2015

- Teva Pharmaceutical Industries Ltd. announced that the New Drug Application (NDA) for SD-809 (deutetrabenazine) has been accepted by the USFDA for the treatment of chorea associated with Huntington disease (HD), a rare and fatal neurodegenerative disorder caused by the progressive breakdown of nerve cells in the brain that affects about five to seven people per 100,000 in western countries, according to the World Health Organization.

**5.4. Pfizer's Trumenba meets late-stage endpoints** August 21,, 2015

- Pfizer Inc. said that two late-stage studies for its Trumenba meningitis B vaccine met their primary endpoint goals, showing "robust immune responses" against some strains of meningococcal disease. One study included 3,600 healthy individuals' ages 10 through 18, while the other included 3,300 individuals aged 18 through 25. Trumenba was granted accelerated approval by the U.S. Food and Drug Administration in October 2014 for 10-25-year-olds.

## MERGER/ACQUISITIONS/COLLABORATION

**6.1. Shire adds to ophthalmic portfolio with buy of Foresight Bio therapeutics** August 03, 2015

- Shire plc announced that it has acquired New York-based, privately held Foresight Bio therapeutics Inc. for $300 million. With the acquisition, Shire acquires the global rights to FST-100 (topical ophthalmic drops combining 0.6% povidone iodine (PVP-I) and 0.1% Dexamethasone), a therapy in late-stage development for the treatment of infectious conjunctivitis, an ocular surface condition commonly referred to as pink eye. This acquisition further strengthens Shire's late-stage pipeline, has a clear strategic fit with lifitegrast, which is in late-stage development for treatment of dry eye disease, another ocular surface condition, and further demonstrates Shire's commitment to building a leadership position in ophthalmics.

**6.2. Synairgen and Pharmaxis enter research collaboration on LOXL2 inhibitor** August 05, 2015

- Australian pharmaceutical company Pharmaxis Ltd and UK biotechnology company Synairgen plc announced they have entered into a research collaboration to develop a selective inhibitor to the lysyl oxidase type 2 enzyme (LOXL2) to treat the fatal lung disease idiopathic pulmonary fibrosis (IPF). IPF affects in the region of 100,000 people in the US. Current products are expected to produce global revenues in excess of $1.1 billion by 2017. The LOXL2 enzyme is being targeted because it is known to promote scar tissue which hardens and irreparably damages the lungs of IPF patients. It is hoped that the inhibition of LOXL2 will slow the build-up of scar tissue and improve survival rates that are worse than for many cancers.

**6.3. Dr Reddy's to market three of Amgen's drugs in India** August 06, 2015

- Dr. Reddy's Laboratories Ltd. announced that it has entered into a strategic collaboration with Amgen one of the world's leading independent biotechnology companies to market and distribute three Amgen medicines in India in the areas of oncology and cardiology. Under the terms of the collaboration, Dr. Reddy's shall perform a full range of regulatory and commercial services to seek approval and launch Kyprolis® (carfilzomib), BLINCYTO® (blinatumomab) and Repatha™ (evolocumab) in India.

**6.4. Genmab in multi-dollar deal with Novo Nordisk for DuoBody technology** August 14, 2015

- Genmab A/S announced today it has entered an agreement to grant Novo Nordisk commercial licenses to use the DuoBody technology platform to create and develop bispecific antibody candidates for two therapeutic programs. The bispecific antibodies will target a disease area outside of cancer therapeutics. Under the terms of the agreement, Genmab will receive an upfront payment of USD 2 million from Novo Nordisk.

**6.5. AVEO Oncology inks $326 million deal with Novartis for AV-380** August 17, 2015

- AVEO Oncology announced an exclusive, worldwide license agreement with Novartis for the development and commercialization of AVEO's first-in-class, potent, humanized inhibitory antibody targeting growth differentiation factor 15 (GDF15), AV-380, and related antibodies, including modified or derivative forms of any such antibody (the § "Product"). AV-380 holds great promise as a potential treatment for cachexia secondary to multiple disease states, including cancer, chronic kidney disease, congestive heart failure and chronic obstructive pulmonary disease.

**6.6. Amneal forms new wholly-owned subsidiary as Amneal Biosciences** August 26, 2015

- Amneal Pharmaceuticals has launched Amneal Biosciences, a wholly owned subsidiary. Amneal Biosciences will focus exclusively on the commercialization of high-barrier-to-entry generic and specialty pharmaceuticals such as injectables, oncologics and biosimilars to healthcare providers globally.

## PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

**7.1. Allergan Confirms Generic Noxafil® Patent Challenge** August 12, 2015

- Allergan plc confirmed that it has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market Posaconazole Delayed-Release Tablets, 100mg. Allergan's ANDA product is a generic version of Merck's Noxafil®. Merck Sharp & Dohme Corp. filed suit against Allergan on August 6, 2015 in the U.S. District Court for the District of New Jersey seeking to prevent Allergan from commercializing its ANDA product prior to the expiration of U.S. Patent No. 5,661,151. For the 12 months ending June 30, 2015, Noxafil® had global sales of approximately $143.6 million, according to IMS Health data.

**7.2. US District Court Rules in Favor of Opana® ER Manufacturer, Endo International**

August 15, 2015

- Endo International plc announced that the U.S. District Court for the Southern District of New York has issued a ruling upholding two Endo patents covering OPANA® ER, the Company's opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The ruling also determined that Endo's patents had been infringed by all of the defendants. As a result, it is expected that the generic version of non-crush-resistant OPANA® ER currently sold by Actavis, the U.S. generics business of Allergan, Inc., will be removed from the market and additional approved but not yet marketed generic versions of the product developed by other generic companies will not be launched in the near term.

**7.3. Mylan Confirms First-to-File Patent Challenge Relating to Zytiga** August 18, 2015

- Mylan confirmed that the company has been sued by BTG International Ltd., Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Abiraterone Acetate Tablets, 250 mg. This product is the generic version of Zytiga, which is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer. For the 12 months ending June 30, 2015, Zytiga had U.S. sales of approximately $1.08 billion, according to IMS Health.

## TECHNOLOGY/NDDS NEWS

**8.1. FDA Approves First Fully Mobile Continuous Glucose Monitor** August 25, 2015

- The US Food and Drug Administration (FDA) has approved the first continuous glucose monitoring (CGM) system that sends data directly to a smart phone and does not require a separate receiver, according to a company release. The Dexcom G5 Mobile CGM System was approved on August 25 for adults and children as young as 2 years of age. Using wireless Bluetooth technology built into the transmitter, the device sends real-time glucose information directly to an app on iOS-enabled devices, such as the iPhone. Android applications are expected early next year, according to the company release.