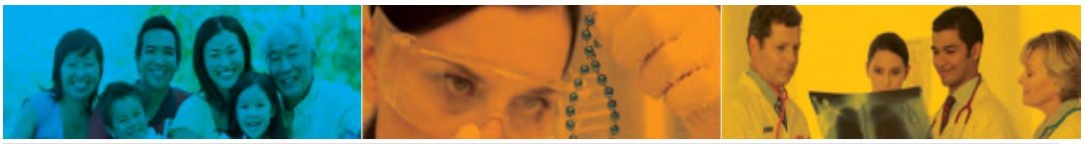

Clinical Research Newsletter Volume - 4, April 2015

LAMBDA

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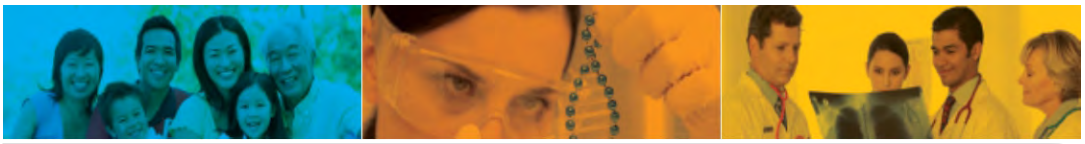


LAMBDA

GLOBAL NEWS

1.1. BI files Pradaxa antidote in US, EU and Canada Mar 03, 2015

- Boehringer Ingelheim has filed idarucizumab for approval in the US, European Union and Canada for use in patients requiring an antidote to the bloodthinner Pradaxa. The drug is a fully humanised antibody fragment designed specifically to reverse the anticoagulant effects of Pradaxa (dabigatran etexilate), and its submission marks a global first for an investigational specific reversal agent to a novel oral anticoagulant, BI said.

1.2. EMA committee issues positive opinion for Brintellix Mar 07, 2015

- H. Lundbeck A/S (Lundbeck) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for a Type-II Variation related to the update of the European summary of the product characteristics (SmPC) for Brintellix. Brintellix (vortioxetine) is an SSRI antidepressant. The CHMP positive opinion was reached after a review of comprehensive data from the international clinical programme comprised of five studies assessing the safety and efficacy of Brintellix including its effect on cognitive performance and function. The application was based primarily on data from one recently completed clinical study (CONNECT) in addition to four clinical studies that were previously submitted as part of the original approval process, as well as a newly completed clinical pharmacology functional magnetic resonance imaging (fMRI) study in remitted patients with depression. The application, known as a Type II Variation, was submitted to the European Medicines Agency (EMA) in September 2014.

1.3. Novartis to present new data from Cosentyx at AAD 2015 meet in San Francisco Mar 14, 2015

- Novartis announced that new results for Cosentyx (secukinumab) in moderate-to-severe plaque psoriasis, including detailed findings from the head-to-head CLEAR study and long-term data from the phase III programme, will be presented as late breaking research at the 73rd Annual Meeting of American Academy of Dermatology (AAD), from 20-24 March in San Francisco, California, USA. In total, 25 posters from the Novartis Dermatology portfolio will be highlighted at this leading congress.

1.4. US pharma market value to reach $550 billion by 2020: GlobalData Mar 19, 2015

- GlobalData, a leading global research and consulting firm, reported that the US pharmaceutical market is forecast to increase from an estimated value of $395.2 billion in 2014 to reach $548.4 billion by 2020, representing a Compound Annual Growth Rate (CAGR) of 5.6%.

1.5. Global breast cancer therapeutics market to reach $13.38 bn by 2018 Mar 19, 2015

- Despite the availability of approximately 25 drugs for the treatment of breast cancer, the unmet need in the global market is vast. To address this drawback, pharmaceutical companies have established a robust pipeline that currently has about 52 drugs in development. While chemotherapy remains the most important class of drugs for breast cancer treatment; the trend toward targeted drugs is on the rise. New analysis from Frost & Sullivan, A Competitive Analysis of the Global Breast Cancer Therapeutics Market, finds that the market earned revenues of approximately $10.0 billion in 2014 and estimates this to reach $13.38 billion in 2018.

1.6. GSK, Theravance announce outcome of US FDA Advisory Committee Mar 20, 2015

- GlaxoSmithKline plc (GSK) and Theravance, Inc. announced the outcome of the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the United States (US) Food and Drug Administration (FDA) regarding the supplemental New Drug Application (sNDA) for Breo Ellipta (fluticasone furoate/vilanterol [FF/VI]) as a once-daily inhaled treatment for asthma in patients aged 12 years and older. The FDA Advisory Committee voted that the efficacy and safety data for FF/VI 100/25 mcg and 200/25 mcg once daily in asthma support approval in adults 18 years of age and older (16 for, 4 against). The Committee voted that the efficacy data provides substantial evidence of a clinically meaningful benefit in adults (18 for, 2 against) and that the safety in this population has been adequately demonstrated (17 for, 3 against).

DOMESTIC NEWS

2.1. Guidelines for management of PCOS in India discussed at PCOS Summit 2015 Mar 09, 2015

- To disseminate the first ever guidelines for Management of Polycystic Ovary Syndrome (PCOS) in India at the PCOS India Summit 2015 held in Delhi and Kolkata, Bayer Zydus Pharma supported the Indian Fertility Society (IFS) on the occasion of Women's Day. This was also marked by a multi-specialty interactive scientific symposium bringing together leading medical practitioners from the field of gynecology, dermatology, endocrinology, paediatrics and radiology.

2.2. Intas Pharma buys hospital business from Combino Pharm in Spain & Portugal Mar 20, 2015

- Intas Pharmaceuticals, growing at 27 per cent CAGR over the last five years, has acquired hospital business in Spain and Portugal from Combino Pharm, a company based out of Spain through its subsidiary Accord Healthcare based out of UK and Spain.

2.3. ICMR issues consensus document for management of gallbladder cancer Mar 28, 2015

- The Indian Council of Medical Research (ICMR) has issued the consensus document for management of gallbladder cancer which summarizes the modalities of treatment including the site-specific anti-cancer therapies, supportive and palliative care and molecular markers and research questions. It also interweaves clinical, biochemical and epidemiological studies.

REGULATORY NEWS

3.1. US priority review for B-MS' Opdivo in lung cancer Mar 01, 2015

- The US Food and Drug Administration has agreed to review Bristol-Myers Squibb's PD-1 inhibitor Opdivo (nivolumab) as a treatment for advanced squamous non-small cell lung cancer (NSCLC) after prior therapy. The regulator also said it would undertake a priority review of the application, and that the Prescription Drug User Fee Act goal date for a decision is June 22, 2015.

3.2. Three new drugs put forward for EU approval Mar 01, 2015

- Novartis' lung cancer treatment Zykadia (ceritinib), Otsuka's kidney disease drug Jinarc (tolvaptan) and Amgen's neutropenia therapy Ristempa (pegfilgrastim) have taken a giant step closer to entering the European market after regulatory advisors endorsed their approval.

3.3. Amgen seeks Japanese marketing approval for Repatha Mar 24, 2015

- Amgen announced that an application seeking marketing approval of Repatha (evolocumab) for the treatment of high cholesterol has been submitted for review to the Ministry of Health, Labour and Welfare in Japan. Repatha is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.

DRUG APPROVALS AND LAUNCHES

4.1. US FDA approves Liletta 52 mg to prevent pregnancy for up to 3 years Mar 02, 2015

- Actavis plc, a leading global specialty pharmaceutical company, and Medicines360, a nonprofit women's health pharmaceutical company, announced the approval of Liletta (levonorgestrel-releasing intrauterine system) by the US Food and Drug Administration (FDA) for use by women to prevent pregnancy for up to three years. Liletta is placed in the uterus by a healthcare professional and works by continuously releasing levonorgestrel, a progestin, to prevent pregnancy.

4.2. Sandoz receives US FDA approval for biosimilar Zarxio Mar 09, 2015

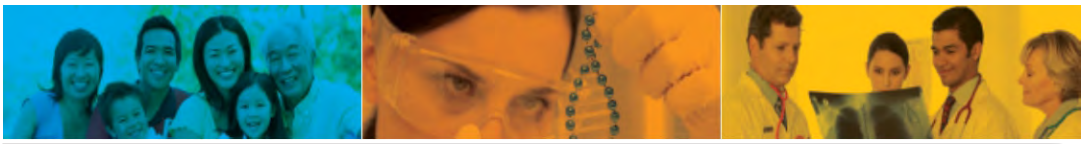
- The US Food and Drug Administration (FDA) approved Sandoz's Zarxio (filgrastim-sndz) for all indications included in the reference product's label. Sandoz is the first company to receive approval of a biosimilar in the US through the new FDA biosimilars pathway established under the Biologics Price Competition and Innovation Act.

4.3. US FDA approves Actavis' Saphris for treatment of bipolar I disorder Mar 16, 2015

- The US Food and Drug Administration (FDA) has approved Actavis' supplemental new drug application (sNDA) for Saphris (asenapine) as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder in pediatric patients (ages 10 - 17). Saphris is the only atypical antipsychotic treatment option with a sublingual (under the tongue) formulation.

4.4. Endo Pharma launches Natesto nasal gel for testosterone replacement therapy Mar 17, 2015

- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc, announced the commercial availability of Natesto (testosterone nasal gel), the first and only nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism. Natesto was approved by the US Food and Drug Administration (FDA) in May 2014 for replacement therapy in adult men with conditions associated with deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). Natesto reduces the risk of transference via intranasal application.



LAMBDA

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Vanda reports top-line results of phase II proof of concept study of tradipitant Mar 07, 2015

- Vanda Pharmaceuticals announced top-line results of the phase II proof of concept clinical study investigating the safety and efficacy of tradipitant as a monotherapy in the treatment of chronic pruritus in patients with atopic dermatitis. Despite a highly significant and clinically meaningful improvement from baseline by tradipitant (40.5mm improvement from baseline, $p<0.0001$) as measured on a 100mm unit Visual Analog Scale (VAS) for itch, a very high placebo effect (36.5 mm improvement from baseline, $p<0.0001$) on the change from baseline led to no statistical difference from placebo. However, subsequent analysis of population PK samples across all patients in the study revealed significant and clinically meaningful responses across multiple outcomes evaluated in individuals with higher levels of tradipitant exposure at the time of their pruritus assessments.

5.2. Protalex begins phase I/II continuation trial of PRTX-100 in patients with RA Mar 14, 2015

- Protalex, a clinical-stage biopharmaceutical company, announced that following completion of its US-based, multicentre phase 1b randomised, multiple-dose, dose-escalation study of PRTX-100 (the 104 Study) in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (RA), the company has initiated enrollment of a phase I/II open-label, multiple, fixed-dose study (the 105 Study) that is open only to 104 Study patients who indicated their desire for additional treatment. Protalex's lead drug PRTX-100 is a highly purified form of Staphylococcal Protein A.

5.3. AstraZeneca reports positive top-line results from Phase III PINNACLE programme Mar 19, 2015

- AstraZeneca announced positive top-line results from the phase III PINNACLE programme, which included two pivotal 24-week studies (PINNACLE 1 and PINNACLE 2) to investigate the potential of PT003 to improve lung function in patients with Chronic Obstructive Pulmonary Disease (COPD). PT003 is a twice-daily fixed-dose combination of glycopyrronium, a long-acting muscarinic antagonist (LAMA) and formoterol fumarate, a long-acting beta-2 agonist (LABA). PT003 is the first LAMA/LABA combination to be delivered in a pressurised metered dose inhaler (pMDI) using the unique porous particle co-suspension technology developed by Pearl Therapeutics, which was acquired by AstraZeneca in 2013.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Sun Pharma to acquire GlaxoSmithKline's Opiates business in Australia Mar 03, 2015

- Sun Pharmaceutical Industries Ltd., a Rs. 16,000 crore India's leading Pharma company, and GlaxoSmithKline (GSK) announced that their respective wholly owned subsidiaries have reached an agreement related to GSK's Opiates business in Australia. The product portfolio consists of poppy-derived opiate raw materials that are primarily used in the manufacture of analgesics for the treatment of moderate to severe pain.

6.2. AZ acquires rights to Actavis' branded respiratory portfolio in US & Canada Mar 04, 2015

- AstraZeneca, a global, innovation-driven biopharmaceutical company, has completed the transaction to acquire the rights to Actavis' branded respiratory business in the US and Canada. As previously announced the strategic transaction strengthens AstraZeneca's respiratory franchise globally and builds on the acquisition of Almirall's respiratory portfolio in 2014 by extending the company's development and commercialisation rights into the US for both Tudorza Pressair and Duaklir Genuair.

6.3. Diagnos inks pact with US-based ophthalmology pharma company Mar 12, 2015

- Diagnos Inc., leader in diabetic retinopathy screening, is announcing the close of a commercial agreement to provide retina screening services to patients in the United States. The sponsor of the services is a major US-based pharmaceutical company that markets a leading ophthalmology product indicated for a variety of ophthalmic complications including those associated with diabetes.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. US court rules against Actavis on Atelvia patent litigation Mar 07, 2015

- Actavis confirmed that the United States District Court for the District of New Jersey has found that United States Patent Nos. 7,645,459 and 7,645,460 protecting Atelvia (risedronate sodium delayed-release tablets, 35 mg) in the US are invalid.

7.2. Provectus gets US patent for photodynamic treatment of disease Mar 16, 2015

- The United States Patent and Trademark Office (USPTO) has granted US Patent No. 8,974,363 to Provectus Biopharmaceuticals, Inc (Provectus). The new patent, entitled "Topical medicaments and methods for photodynamic treatment of disease," provides detailed protection of the company's investigational dermatological drug PH-10.

TECHNOLOGY NEWS

8.1. Waters Full Spectrum Molecular Imaging and Acquity UPLC bags awards Mar 07, 2015

- Waters new full spectrum molecular imaging system and its Acquity UltraPerformance LC (UPLC) Technology received awards at the 2015 Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy. The Full Spectrum Molecular Imaging System pinpoints with greater specificity, the distribution of large and small molecules within tissue samples. It is the first system ever to allow scientists to access enhanced matrix-assisted laser desorption ionization (MALDI) and desorption electrospray ionization (DESI) with ion mobility separation (IMS) in a single mass spectrometry platform.

8.2. Assurex Health selects Luminex xTAG technology

Mar 16, 2015

- Luminex Corporation, a biotechnology company develops, manufactures and markets innovative biological testing technologies, announced that its xTAG Technology has been selected for use in enhancing the processing speed and capacity of Assurex Health's patented GeneSight tests. Healthcare providers use GeneSight to help patients affected by neuropsychiatric conditions including depression, posttraumatic stress disorder (PTSD), anxiety, bipolar disorder, schizophrenia, ADHD, and acute and chronic pain.

LAMBDA NEWS

9.1. Lambda's New Initiative - Introducing panoply of Panomics related services

- Lambda is proud to announce its new initiative towards delivering panoply of services related to genomics, pharmacogenomics, proteomics and metabolomics. We at Lambda are equipped with a veteran team of talented scientists and state-of-the-art technologies and infrastructure to cater to the specific needs of its our reputed clientele in compliance with applicable regulatory requirements.

PANOMICS SERVICES

- Shotgun proteomic analysis
- Protein identification and Global proteomic profiling
- Post-translational modifications
- Biosimilars (peptide mass fingerprinting profiles)
- Targeted proteomic analysis
- LC-MS/MS, SRM/MRM based assays
- Cell based assays, Immunogenicity studies
- RT-PCR validation assays
- Global and targeted metabolite profiles

OUR APPROACH

- Collaborative, consultative and comprehensive biotherapeutics
- Transforming clinical development to commercial reality
- Advanced instrumentation for accurate and affordable analytical solutions
- Shotgun proteomic analysis (GeLC-MS, Proteolytic Digestions)
- Protein identification and Global proteomic profiling (Sequence Coverage)
- Biosimilars (Peptide Mass Fingerprinting Profiles)

9.2. Successful completion of EMEA inspection at Lambda's Ahmedabad based BA / BE facility

- We are glad to announce that Lambda's Ahmedabad based BA / BE facility was inspected by EMA in connection with the trial of a BE study. The purpose of the inspection was to verify that the trial was conducted in compliance with GCP and applicable regulations. The inspection was carried out by the agency between 2nd to 6th December, 2014. The audit has been successfully completed.