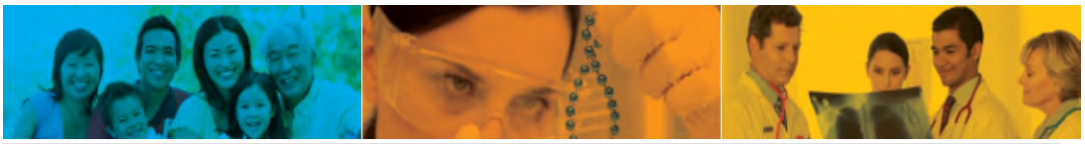

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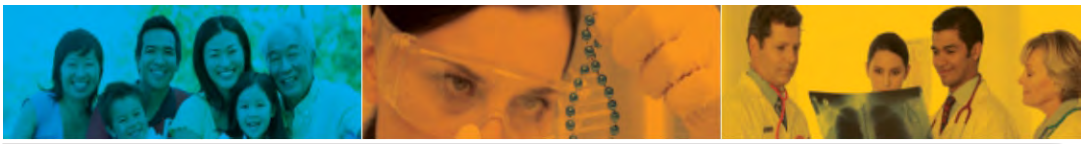

LAMBDA

GLOBAL NEWS

1.1. Abbott introduces new options for people with cataracts in US Feb 2, 2015

- Two new intraocular lenses (IOLs) that restore vision to people with cataracts are now available in the United States. The new TECNIS Multifocal IOLs, developed by Abbott, provide people with cataracts options to have a full range of near, intermediate and distance vision, while customising their treatment based on their personal vision needs and lifestyle. An IOL is an artificial lens placed in a person's eye to restore vision after a cataract has been removed.

1.2. Astellas to make available clinical trial data through website Feb 3, 2015

- Astellas Pharma announced that the company will now make trial data available through www.clinicalstudydatarequest.com, an independent Web site that enables researchers to request and access clinical trial data after approval of a research proposal by an independent review panel. Astellas will provide access to anonymised patient-level data from interventional clinical trials in patients completed after January 2010 for products and indications that have been approved in the US and/or in the EU.

1.3. NSU researchers discover DNA repair is high in heart, nonexistent in brain Feb 6, 2015

- Nova Southeastern University (NSU) researchers recently discovered that, contrary to prior belief, tissues of different mammalian organs have very different abilities to repair damage to their DNA. These new findings indicate that the heart has the greatest capacity to repair its DNA, followed by the intestines, kidneys, spleen, testes, and lungs. The brain, however, exhibited no ability to repair damage to its DNA. These studies were performed in murine cell tissue culture.

DOMESTIC NEWS

2.1. More AMCs to be identified for access to WHO database through Vigiflow software as part of PvPI Feb 03, 2015

- Around 40 ADR Monitoring Centres (AMCs) out of the 150 are in the process of getting identified for registration with the Vigiflow software which is meant to report adverse drug reaction (ADR) data to World Health Organization (WHO) database on a consistent basis, as a part of the Pharmacovigilance Programme of India (PvPI), informed an official associated with the development. Of the 150 AMCs set up under the PvPI, 110 centres have the Swedish software, Vigiflow, which helps in accurate reporting of ADRs with the help of Technical Data Associates (TDAs) working in 82 centres. They are working in coordination with Indian Pharmacopoeia Commission (IPC) Ghaziabad for final analysis and reports.

2.2. Gujarat FDCA develops & implements country's first software application IDMLA for granting product license Feb 06, 2015

- The Gujarat Food and Drug Control Authority became the first state drug regulatory body to yet again develop and successfully implement the country's first software for issuing manufacturing license through IT application called the drug manufacturing license application for allopathic. The aim

behind this initiative is not only to bring in good governance to ensure public safety and transparency in the system, but also simplify the process of product approval for manufacturers.

2.3. IISc, Bengaluru develops shock wave induced drug delivery patch for vaccines, insulin & antibiotics Feb 17, 2015

- The Indian Institute of Science (IISc), Bengaluru has now developed a novel shock wave induced drug delivery patch that will replace the painful injections and stall needle stick injuries. The patch developed with hydro collide material is designed to hold on active molecules like vaccines, insulin and antibiotics. The pre-clinical studies are complete and now the Institute is set to scout for bio-pharma industry partners to take the research to human trials and technology transfer for commercialisation thereafter.

2.4. Becton, Dickinson introduces new point-of-care system for HIV/AIDS CD4 monitoring in India Feb 21, 2015

- Becton, Dickinson and Company has now unveiled the BD FACSPresto, a near patient CD4 monitoring system that provides absolute and percentage results of CD4 T lymphocytes and hemoglobin (Hb) concentration in whole blood samples. The device weighs less than 7kgs and is capable of testing samples from a single drop of capillary or venous blood and can work for 6 hours using in-built rechargeable battery, enabling testing even in remote settings. India prevalence of HIV is estimated 25 lakh positive cases, out of which around 8.5 lakh people are under the CD4 monitoring program.

2.5. DoP organised launch ceremony of '2015- The Year of API' in New Delhi on Feb 25 Feb 23, 2015

- With an aim to boost the active pharmaceutical ingredients (APIs) manufacturing industry on a bigger scale in India, the central government has decided to declare the year 2015 as 'Year of API'. The government had conducted a launch ceremony of '2015 - The Year of Active Pharmaceutical Ingredients' in New Delhi on February 25. As part of this, the government under its much campaigned 'Make in India' programme had decided to declare 2015 year as 'Year of Active Pharmaceutical Ingredients'.

REGULATORY NEWS

3.1. Centre approves 25 panels of experts for SECs for evaluation of clinical trials, new drugs & devices Feb 02, 2015

- The Union health ministry has approved 25 panels of experts of various therapeutic areas for evaluation of various categories of applications of clinical trials, new drugs and new medical devices. Subject Expert Committees (SECs), comprising eight medical experts have to be constituted drawing the names of the experts from the respective panels approved by the ministry. In case any of the experts fail to attend the SEC meeting, another from the same panel will be invited to attend the meeting.

3.2. CDSCO to work with international regulators on exploring regulatory opportunities Feb 04, 2015

- Giving a huge thrust to boost the drug regulatory mechanism in the country and ease stakeholders concerns, the Central Drugs Standard Control Organisation (CDSCO) and top drug regulators from across the globe have agreed to cooperate on exploring regulatory opportunities. The Pharmaceutical Export Promotion Council of India (Pharmexcil) states that stronger relation with the global drug regulators is expected to not only strengthen the regulatory framework, but also boost exports from the country.

3.3. US FDA to involve Indian regulators for inspections to create awareness about its inspection activities in India Feb 21, 2015

- The US FDA will invite Indian regulators for its inspections to create more awareness about its inspection activities in India. The US regulatory agency has also decided to increase its staff strength in India. Dr Venkataraman, who attended the DIA-hosted conference on Pharmacovigilance and Risk Management Strategies-2015 in Washington from 26th to 28th January, quoting some reports said that the US FDA, which has offices in New Delhi and in Mumbai, will increase the number of their Indian officials from 10 to 19.

DRUG APPROVALS AND LAUNCHES

4.1. Roche gets USFDA breakthrough therapy designation for MPDL3280A in NSCLC Feb 03, 2015

- The United States Food and Drug Administration has granted Breakthrough Therapy Designation to Roche's investigational cancer immunotherapy MPDL3280A. The designation was granted for the treatment of people with PD-L1-positive non-small cell lung cancer whose disease has progressed during or after platinum-based chemotherapy. This breakthrough therapy designation is based on early results of MPDL3280A in people whose NSCLC was characterised as PD-L1-positive by an investigational test being developed by Roche.

4.2. US FDA approves Pfizer's Ibrance for Breast Cancer Feb 05, 2015

- The US Food and Drug Administration (FDA) has granted accelerated approval to Pfizer's Ibrance (palbociclib), in combination with letrozole, for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer as initial endocrine-based therapy for their metastatic disease. The Ibrance new drug application was based on the final results of the phase 2 PALOMA-1 trial. The most frequently reported adverse event for Ibrance plus letrozole in PALOMA-1 was neutropenia.

4.3. FDA Clears Ranibizumab for Diabetic Retinopathy With DME Feb 09, 2015

- TThe US FDA has expanded the approved use of ranibizumab (Lucentis, Genentech, Inc) injection (0.3 mg) to treat diabetic retinopathy in patients with diabetic macular edema (DME). The safety and efficacy of ranibizumab to treat diabetic retinopathy with DME were established in two clinical studies involving 759 participants who were treated and followed for three years. In the two studies, treatment with ranibizumab led to significant improvement in severity of diabetic retinopathy at two years compared with that in patients who did not receive the drug, the FDA says.

4.4. Teva Pharma launches generic Lovenox & Zyvox in US markets Feb 19, 2015

- Teva Pharmaceutical Industries, a leading global pharmaceutical company, announced the launch of the generic equivalent of Lovenox (enoxaparin sodium injection) in seven dosage strengths in the United States. Enoxaparin s injection, USP is used for prophylaxis of deep vein thrombosis (DVT) in patients undergoing abdominal surgery, hip or knee replacement surgery, or in medical patients with severely restricted mobility during acute illness; and also for the treatment of acute DVT.

4.5. Norgine launches Targaxan 550 in Eng. & Wales to treat hepatic encephalopathy Feb 20, 2015

- Norgine, a leading independent European specialty pharmaceutical company, has announced that Targaxan 550 (rifaximin-a 550mg), an innovative treatment for hepatic encephalopathy (HE), will be available to patients in England and Wales following its approval by the National Institute for Health and Care Excellence. Hepatic encephalopathy is a serious and potentially life-threatening neuropsychiatric condition associated with advanced liver disease that affects around 10,000 patients in the UK.

4.6. Lupin gets US FDA approval for generic Lumigan Ophthalmic solution 0.03% Feb 23, 2015

- Lupin has received final approval for its Bimatoprost Ophthalmic Solution, 0.03% (Bimatoprost) from the US FDA to market a generic version of Allergan's Lumigan ophthalmic solution, 0.03%. Its subsidiary, Lupin Pharmaceuticals Inc, will commerce marketing shortly. Lupin's Bimatoprost is the AT rated generic equivalent of Lumigan Ophthalmic solution, 0.03% and is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Roche announces positive results from phase III GADOLIN study of Gazyva/Gazyvaro

Feb 05, 2015

- Roche announced positive results from the phase III GADOLIN study, which evaluated treatment options for people with indolent non-Hodgkin's lymphoma. The study showed that people lived significantly longer without disease worsening or death when treated with Gazyva (obinutuzumab) plus bendamustine followed by Gazyva alone, compared to bendamustine alone. The study was stopped prior to its protocol-specified final analysis due to the high level of benefit seen in the Gazyva arm compared to the bendamustine arm. There were no unexpected adverse events with Gazyva.

5.2. Daiichi begins large-scale, multi-national phase 3 clinical programmes for mirogabalin

Feb 05, 2015

- Daiichi Sankyo Company Limited announced enrollment of the first patients in large-scale, multi-national clinical programmes evaluating the safety and efficacy of investigational mirogabalin, the first preferentially selective alpha-2 delta ligand. The phase 3 clinical programme across Asia includes the REDUCER study and the NEUCOURSE study which will evaluate investigational mirogabalin for the treatment of diabetic peripheral neuropathic pain and postherpetic neuralgia, respectively.

5.3. US FDA accepts Pfizer's sNDA for Xeljanz to treat chronic plaque psoriasis Feb 06, 2015

- The US Food and Drug Administration has accepted for review the Pfizer Inc's supplemental New Drug Application for Xeljanz (tofacitinib citrate) 5 mg and 10 mg tablets, a Janus kinase (JAK) inhibitor, the first in a new class of oral medicines being investigated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in October 2015 for the sNDA.

5.4. Takeda's phase 3 study of oral Ixazomib in relapsed/refractory MM patients meets primary endpoint Feb 11, 2015

- Takeda Pharmaceutical Company announced that the randomised, double-blind, placebo-controlled TOURMALINE-MM1 pivotal phase 3 trial evaluating the safety and efficacy of ixazomib, the first oral proteasome inhibitor, conducted in patients with relapsed or refractory multiple myeloma achieved its primary endpoint of improving progression-free survival at the first pre-specified interim analysis. Efficacy and safety data were reviewed by an Independent Data Monitoring Committee.

5.5. Zydus completes phase I studies of ZYAN1 for treating anaemia Feb 16, 2015

- Zydus Cadila, an Ahmedabad-based innovative, global pharmaceutical company, has completed the single ascending dose (SAD) range finding studies of ZYAN1 in healthy human volunteers as a part of the phase I study currently ongoing in Australia. The molecule, ZYAN1 is an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor being developed for the treatment of anaemia. ZYAN1 has been designed to increase the natural production of erythropoietin (EPO) in anaemic patients.

5.6. US FDA accepts Pfizer's ALO-02 NDA for review Feb 17, 2015

- Pfizer announced that the US Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride), extended-release capsules, an abuse-deterrent formulation (ADF) opioid 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.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Venus Remedies eyes collaborations to commercialise its oncology drugs pipeline Feb 07, 2015

- Venus Remedies is now scouting for suitable collaborations for co-development or technology commercialisation of its oncology research pipeline products including VRP007, a targeted therapy for cancer treatment. Its research arm is now working to come up with revolutionary drugs to reduce side-effects. These include Taxedol which is a ready-to-use single vial injectable, VRP1620, a cancer detection therapy and VRP007 . All these drugs are in different stages of development but under patent protection.

6.2. Panacea, Accelovance establish clinical development service pact for oncology immuno-therapy pipeline Feb 12, 2015

- Panacea Pharmaceuticals, Inc. and Accelovance Inc., an industry award-winning CRO announced the establishment of a clinical development services agreement to develop and advance Panacea's oncology immunotherapy pipeline. Through this agreement, Accelovance will support Panacea's clinical development strategies by offering scientific and regulatory expertise, contract research organization (CRO) support through project management, clinical monitoring, data management, biostatistics, and safety services for Panacea's clinical trials.

6.3. Lupin enters licensing agreement with Celon Pharma for generic Advair Diskus Feb 18, 2015

- Lupin has entered into a definitive agreement with Celon Pharma S A (Celon) to develop fluticasone / salmeterol dry powder inhaler (DPI) product which is a generic version of GlaxoSmithKline's (GSK) Advair Diskus. Lupin will undertake marketing of the product and Celon will supply the product for commercialization in the the US, Canada, Mexico, and other key markets. GSK's Advair Diskus had global sales of over US$ 7 billion as of last fiscal.

6.4. Sanofi inks research pact with Lead Pharma to develop treatments for autoimmune diseases Feb 19, 2015

- Sanofi has entered into a research collaboration and license agreement with Lead Pharma, to discover, develop and commercialize small-molecule therapies directed against the nuclear hormone receptors called ROR gamma (t) to treat a broad range of autoimmune disorders, including rheumatoid arthritis, psoriasis and inflammatory bowel disease. Under the terms of the agreement, Sanofi and Lead Pharma will collaborate during the early phase of research and development with a goal of identifying drug candidates and beginning human trials within 3-4 years.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. NeuroNascent gets expanded patent coverage in US & Russia for Alzheimer's disease and Down syndrome therapeutics Feb 09, 2015

- Neuronascent, Inc. announced that the US Patent Office has granted expanded patent protection to the company's new therapeutic candidate, NNI-362, beyond composition of matter and pharmaceutical compositions to coverage of its use for patients suffering from neurodegenerative disorders including Alzheimer's, Parkinson's and Huntington's diseases. In addition, the Russian Patent Office issued a first notification to grant patent coverage of the company's lead therapeutic candidate, NNI-351, for pharmaceutical composition and a method of treatment of Down syndrome mediated by Dyrk1a activity.

7.2. Venus Remedies gets Indian patent for Vancoplus Feb 09, 2015

- Venus Remedies Ltd has received a product patent grant for its unique antibiotic research product, Vancoplus, from the Indian Patent Office (IPO). The patent is valid till 2025. Vancoplus is a novel antibiotic adjuvant entity that is highly effective against the notorious MRSA bacterial strain and multi-

-drug resistant microbes primarily responsible for causing infections like meningitis, pneumonia, typhoid, septicemia, urinary tract infections, skin infections and staphylococcal endocarditis.

TECHNOLOGY NEWS

8.1. New protocol promises to transform remote monitoring of patients through implanted medical sensors Feb 02, 2015

- In modern western societies the fitting of pacemakers and implantable cardioverter defibrillators (ICDs) is growing rapidly. Devices of this type control heart rhythm and, if necessary, send an appropriate response to make the heart beat at the right rhythm. They also record heart activity patterns when abnormal heart rhythm is detected. This information is periodically checked and monitored by a doctor to plan future treatment. To do this, the information is transmitted in wireless mode to an external device. At the moment this communication is carried out in hospitals.

8.2. CellDetect urine test for detecting bladder cancer meets primary endpoint in multi-center clinical study Feb 03, 2015

- BioLight Life Sciences Investments Ltd announced today that a blinded, multi-center clinical study of the CellDetect® non-invasive test for detecting bladder cancer in urine, successfully achieved the study's primary endpoint for effectively detecting the recurrence of bladder cancer in subjects with a history of the disease. The CellDetect® technology is being developed by Micromedic Technologies (TASE: MCTC), BioLight's cancer diagnostics subsidiary, and allows an accurate diagnosis of cancerous and precancerous cells.

8.3. New app for clinical detection of skin cancer launched on World Cancer Day Feb 04, 2015

- Developed by Lûbax, the app is the world's first skin identification system using state-of-the-art image recognition software. The app is designed to provide a simple, inexpensive software system to support health professionals in the identification of all types of skin lesions. The first clinical studies of the app carried out in collaboration with Harvard, Stanford, Oxford, and the University of São Paulo show greater than 90% sensitivity and specificity in detecting large melanomas in patients.

8.4. Researchers devise new technique to deliver cancer treatment Feb 05, 2015

- A team of researchers has devised a new way to target tumors with cancer-fighting drugs, a discovery that may lead to clinical treatments for cancer patients. Called iontophoresis, the technique delivers high concentrations of chemotherapy to select areas, reducing the risk of damaging healthy tissue, according to a study this week in Science Translational Medicine. This technology basically forces drugs directly to and through the tumor, allowing all cancer cells in the treatment zone to get that exposure.