Clinical Research Newsletter Volume - 1, January 2015

LAMBDA

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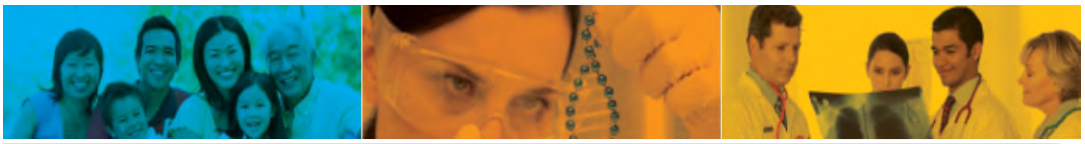


LAMBDA

GLOBAL NEWS

1.1. New survey from Pfizer finds 77% of working women with breast cancer feel working aids in recovery

Dec 04, 2014

- A new survey reveals that 77 per cent of working women with breast cancer, including those with metastatic disease, feel that working aids in their recovery a view shared almost unanimously by healthcare professionals, who were also surveyed (92 per cent). The Supporting Workplace Conversations survey is the first to comprehensively examine the perspectives of working women with breast cancer, healthcare professionals and employers on the topic of breast cancer and the workplace.
- The survey was commissioned by Pfizer Inc. and Cancer and Careers, an organisation that empowers and educates people with cancer to thrive in their workplace, and conducted online by Harris Poll with 1,002 female breast cancer patients and survivors who have worked or looked for work since their diagnosis, as well as 102 employers and 200 healthcare professionals who treat breast cancer patients.

1.2. Takeda Pharma creates Takeda Oncology to enhance discovery & commericalisation of cancer drugs

Dec 09, 2014

- Takeda Pharmaceutical Company Limited announced its global oncology business unit, will be called Takeda Oncology. The creation of Takeda Oncology will improve the company's ability to meet the unique and urgent needs of cancer patients, their loved ones and health care providers worldwide. Takeda will sustain its long-standing entrepreneurial approach to oncology research and development while expanding its global commercial network and resources as Takeda Oncology. Takeda is retiring the Millennium: The Takeda Oncology Company brand, and replacing it with Takeda Oncology to reflect the new global oncology business unit.

1.3. Pharma entities may lose $65 bn by 2019 from patent expiration: GlobalData Dec 11, 2014

- Global Data, a research and consulting firm, has projected in its study that pharmaceutical companies may suffer an estimated $65 billion drop in sales by 2019 due to the patent expiries of several leading drugs. Its report PharmaLeaders: Global Pharmaceutical Market Benchmark Report stated that the drug makers hit hardest will include Otsuka, Eli Lilly, and AstraZeneca (AZ), with a significant proportion of losses coming in the central nervous system (CNS) treatment sector.

1.4. GSK & 3 leading institutions form EU consortium to help further development of vaccine against Ebola

Dec 18, 2014

- A new European consortium has been formed including GSK and three leading research institutions, University of Oxford, Centre Hospitalier Universitaire Vaudois in Lausanne and the Bernhard-Nocht Institute, to help further advance development of a candidate vaccine against Ebola, which is being co-developed by GSK and the US National Institutes of Health (NIH). The funding is already helping to implement an ongoing trial of an Ebola candidate vaccine being carried out in 120 healthy adult volunteers in Lausanne, Switzerland.

DOMESTIC NEWS

2.1. NABH issues draft accreditation norms for clinical trial sites, ethics committees & investigators Dec 01, 2014

- The National Accreditation Board for Hospitals and Healthcare Providers (NABH), a constituent board of Quality Council of India, has issued draft accreditation standards for clinical trial sites, ethics committees and investigators. The NABH has prepared this draft document in consultation with various stakeholders for starting new accreditation programme. The criteria to be followed for accreditation of ethics committee, investigator and the sites where clinical trials are to be carried out are given separately in the draft document. The NBH has invited comments, suggestions, objections, including deletions/additions if required in the draft document from public at large, including the stakeholders like hospitals and other clinical establishments, industry, consumer groups, etc.

2.2. CPhI India report forecasts new MNCs to emerge from India's pharma SMEs Dec 02, 2014

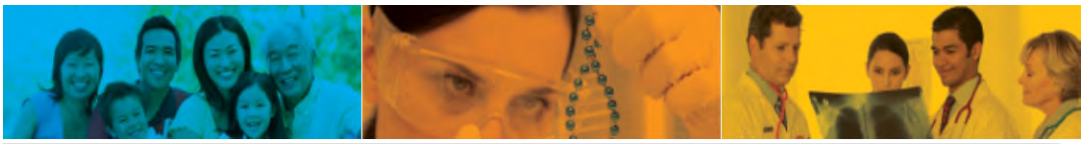
- India is set to take a larger share of European and USA generics markets as demand expands, with generics still representing the core strength of manufacturers. Moreover, as developing nations continue to grow their healthcare systems, the market penetration across regions like Africa will expand rapidly- where total growth is predicted to expand by a remarkable 25-30 per cent by volume per year. These were some of the thoughts shared at Asia's biggest pharma show, the CPhI /P-MEC India 2014 being held in Mumbai organised by UBM.

2.3. India needs to conduct more clinical trials for discovering new drugs: KIMS experts Dec 04, 2014

- India needs to conduct more clinical trials for discovering new drugs for chronic diseases. With large number of block buster drugs coming off patent by 2015, the Indian pharmaceutical industry should get ready for not just making generic drugs, but should also increase the number of clinical trials for discovering new drugs for treating chronic diseases, opined experts at Krishna institute of Medical sciences (KIMS). According to Dr Ramana Prasad, pulmonologists at KIMS, it is high time that the policy makers, drug regulators, the pharma industry and clinical research organizations should come together to devise a perfect path to rejuvenate the clinical trial industry in India.

2.4. IMA to come out with uniform guidelines on rational use of drugs to tackle antibiotic resistance, ADRs Dec 11, 2014

- Considering the fact that many cases of adverse drug reactions (ADRs) go unreported in the absence of a strong notification or investigation system, Indian Medical Association (IMA) is in the process of framing guidelines on antibiotic resistance and irrational usage of drugs. The guidelines which will be prepared shortly are meant to address issues related to adverse drug reactions and multi-drug resistance taking into account that as many as 85 lakh ADR cases were reported by WHO last year, of which one per cent were from India.



2.5. Three cancer drugs get clinical trial waiver for importing, marketing in India Dec 16, 2014

- The Union health ministry has accorded permission to three cancer drugsObinutuzumab injection, Pertuzumab and Afatinibfor importing and marketing in India without local clinical trial on Indian population on the plea that these drugs come under the category of 'the drugs indicated for diseases for which there is no therapy' in the country at present. The waiver of clinical trial on Indian population for approval of new drugs, which have already been approved outside India, can be considered only in cases of national emergency, extreme urgency, epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy.

2.6. Pharmacovigilance need highlighted for India Dec 27, 2014

- In order to boost Pharmacovigilance (PV) in India, there is a need for a participation from all the stakeholders to address issues in ADR reporting and analysis, considering the fact that drug is new for the first few years and its behaviour has to be assessed in the context of the patients. Regulations governing the respective drug should also be based on the respective population of the country. These were some of the thoughts shared during the Pharmacovigilance Symposium titled 'Comprehensive Pharmacovigilance for India The Road Ahead' held in Mumbai recently. It was organised by Pharmacovigilance Working Group (PVWG) of the Indian Society for Clinical Research (ISCR).

REGULATORY NEWS

3.1. Centre launches scheme to strengthen CDSCO & states' drug regulatory systems at Rs.1750 cr - India Dec 10, 2014

- The Union health ministry launched a Scheme for strengthening the Central Drugs Standard Control Organisation (CDSCO) and another for strengthening the states' drug regulatory systems with a financial outlay of Rs. 1750 crore. The proposed strengthening of drug regulatory structures will facilitate expeditious consideration and faster decision making and testing of medical products wherever required and serve the objective of the quality, safety and efficacy of drugs and other medical and cosmetics products in the country. The Health Ministry has invited comments and suggestions from the stakeholders including the general public on this proposal.

3.2. Industry urges DCGI to treat all SLA-approved FDC drugs prior to 2008 as rational Dec 11, 2014

- The pharmaceutical industry in the country has asked the Drug Controller General of India (DCGI) to consider all the SLA-approved FDC drugs being marketed prior to 2008 as rational, as these drugs were already reviewed by the then DCGI office. The industry also urged the DCGI that FDCs of vitamins, minerals, other nutrients; probiotics/prebiotics/synbiotics;antacids/enzyme formulations, cough & cold permutation combination products, topicals, and such simple FDCs should be cleared as rational in view of the fact that these FDCs are unlikely to have any concern with respect to safety issues and being used on day to day basis as household products.

3.3. Apex committee on clinical trials grants approval to 28 proposals Dec 18, 2014

- The Apex Committee on clinical trials, constituted by the union health ministry on the directive of the Supreme Court to monitor the clinical trial sector in India, has given its green signal for a total of 28 clinical trial proposals, 7 proposals of global clinical trials (GCTs) and 21 in other areas, after these were approved by Subject Expert Committees (SECs) and thereafter the Technical Committee, another high-level committee constituted by the ministry on this purpose on the directive of the Supreme Court.

3.4. First-Ever Stem Cell Therapy Recommended in EU Dec 22, 2014

- For the first time, a medicinal product containing stem cells has been recommended for approval in the European Union (EU). On December 19, the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) recommended the stem cell product Holoclar as a first-ever medicinal treatment for severe limbal stem cell deficiency, a condition caused by physical or chemical burns to the eye or eyes in adults, which can result in blindness. The product is made from tissue taken from an undamaged area of the patient's cornea, grown in cell culture, and transplanted in the affected eye or eyes after removal of the damaged area.

DRUG APPROVALS AND LAUNCHES

4.1. Eisai seeks South Korean marketing approval for anticancer agent, lenvatinib Dec 02, 2014

- Eisai Co., Ltd., has submitted its application to the regulatory authority in South Korea (Ministry of Food and Drug Safety) for marketing approval of its novel in-house developed anticancer agent lenvatinib mesylate (lenvatinib) as a treatment for progressive radioiodine-refractory differentiated thyroid cancer. Following the submission of marketing authorization applications in Japan, the United States and Europe, this marks the first time Eisai has submitted a marketing authorization application for lenvatinib in Asia.
- The application submitted for South Korea was based on the positive results from a global phase III clinical study known as the SELECT (Study of (E7080) LEnvatinib in differentiated Cancer of the Thyroid) trial.

4.2. Ranbaxy launches India's first biosimilar of infliximab drug 'Infimab' Dec 02, 2014

- Ranbaxy Laboratories has launched Infimab (BOWO15), the first “Remicade” (infliximab) biosimilar in India through a licensing partnership with Epirus Biopharmaceuticals, Inc., a US and Swiss based biopharmaceutical company focused on the global development and commercialization of biosimilar monoclonal antibodies. With this launch, Ranbaxy's entered into mAb (monoclonal antibodies) biologics segment, and will help the company provide greater access to quality biologic medicines in management of conditions like rheumatoid arthritis. The product was launched at the Indian Rheumatology Association Conference (IRACON) in Chandigarh.

4.3. Actavis launches generic Intuniv to treat ADHD Dec 03, 2014

- Actavis has launched a generic version of Intuniv (guanfacine hydrochloride), as part of a settlement agreement with Shire plc. Actavis has begun shipping the product and, under applicable Hatch Waxman Rules, is entitled to 180 days of marketing exclusivity. Intuniv is a prescription medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD) in patients ages 6 to 17. For the 12-month period ending June 30, 2014, Intuniv had US sales of approximately $668 million, according to IMS Health data.

4.4. Zydus's biosimilar product Adalimumab now accessible in India Dec 09, 2014

- Zydus Cadila, an innovative, global pharmaceutical company that discovers, develops, manufactures and market a broad range of healthcare therapies has announced the launch of the biosimilar of Adalimumab, the world's largest selling therapy. Zydus becomes the first company in the world to launch this biosimilar product. Developed by the researchers at the Zydus Research Centre, the biosimilar has been approved by the Drug Controller General of India and will be marketed under the brand name, Exemptia to treat auto immune disorders such as rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and Ankylosing Spondylitis.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Amgen presents data from phase 2 study of Blincytotm to treat patients with relapsed/refractory ALL Dec 10, 2014

- Amgen announced that new data from a pivotal phase 2 study evaluating Blincyto (blinatumomab) for the treatment of adult patients with relapsed/refractory B-cell precursor acute lymphoblastic leukaemia (ALL) was presented at the 56th American Society of Hematology (ASH) Annual Meeting and Exposition. In one analysis from the '211 study, 40 per cent of patients treated with Blincyto who achieved a complete remission (CR) or complete remission with partial hematologic recovery (CRh) were enabled to proceed to allogeneic hematopoietic stem cell transplant (HSCT).

5.2. Novogen announces breakthrough discovery in treatment of melanoma Dec 18, 2014

- Novogen Limited, Australian drug-development company, has confirmed that its lead candidate product, TRXE-009, originally developed for the treatment of brain cancers, has been shown in pre-clinical studies also to be highly active against melanoma. The company believes this is an important breakthrough discovery for two reasons. The first is that it confirms that TRXE-009 is an important new potential treatment for melanoma. The second is that it offers evidence for the first time of an hypothesized link between brain cancer and melanoma.

5.3. US FDA accepts filing of Apotex' biosimilar application for pegfilgrastim Dec 19, 2014

- Apotex Inc., the largest Canadian owned pharmaceutical company, announced that the US Food and Drug Administration has accepted for filing the company's application for pegfilgrastim, a biosimilar version of Amgen's Neulasta. The product has been jointly developed with Intas Pharmaceuticals Ltd.

The application was filed under the 351(k) abbreviated approval pathway created by the Biosimilar Price Competition and Innovation Act (BPCIA).

5.4. GSK's phase 3 study of shingles candidate vaccine, HZ/su meets primary end point Dec 20, 2014

- GSK announced that a pivotal phase III study to assess the efficacy of HZ/su, an investigational vaccine for the prevention of shingles, has met its primary endpoint. Analysis of the primary endpoint showed that HZ/su reduced the risk of shingles by 97.2 per cent in adults aged 50 years and older compared to placebo. These are the first results from the ZOster Efficacy study in adults aged 50 years and over (ZOE-50). The study, which started in August 2010, is ongoing in 18 countries and involves more than 16,000 individuals.

5.5. Roche reports top-line results of phase III study in patients with HER2-positive breast cancer Dec 20, 2014

- Roche announced top-line results of the phase III MARIANNE study. The study evaluated three HER2-targeted regimens Kadcyla (trastuzumab emtansine) plus Perjeta (pertuzumab), Kadcyla alone, and Herceptin (trastuzumab) plus taxane chemotherapy in people with previously untreated (first line) advanced HER2-positive breast cancer. The study showed the three regimens helped people live without their disease worsening (PFS) for a similar amount of time, meeting its non-inferiority endpoint as assessed by an Independent Review Committee (IRC).

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Pfizer completes acquisition of Baxter's marketed vaccines Dec 02, 2014

- Pfizer Inc. has completed the acquisition of Baxter International Inc.'s portfolio of marketed vaccines. The portfolio that was acquired consists of NeisVac-C and FSME-IMMUN/TicoVac. As previously announced, Pfizer also acquired a portion of Baxter's facility in Orth, Austria, where these vaccines are manufactured. “NeisVac-C and FSME-IMMUN/Ticovac are a strong fit with our vaccines business and this acquisition adds value, scale and depth to our existing portfolio of innovative vaccines,” said Susan Silbermann, president and general manager, Pfizer Vaccines. “These best-in-class products enable us to reach a broader population with vaccines that prevent infections from serious and often fatal diseases.”

6.2. Merck to buy Cubist Pharma for $9.5 billion Dec 09, 2014

- Merck and Cubist Pharmaceuticals, Inc., a global biopharmaceutical company, have entered into a definitive agreement under which Merck will acquire Cubist for $102 per share in cash. “Cubist is a global leader in antibiotics and has built a strong portfolio of both marketed and late-stage pipeline medicines,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “Combining this expertise with Merck's strong capabilities and global reach will enable us to create a stronger position in hospital acute care while addressing critical areas of unmet medical need, such as antibiotic resistance.”

6.3. Dr Reddy's Lab acquires Habitrol brand from Novartis Dec 19, 2014

- Dr Reddy's Laboratories has closed the acquisition of Habitrol brand (an over-the-counter nicotine replacement therapy transdermal patch) from Novartis Consumer Health Inc. following issuance of the proposed consent order from the US Federal Trade Commission (FTC) on November 26, 2014. The company had earlier entered into an asset purchase agreement with Novartis Consumer Health Inc. to acquire the title and rights of Habitrol brand and to market the product in the US market.

6.4. Torrent Pharma ties up with Reliance Life Science to market 3 biosimilars Dec 26, 2014

- Torrent Pharmaceuticals Ltd , Ahmedabad based pharma company, has announced its entrance into an exclusive licensing agreement with Reliance Life Sciences for marketing 3 biosimilars in India Rituximab, Adalimumab and Cetuximab. As per that agreement, Reliance Life Science will develop and supply these products to Torrent Pharma after obtaining all necessary regulatory approvals. Torrent Pharma will be the only company to market there biosimilars in India other than Reliance Life Science.

TECHNOLOGY NEWS

7.1. Scientists investigate Veto Cell technology to treat blood cancers, bone marrow transplants Dec 02, 2014

- Overcoming graft rejection is the main obstacle when it comes to stem cell regeneration or organ transplantation. Current treatment includes the use of systemic immunosuppression, which leaves the patient at risk for opportunistic infections. Scientists now are investigating whether Veto Cell technology, which selectively tunes immune response, can change how immunologists treat blood cancers and bone marrow transplants, as well as the process of how organs are repaired and new ones are regenerated.

7.2. Ceres to develop new method for detecting the presence of Ebola virus in saliva Dec 03, 2014

- Ceres Nanosciences Inc. (Ceres) today announced the commencement of a development program, funded by the Gates Foundation, to use Ceres' Nanotrap® particle technology to develop a new method of detecting the presence of the Ebola virus in saliva. During the four-month performance of this program, Ceres will work in close collaboration with George Mason University and the United States Army Medical Research Institutes of Infectious Diseases (USAMRIID) to assess the ability of the Nanotrap technology to develop a more sensitive and safer Ebola virus detection method that uses saliva instead of blood.

7.3. Two medical imaging techniques could predict effectiveness of TB drugs Dec 05, 2014

- Two medical imaging techniques, called positron emission tomography (PET) and computed tomography (CT) could be used in combination as a biomarker to predict the effectiveness of antibiotic drug regimens being tested to treat tuberculosis (TB) patients, according to researchers at the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health. With

multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) on the rise worldwide, new biomarkers are needed to determine whether a particular TB drug regimen is effective.

7.4. Photoacoustic imaging has potential to be used as noninvasive method to detect cervical cancer

Dec 15, 2014

- Now a team of researchers from Central South University in China have demonstrated that a technique known as photoacoustic imaging, which is already under investigation for detecting skin or breast cancers and for monitoring therapy, also has the potential to be a new, faster, cheaper and non-invasive method to detect, diagnose and stage cervical cancer with high accuracy. Their work appears in a new paper in The Optical Society journal Biomedical Optics Express.

LAMBDA NEWS

8.1. LAMBDA achieves GLP Compliance Certification

- On the basis of inspection conducted by National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA) in October 2014, Lambda has been granted with GLP compliance certificate acknowledging its expertise for Physical-chemical testing, Analytical and clinical chemistry testing, Bio-analysis and Pharmacokinetic analysis, etc.
- This certification recognises Lambda's capability of conducting the Analytical and Clinical Chemistry Testing in compliance with Organization for Economic Co-operation & Development (OECD) Principles of GLP.

8.2. LAMBDA exhibiting at "VIBRANT GUJARAT GLOBAL TRADE SHOW '15" - VGGTS 2015

- Gujarat Government has been holding Vibrant Gujarat Summit since the year 2003. Over a period of time, the event that started as a Global Business Meet has today metamorphosed into an international knowledge sharing platform. This year the event will take place under the banner of "**Vibrant Gujarat Global Trade Show '15" - VGGTS 2015** where Lambda is one of the proud exhibitors.