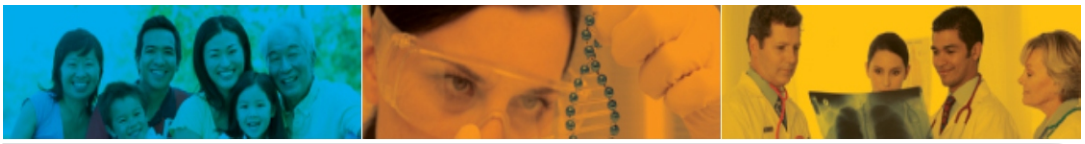

Clinical Research Update Volume - 12, December 2012

LAMBDA

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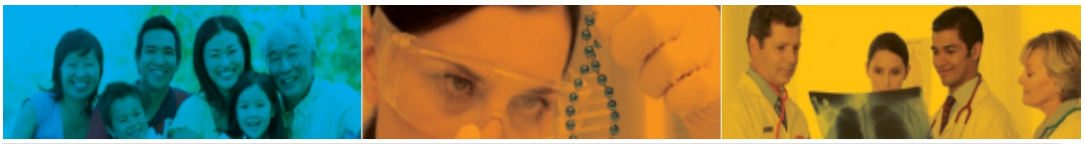


LAMBDA

GLOBAL NEWS

1.1. Top 15 Drug Patent Losses for 2013

Nov 01, 2012

- Pharmaceutical Researcher, Evaluate Pharma, estimates there are $290 billion of sales at risk from patent expirations between this year and 2018. Evaluate Pharma has determined that in 2013, patents will expire on drugs that currently have sales of $29 billion annually. The research firm expects more than 70% of that total will be lost to generics. Top 15 drugs that will see patents expire next year are Cymbalta, Avonex, Humalog, Oxycontin, Rebif, Aciphex, Xeloda, Procrit, Neupogen, Zometa, Lidoderm, Temodar, Asacol, Reclast & Niaspan

1.2. Janssen R&D establishes global cross-pharma clinical trial Investigator Databank

Nov 19, 2012

- Janssen Research & Development, based in Raritan, N.J., has established a global cross-pharmaceutical Investigator Databank designed to improve efficiencies of industry-sponsored clinical trials. Merck and Eli Lilly are the first two companies to join Janssen in this effort. The new Investigator Databank, established as part of this novel industry collaboration, will serve as a one-stop repository where key information about clinical trial sites, such as infrastructure and Good Clinical Practice (GCP) training records, is housed. This will allow participating pharmaceutical companies to reduce time-consuming and sometimes redundant administrative work involved in identifying appropriate clinical trial sites.

1.3. GSK pays £650 million to up stakes in India, Nigeria units

Nov 26, 2012

- GlaxoSmithKline has unveiled plans to increase its holdings in the drug major's consumer healthcare divisions in India and Nigeria. The firm will raise its stake in India's GlaxoSmithKline Consumer Healthcare from 43.2% to up to 75% and pay 3,900 rupees per share through an open offer. That represents an investment of 52.20 billion rupees or around £591 million and a premium of 28% to the unit's share price on November 23. The company is taking a similar step in Africa where it plans to increase its ownership in GlaxoSmithKline Consumer Nigeria from 46.4% to 80%. That proposal also represents a premium of 28% to the latter's closing share price on Friday and the transaction is valued at 15.40 billion naira (£62 million).

1.4. Asia goes paperless for Patient Records

Nov 29, 2012

- The rising demand for cost containment, need for improved quality of services, and call for cost-effective protocols in healthcare is emphasizing on the need to have a paperless electronic medical records (EMR) system. Countries such as China, Singapore, South Korea and Taiwan are already taking steps to overhaul their systems in this regard. The global EMR market, at $4,355 million in 2009, is expected to grow to $9,957 million in 2015 at an estimated compound annual growth rate (CAGR) of 14.9 percent between 2010 and 2015.

1.5. Abbott separates its R&D arm, calls it AbbVie Nov 29, 2012

- Abbott has decided to separate its research-based pharmaceuticals business, which will be known as AbbVie. It will be a research-based specialty biopharma firm with a portfolio of immunology and virology, and a pipeline of breakthrough therapies. Abbott will be remain a science-based healthcare company with diversified market-leading offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals.

DOMESTIC NEWS

2.1. Health Ministry to withdraw licences issued to more than 200 Irrational FDCs Nov 01, 2012

- The fixed dose combination (FDC) issue, triggered by the withdrawal of licences to 294 irrational FDCs by the then DCGI way back in 2007, still lingers on in Madras High Court; the Union health ministry is preparing another long list of irrational FDCs which will be withdrawn from the market in the near future. Most of the atrovastatin combinations, rabeprazole combinations, paracetamol combinations and multivitamin combinations will be withdrawn from the market.

2.2. Biocon hitches growth to R&D spend, to double revenue by 2018 Nov 02, 2012

- Biocon, India's leading biotechnology major, foresees a huge opportunity for itself for the biosimilars in the emerging markets of MENA (Middle East- North Africa) and BRIC (Brazil, India, Russia and China). The entire South East Asian region too unfolds bright prospects for insulin and branded formulations, hence, Biocon ramping up investments in R&D over the next four to five years. As a result, it expects its revenues, currently at Rs. 2050 crore, to nearly double to Rs. 4, 000 crore by 2018.

2.3 Intas Pharma Inks Licensing Deal with Australia's Mayne Pharma Nov 03, 2012

- Intas Pharmaceuticals entered into a licensing deal with Australia's Mayne Pharma Corporation to supply eleven injectables products for the Australian market thereby Mayne Pharma gaining access to eleven hospital products. The combined estimated sales of these injectable are around $73 million (around Rs 390 crore) per annum (as per IMS Health).
- Earlier this year, Intas had signed a licensing agreement with another Australian drug company, Phosphagenics Limited, for the manufacture and sale of three anti-ageing products specifically formulated by Phosphagenics for the Indian market.

2.4. CDSCO Plans for Speedy Approval that are Focused on Emerging Diseases Nov 15, 2012

- The Central Drugs Standard Control Organisation (CDSCO) is soon likely to adopt a mechanism that will ensure speedy approval of genuine and authentic innovative projects that are focused on research activities related to the field of immunological disorders and other emerging diseases segment. The regulatory body will give special consideration to innovative research based ideas that will focus on developing strong base in the emerging area of stem cell therapy, gene therapy, transplantation etc.

2.5. CDSCO wants pharma cos to explore in Preventive Healthcare

Nov 16, 2012

- The Central Drugs Standard Control Organisation (CDSCO) recently expressed its concern over the lack of research initiatives taken by the pharma companies and researchers in developing a sound preventive system of the healthcare mechanism to suit the demand of the patients in the country. Top officials pointed out that keeping in mind the interest of the indigenous patients, serious consideration should be given to explore the research potential in this segment which till now remains to be comparatively low. In the coming years, one of the main agenda of the CDSCO will be to focus on developing and strengthening the preventive mechanism of healthcare system in the country along with cementing its hold in the curative techniques.

2.6. India's Sun to acquire Dusa Pharma

Nov 09, 2012

- Sun Pharmaceutical Industries of India is shelling out around $230 million to buy US dermatology specialist Dusa Pharmaceuticals. It is getting access to the latter's Levulan (aminolevulinic acid), a combination therapy is approved by the US FDA for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp. The firm also markets Blu-U, for moderate inflammatory acne vulgaris and general dermatological conditions.

REGULATORY UPDATES

3.1. EMA to set up Advisory Groups over Clinical Trial Transparency

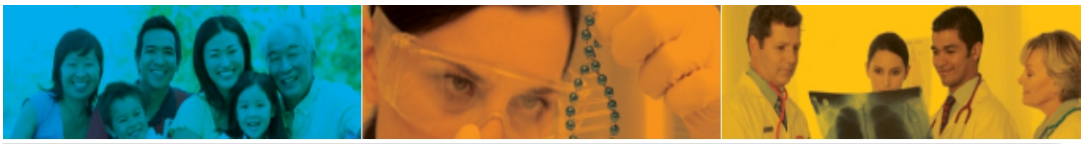
Nov 26, 2012

- The European Medicines Agency is committed to proactive publication of clinical-trial data, once the marketing-authorisation process has ended. EMA will establish policies with its stakeholders in five different areas i.e. protecting patient confidentiality; clinical-trial-data formats; rules of engagement; good analysis practice and legal aspects. Final advice from each group is expected by the end of April 2013 and the proactive publication of clinical-trial data is expected to come into force on January 1, 2014.

3.2. US FDA issues Guidance for Industry on Electronic Source Data in Clinical Investigations

Nov 26, 2012

- This draft guidance document provides recommendations to sponsors, Contract Research Organizations (CROs), data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. This draft guidance document promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.



LAMBDA

DRUGS APPROVALS

4.1. FDA Grants Bayer's Stivarga NDA Priority Review Nov 01, 2012

- Bayer HealthCare and Onyx Pharmaceuticals, a biopharmaceutical company based in South San Francisco, announced today that the FDA has granted priority review to the New Drug Application (NDA) for Stivarga (regorafenib) tablets. Stivarga is a Bayer compound developed by Bayer and jointly promoted with Onyx in the U.S. In 2011, Bayer entered into an agreement with Onyx, under which Onyx receives a royalty on all future global net sales of Stivarga in oncology.

4.2. EU Grants Orphan status to Liposomal Daunorubicin to treat AML Nov 17, 2012

- Galen, a global pharmaceutical company, has announced that the European Commission has designated liposomal daunorubicin as orphan medicinal product for the treatment of acute myeloid leukaemia (AML). The product has a different delivery system in comparison with conventional anthracycline; has a coating type and liposomal particle size, allowing to effectively target malignant tumours.

4.3. Simcere Pharma receives SFDA Approval to begin First-In-Man Trials Nov 15, 2012

- The State Food and Drug Administration of China have granted approval to Apexigen's partner Simcere Pharmaceutical Group to begin first-in-man trials with APX003, which is also known as BD0801, for the treatment of cancer.
- With this approval, APX003/BD0801 becomes the first humanized monoclonal antibody derived from Apexigen's proprietary antibody technology platform to enter human trials.
- This approval marks the success of the dedicated work of the collaboration team to file and defend an IND application, and initiates the next phase of collaboration in clinical development.

4.4. Novartis receives FDA Approval for Flucelvax® Nov 22, 2012

- Novartis announced that the US FDA approved the use of Flucelvax® (Influenza Virus Vaccine), the first cell-culture-derived vaccine, for individuals 18 years of age and older. Flucelvax utilizes full-scale cell-culture manufacturing technology, an alternative production method to traditional egg-based production.

DRUGS IN DEVELOPMENT

5.1. Galapagos discovers 'Entirely New Class of Antibiotics' Nov 26, 2012

- Galapagos says it has begun clinical development on a compound from a novel class of antibiotics. The Belgian company has selected a candidate that shows "strong activity against all tested drug resistant Staphylococcus aureus, including hospital and community acquired MRSA strains". The antibiotic, called CAM-1, works by inhibiting the target DNA pol III alpha, an enzyme present in all bacteria and essential for their growth. It has shown better efficacy than standard antibiotics.

5.2. More Positive Data on Gilead's Hep C Drug Sofosbuvir Nov 28, 2012

- Gilead Sciences has presented promising top-line results from a Phase III trial investigating a combination treatment for hepatitis C virus based around its experimental drug sofosbuvir. The trial, called Positron, is the first of three Phase III studies to be completed that are evaluating sofosbuvir therapy in HCV genotype 2 or 3 infected patients. After a 12-week course of once-daily sofosbuvir plus ribavirin in patients with genotype 2 or 3 chronic HCV infection who are not candidates to take interferon, the study found that 78% of patients remained clear of the virus 12 weeks after completing therapy.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Takeda to acquire Envoy Therapeutics Nov 07, 2012

- Takeda America Holdings, a subsidiary of Japanese research-based company Takeda Pharmaceutical, has agreed to acquire Envoy Therapeutics, a privately-held drug discovery company based in Jupiter, Fla.
- The acquisition of Envoy provides Takeda with proprietary bacTRAP technology, know-how, materials, datasets and analysis techniques enabling the identification of novel targets expressed in disease-relevant cell populations. In addition, Takeda gains access to Envoy's preclinical CNS assets including programs for Parkinson's disease and cognitive impairment associated with schizophrenia (CIAS).

6.2. Bayer to acquire Schiff Nutrition International for $ 1.2B Nov 01, 2012

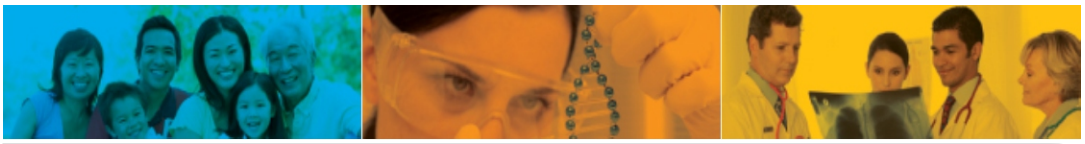
- Bayer HealthCare has signed a merger agreement to acquire Schiff Nutrition International, a company offering vitamins and nutritional supplements in the U.S. and other countries, for $1.2 billion, representing a value of $34 per share in cash. Schiff's product portfolio includes core brands MegaRed, Move Free and Airborne.

6.3. Allergan to acquire SkinMedica for $350M Nov 19, 2012

- Allergan, a multi-specialty health care company, has entered into a definitive agreement to acquire SkinMedica, a privately held, topical aesthetics skin care business. Allergan will pay SkinMedica $350 million up-front for the business, which includes a variety of “physician dispensed” non-prescription aesthetic skin care products and prescription products. Allergan will also pay SkinMedica an additional $25 million contingent upon the acquired products achieving a specific level of net sales.

6.4. AstraZeneca, Pfizer Partner on $100M Drug Research Collaboration Project Nov 26, 2012

- Pfizer ($PFE) and AstraZeneca ($AZN) are joining forces with the local government in Quebec to set up a new, $100 million research center to house a broad range of talent in hopes of inspiring a research renaissance in the ailing biotech hub.



LAMBDA - PHARMACOVIGILANCE CAPABILITIES

Lambda, as a Pharmacovigilance (PV) Partner, provides end-to-end pharmacovigilance and Materiovigilance (Pharmacovigilance for medical devices) services along with a flexible range of safety monitoring services to precisely compliment client's needs.

Pharmacovigilance at Lambda is carried out through well defined systems and procedures based on Good Pharmacovigilance Practices which are periodically reviewed in order to update them as needed.The Pharmacovigilance system is organized to ensure coordination and harmonization of approach across regions in consonance with regional regulatory/business requirements and global imperatives. Lambda ensures full compliance with National and International Regulatory and Pharmacovigilance requirements, both for Investigational and Marketed products of the clients.

GUIDING PRINCIPLES

- Scientific objectivity with focus on patient safety and well being
- Provide safety monitoring services of the highest quality
- Global Compliance to meet the regulatory expectations of the authority(ies) with the most comprehensive requirements
- Continuous assessment of the risk-benefit balance of drugs, ensuring emerging safety information is reported and appropriate remedial actions are taken in time

REGULATORY TRACK RECORD

US- FDA | AIFA - Italy | UK-MHRA

Belgium | Polish MOH | HEALTH CANADA | The Netherlands

- Successfully faced 15 Regulatory Inspections including MHRA- United Kingdom, AIFA- Italy, Polish MOH, FAAG-AFMPS- Belgium, Health Canada, CBG-MEB- Netherlands, US FDAover last couple of years

KEY STRENGTHS

- End-to-end Pharmacovigilance and Materiovigilance (Pharmacovigilance for Medical Devices) services along with a flexible range of safety monitoring services
- Promotes optimum patient safety, product stewardship and meets most comprehensive regulatory requirements
- Robust and compliant Systems & Processes
- PvNET - an E2B compliant advanced software solution that offers complex data analysis and querying of safety data sets, thus proactively meeting all risk management requirements
- Currently performing end-to-end pharmacovigilance for over 4000 authorisations globally, involving all therapeutic areas including oncology, anti retrovirals, biological and more.
- Providing premarketing vigilance services for all phase clinical trials for Drugs and Devices