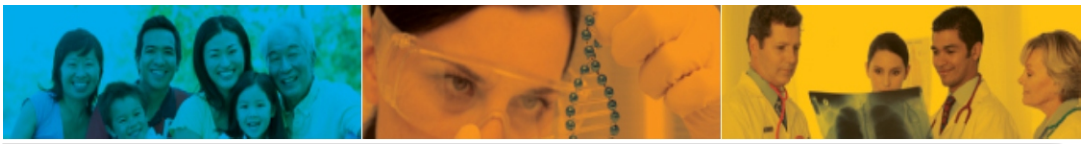

Clinical Research Newsletter Volume - 8, August 2014

LAMBDA

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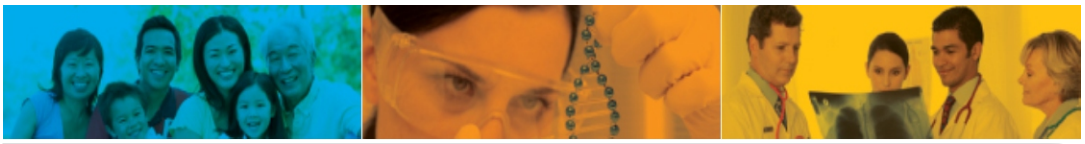


LAMBDA

GLOBAL NEWS

1.1. Novartis charged in Japan over Diovan data manipulation Jul 02, 2014

- Novartis is likely to face criminal charges in Japan relating to manipulation of data by an employee on its blood pressure blockbuster Diovan. The long-running problem stems from data manipulation of a post-marketing trial of Diovan (valsartan) conducted by a team at Kyoto Prefectural University of Medicine led by a former professor whose published papers on valsartan were withdrawn from medical journals after questions were raised over the validity of the findings.

1.2. Global cos reluctant to introduce latest cancer drugs Jul 09, 2014

- Global pharma companies are reluctant to introduce the latest cancer drugs because they fear patent infringement allegations from India. The stalling of clinical trials since January 2013 has also made access to advanced cancer drugs impossible in the country, said Dr. BS Ajaikumar, chairman, Healthcare Global Enterprises (HCG) which is India's largest network chain of 27 dedicated cancer care centres in the country. The hostile response from global pharma majors to boycott new cancer medicines into India ensues Novartis' Gleevac drug which lost its patent protection here.

1.3. EMA: 39 human-use drug OKs in first-half 2014 Jul 10, 2014

- The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) recommended 39 human-use medicines for marketing authorisation in first-half 2014, compared to 44 in the same period of 2013 and 33 in first-half 2012. However, this year's approvals include a number of new innovative medicines with the potential to meet unmet medical needs, treat diseases for which no treatments were previously available and bring significant added benefit to patients over existing therapies, says EMA.

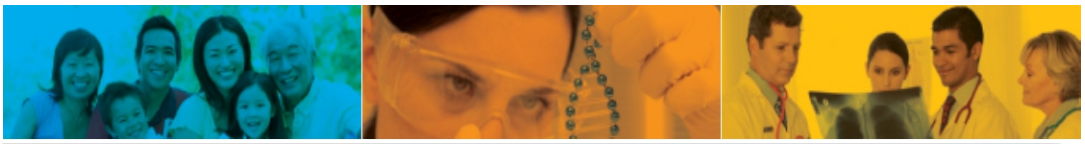
DOMESTIC NEWS

2.1. Industry up in arms against NPPA for bringing 108 non-scheduled drugs Jul 15, 2014

- The pharmaceutical industry in the country is up in arms against the recent notification of the National Pharmaceutical Pricing Authority (NPPA) in which the national drug price regulator has brought prices of 108 non-scheduled formulation packs involving the anti-diabetic and cardiovascular drugs under government control under Paragraph 19 of DPCO, 2013. Paragraph 19 of DPCO, 2013, authorises the NPPA in extraordinary circumstances, if it considers necessary so to do in public interest, to fix the ceiling price or retail price of any drug for such period as it deems fit.

2.2. Bombay HC upholds India's first compulsory license granted to Natco Pharma Jul 16, 2014

- In yet another landmark decision, the Bombay High Court has upheld the compulsory license (CL) granted to Natco Pharma for manufacturing Nexavar, sending a strong message by sticking to the patent office's patient centric decision to ensure availability of affordable life saving drugs to the patients. With this decision, Natco will now be legally able to manufacture and sell the generic copy of sorafenib tosylate, a patented kidney cancer drug invented by German pharma giant Bayer, at a far more affordable price.



LAMBDA

2.3. Fortis C-DOC bags 'Best Hospital in India in Diabetic Care' Jul 31, 2014

- Fortis C-DOC, Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology, a unique hospital for diabetes and allied disorders as been awarded the 'Best Hospital in India in Diabetic Care' at Current Index of Medical Specialities (CIMS) Healthcare Excellence Awards 2014. The Award ceremony was held at The Lalit, Mumbai. The awards are instituted among 20 categories in India's healthcare industry to recognise India's best healthcare providers.

REGULATORY NEWS

3.1. FICCI asks govt to recast adverse rules of 2013-14 Jul 01, 2014

- The Federation of Indian Chamber of Commerce and Industry (FICCI) has asked the Union health ministry to recast the adverse regulations introduced in the year 2013-14 as there is an urgent need to revive the clinical trial sector in the country to address the burden of existing and new diseases.

3.2. Novartis releases new global guidelines for Investigator Initiated Trials Jul 09, 2014

- Novartis released new global guidelines for Investigator Initiated Trials (IITs). An IIT may be a clinical or non-clinical study and is conducted without the participation of Novartis, where the sponsor of the IIT makes a request to Novartis to provide either funding, drug product or both. For these IITs, Novartis provides financial support and /or drug product according to a written agreement, which requires that third-party sponsors comply with applicable local laws and regulatory requirements.

3.3. GSK submits regulatory application to EMA for malaria vaccine Jul 26, 2014

- GSK has submitted a regulatory application to the European Medicines Agency (EMA) for its malaria vaccine candidate, RTS,S. The submission will follow the Article 58 procedure, which allows the EMA to assess the quality, safety and efficacy of a candidate vaccine, or medicine, manufactured in a European Union (EU) member state, for a disease recognised by the World Health Organization (WHO) as of major public health interest, but intended exclusively for use outside the EU. This assessment is done by the EMA in collaboration with the WHO, and requires products to meet the same standards as vaccines or medicines intended for use in the EU.

DRUG APPROVALS AND LAUNCHES

4.1. US FDA grants breakthrough therapy to Amgen's BiTE antibody blinatumomab Jul 03, 2014

- The US Food and Drug Administration (US FDA) has granted Breakthrough Therapy Designation to Amgen's investigational bispecific T cell engager (BiTE) antibody blinatumomab, for adults with Philadelphia-negative (Ph-) relapsed/refractory B-precursor acute lymphoblastic leukaemia (ALL), a rapidly progressing cancer of the blood and bone marrow1. A Breakthrough Therapy Designation conveys all of the fast-track programme features, more intensive FDA guidance on an efficient drug development programme, an organisational commitment involving senior managers, and eligibility for rolling review and priority review2.

4.2. New EU plan to fast-track next-generation drugs launches Jul 09, 2014

- Europe's second Innovative Medicines Initiative (IMI 2) has been announced, with a 3.3 billion-euro budget and a goal of fast-tracking development of the next generation of medicines, especially in areas of unmet medical or societal need. The IMI 2 Strategic Research Agenda, which draws heavily on the World Health Organisation Priority Medicines for Europe and the World report, will also place a greater emphasis on speeding up patient access to new medicines.

4.3. US FDA grants permission to ImQuest Pharma to begin trials of vaginal gel Jul 18, 2014

- ImQuest Pharmaceuticals, a leading drug discovery and development company, announced that the US Food and Drug Administration has approved its Investigational New Drug (IND) application to study the safety in phase 1 clinical trials of its vaginal gel containing the nonnucleoside reverse transcriptase HIV Inhibitor IQP-0528. ImQuest Pharmaceuticals developed the HIV inhibitor in partnership with Samjin Pharmaceutical Co. Ltd of Seoul Korea.

4.4. US FDA accepts Sandoz biologics license application for filgrastim Jul 25, 2014

- Sandoz, the generic pharmaceuticals division of Novartis, announced that the US Food and Drug Administration (FDA) has accepted its Biologics License Application for filgrastim, which was filed under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA). Under the brand name Zarzio, the Sandoz biosimilar filgrastim has been marketed in more than 40 countries outside the US, generating nearly six million patient-exposure days of experience.

4.5. US FDA approves Gilead's Zydelig Jul 25, 2014

- Gilead Sciences announced that the US Food and Drug Administration (US FDA) has approved Zydelig (idelalisib) 150 mg tablets for the treatment of three B-cell blood cancers. Zydelig is indicated in combination with rituximab for patients with relapsed chronic lymphocytic leukaemia (CLL) for whom rituximab alone would be considered appropriate therapy and as monotherapy for patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) and small lymphocytic lymphoma (SLL) who have received at least two prior systemic therapies.

4.6. EU approves Novartis' glaucoma combo Jul 29, 2014

- Patients with glaucoma in Europe can now get access to Novartis' Simbrinza (brinzolamide / brimonidine tartrate), the only fixed-combination therapy that doesn't involve a beta-blocker. The European Commission has approved the eye drops to decrease elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension, for which monotherapy provides insufficient IOP reduction.

4.7. US FDA approves Eylea injection for treatment of diabetic macular edema Jul 31, 2014

- The USFDA has approved Regeneron Pharmaceuticals' Eylea (aflibercept) injection for the treatment of Diabetic Macular Edema (DME). The European Commission has approved the eye drops to decrease elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension, for which monotherapy provides insufficient IOP reduction.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. GSK/Genmab's phase III study fails to meet primary endpoint Jul 01, 2014

- GlaxoSmithKline plc and Genmab announced that the phase III study of ofatumumab (Arzerra) versus physicians' choice in patients with bulky fludarabine-refractory chronic lymphocytic leukaemia (CLL) did not meet its primary endpoint of progression free survival (PFS). The median PFS, as assessed by the Independent Review Committee, was 5.36 months for ofatumumab and 3.61 months for physicians' choice (Hazard Ratio 0.79, p=0.267).

5.2. Exelixis reports positive results from cobimetinib in combo with vemurafenib Jul 15, 2014

- Exelixis, Inc, a biopharmaceutical company, announced positive top-line results from coBRIM, the phase 3 pivotal trial evaluating cobimetinib, a specific MEK inhibitor discovered by Exelixis, in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring the BRAFV600 mutation.
- Exelixis' collaborator Genentech, a member of the Roche Group, informed the company that coBRIM met its primary endpoint, delivering a statistically significant increase in progression-free survival (PFS) for the combination of cobimetinib plus vemurafenib as compared to vemurafenib alone. Adverse events were consistent with those observed in a previous study of the combination.

5.3. Phase III study of sorafenib and capecitabine combo fails to meet primary endpoint Jul 26, 2014

- Bayer HealthCare Pharmaceuticals, a subgroup of Bayer AG, and Onyx Pharmaceuticals, Inc., an Amgen subsidiary, announced that an investigational phase III trial of sorafenib (Nexavar) tablets plus capecitabine in patients with advanced breast cancer did not meet its primary endpoint of improving progression-free survival (PFS).
- The study, called RESILIENCE, evaluated the efficacy and safety of sorafenib in combination with capecitabine, an oral chemotherapeutic agent, compared to placebo plus capecitabine, in patients with HER2 negative breast cancer who are resistant to or have failed prior taxane, and are resistant to or have failed an anthracycline or for whom further anthracycline therapy is not indicated.

MERGER, ACQUISITIONS AND SETTLEMENTS

6.1. Genentech to buy California-based biotech company, Seragon Pharma Jul 03, 2014

- Genentech, a leading biotechnology company, has entered into a definitive agreement to acquire Seragon Pharmaceuticals, Inc. (Seragon), a privately held biotechnology company based in San Diego, California. With this acquisition, Genentech obtains rights to Seragon's entire portfolio of investigational next-generation oral selective estrogen receptor degraders (SERDs) for the potential treatment of hormone receptor-positive breast cancer.

6.2. Actavis' subsidiary Forest Labs completes acquisition of Furiex Pharma Jul 04, 2014

- Actavis plc, a unique specialty pharmaceutical company, announced that its subsidiary Forest Laboratories, LLC has successfully completed its acquisition of Furiex Pharmaceuticals, Inc. in an all-

cash transaction valued at approximately $1.1 billion, and up to approximately $360 million in a Contingent Value Right (CVR) that may be payable based on the status of eluxadoline, Furiex's lead product, as a controlled drug following approval.

6.3. Mylan acquires Abbott branded generics unit Jul 14, 2014

- Mylan is acquiring Abbott Laboratories' main branded generics business in an equity deal valued at $5.3 billion, a move that will also cut the former's tax bill considerably. Under the terms of the deal, Abbott will sell the business, which operates in Europe, Japan, Canada, Australia and New Zealand, for 105 million shares or 21% of the expanded company.

TECHNOLOGY NEWS

7.1. Roche introduces fully automated urine testing system, cobas 6500 Jul 01, 2014

- Roche has launched cobas 6500, a fully automated urine testing system that consists of two modular analyzers combining urine strip testing and digital urinary microscopy. The system tests for 23 parameters to help diagnose diseases such as urinary tract infection, kidney disease, and diabetes. The cobas 6500 offers the highest throughput on the market, ensures high-quality results and increases laboratory productivity significantly, while reducing manual steps and contamination risks for laboratory staff.

7.2. Boston Scientific introduces Polaris imaging system Jul 25, 2014

- Boston Scientific Corporation, a global medical technology leader, has launched the new Polaris Imaging System. This system will support the Boston Scientific family of intravascular ultrasound (IVUS) catheters, including coronary, peripheral and intra-cardiac echo products. The Polaris System offers enhanced ease-of-use and more powerful processing capabilities. Its modular design would also support the planned release of new Boston Scientific imaging products including a fractional flow reserve (FFR) wire, a new family of IVUS catheters, enhanced software features and better system control tools.

LAMBDA NEWS - SUCCESSFUL USFDA INSPECTION AT LAMBDA CANADA FACILITY

- Lambda's Canada facility was inspected by US FDA during July 14-15, 2014. The inspection was conducted for all services being offered by Lambda Canada including clinical and bioanalytical departments. The inspection was concluded without issuance of any 483. In addition, paperless execution of BE studies courtesy Lambda's proprietary 21CFR Part 11 compliant EDC software was a factor appreciated during the inspection.
- Lambda has faced several successful regulatory inspections by various regulatory agencies at it's all facilities across globe.