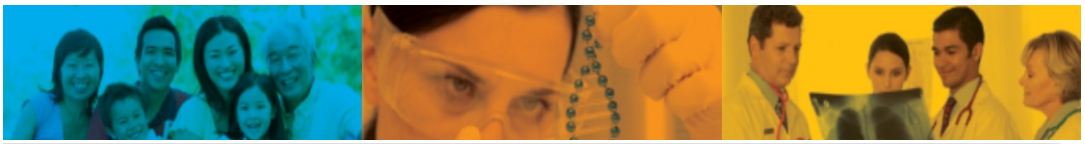

Clinical Research Newsletter Volume - 12, December 2013

LAMBDA

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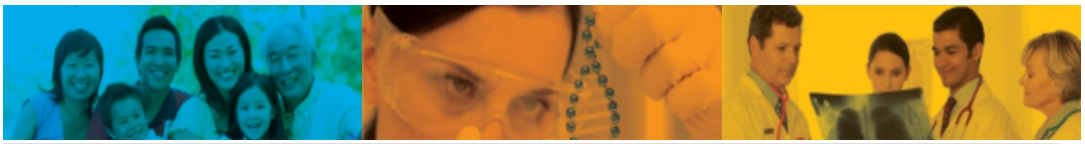

LAMBDA

GLOBAL NEWS

1.1. BI HCV drug faldaprevir shows promise Nov 04, 2013

- Boehringer Ingelheim has presented new data from a Phase III trial programme which shows that faldaprevir was highly effective in a broad range of patients with genotype-1 hepatitis C. Prof Dugi concluded by saying that the protease inhibitor "is the foundation of our HCV pipeline" and the company will present Phase III data using faldaprevir as part of an interferon-free regimen in 2014.

1.2. NICE rejects first-line Velcade for MM Nov 11, 2013

- Cost regulators have issued a preliminary rejection of Janssen Cilag's Velcade (bortezomib) for certain patients with newly diagnosed multiple myeloma (MM), asking for more data comparing its drug to standard treatment. The National Institute for Health and Care Excellence (NICE) has issued draft guidance turning down the first-line use of Velcade in patients with the blood cancer, after uncertainties in the data led an independent appraisal committee to conclude that its cost per QALY would likely "substantially" exceed £39,000.

1.3. Naturex enters into blood sugar control market Nov 19, 2013

- Naturex has developed a patented extract standardized to 10% Nuzhenide and GI3. This extract was tested in several clinical studies targeted at different populations. The latest one was a randomized, double-blind, placebo-controlled, cross-over clinical study in which overweight and mature volunteers received 1,000 mg of Glucevia per day for 3 weeks. The results showed that post-prandial glycaemia expressed as Area under the Curve (AUC) was significantly reduced by 28.2% versus baseline. Glucevia is able to work on all types of sugars both complex and simple. This is in contrast with other products available on the market.

1.4. Merck & Co to close plant in Ireland, 570 jobs to go Nov 29, 2013

- Merck & Co has announced plans to shutter a plant in Ireland by the end of 2017 which will affect 570 staff. The drugs giant, known as MSD outside the USA, says the closure of the facility in Swords, Co Dublin, is the result of an ongoing review of its worldwide manufacturing capabilities "that has resulted in sites being sold, closed or consolidated in § all regions." About 130 people are expected to leave in the second half of 2014 with the remaining posts being phased out over the following three years.

DOMESTIC NEWS

2.1. Diabetic cases high among women in major cities Nov 02, 2013

- A 39 per cent increase has been observed in diabetic cases among women in Delhi, compared to 18 per cent increase among men, according a study by Indus Health Plus ahead of the World Diabetes Day. The increase in diabetic cases among men grew by 18 percent while that among women made a whooping increase of 39 per cent," says the Abnormality Report by Indus.

2.2. GSK to invest Rs. 864 crore in pharmaceutical manufacturing in India Nov 15, 2013

- As part of its continued efforts of expansion and ensuring access to medicines to the people in India, GlexoSmithKline (GSK) has announced its plans to invest Rs.864 crores and establish a new pharma manufacturing unit creating 250 more jobs in India. Over the past one decade the company has invested about Rs.1017 crores and continuously expanding its presence in different parts of the country.

2.3. ConvaTec opens India's first "Advanced Wound Clinic and Limb Salvage Centre" Nov 18, 2013

- ConvaTec, a US-based multinational company in Advance Wound Management, Ostomy Care and Critical & Continence Care in a joint venture with Narayana Health has launched India's first of its kind- 'Advanced Wound Clinic and Limb Salvage Centre' located at NH Health City campus in Bengaluru.

2.4. Health ministry makes audio-visual recording of informed consent mandatory Nov 22, 2013

- Apparently browbeaten by the Supreme Court for not maintaining the required level of transparency in clinical trials in the country, the union health ministry has made mandatory the audio-visual recording of informed consent process of each subject who participates in the clinical trials in the country. This is in addition to the requirement of obtaining written informed consent from the participating subjects.

2.5. Pfizer and Wyeth to merge to create single Pfizer brand Nov 25, 2013

- The Board of Directors of Pfizer Ltd (Pfizer India) and Wyeth Ltd. (Wyeth India), in their respective meetings, have approved a proposal to merge Wyeth India with Pfizer India. The Board of Directors of Pfizer India and Wyeth India have also announced an interim dividend of Rs.360 per share and Rs.145 per share respectively. The merger process is expected to be completed in approximately nine months. Ernst & Young LLP is acting as tax advisors to Pfizer India and AZB & Partners, Advocates and Solicitors are acting as Legal Advisors.

REGULATORY NEWS

3.1. New medical device regulation to boost innovation: Experts Nov 01, 2013

- Enactment of the new medical device regulation, the Drugs and Cosmetics Amendment Bill 2013, which is to be introduced in Parliament soon, would translate the medical devices into an affordable and user-friendly product. This according to experts will be the outcome of right differentiation between drug and device which would further boost innovation. This would also help in categorization of medical devices into different types - capital equipment, implants, consumables, in-vitro diagnostics which will further facilitate the process of regulating them.

DRUGS APPROVALS & LAUNCHES

4.1. Tolmar's ANDA for generic Solaraze gel receives US FDA final approval Nov 01, 2013

- Impax Laboratories, Inc., a technology based specialty pharmaceutical company, and northern Colorado based Tolmar, Inc. have announced that the US Food and Drug Administration (FDA) has granted final approval of Tolmar's Abbreviated New Drug Application (ANDA) for its generic version of Solaraze Gel (diclofenac sodium-3%). Tolmar was the first company to file a substantially complete ANDA containing a Paragraph IV certification, and Impax's generics division, Global Pharmaceuticals, intends to commercialize this first-to-file product shortly. The last Orange Book listed patent expires August 11, 2015.

4.2. FDA launches new plan to tackle drug shortages Nov 02, 2013

- The US Food and Drug Administration have launched a two-pronged plan designed to combat the problem of medicine shortages. The first scheme will see the agency look to improve its own response to "imminent or existing shortages, and for longer-term approaches for addressing the underlying causes of drug shortages". Secondly, the FDA has issued a proposed rule requiring all manufacturers of "certain medically important prescription drugs" to notify the agency of a "permanent discontinuance or a temporary interruption of manufacturing likely to disrupt their supply". The rule also extends this requirement to makers of biologics.

4.3 Sanofi MS drug Lemtrada backed by FDA panel Nov 14, 2013

- Sanofi has been boosted by the news that advisors to the US Food and Drug Administration have unanimously recommended approval of its multiple sclerosis treatment Lemtrada. The agency's Peripheral and Central Nervous System Drugs Advisory Committee voted in favour of Lemtrada (alemtuzumab), which came as a surprise to some observers given that last week FDA staffers spoke about "multiple serious and potentially fatal safety issues" linked to the drug. However, while the panel voted 12-6 that the drug provided substantial evidence of effectiveness, it went 14-2 (with two abstentions) that Lemtrada did not improve disability.

4.4. Venus becomes first Indian co to get marketing approval for meropenem Nov 21, 2013

- Venus Remedies Limited, a research-based global pharmaceutical firm, has emerged as the first Indian company to get approval for meropenem in the Gulf with marketing authorisation from the Saudi Food and Drug Authority (SFDA). The company is planning to launch this product in Saudi Arabia, considered one of the most lucrative pharmaceutical markets in the world, early next year.

4.5. Cadila Pharma announces launch of innovative drug to treat lung cancer Nov 21, 2013

- Cadila Pharmaceuticals has announced the launch of Mycidac-C, claimed to be a unique innovative drug for the treatment of lung cancer which accounts for more than 20 per cent of cancer cases across the globe. Announcing this at a press conference here on Thursday, company chairman and the managing director Dr Rajiv Modi said the formulation was the third major innovative product from the company which has a strong pipeline of products coming up. Mycidac-C is an innovative research

product for the patients suffering from non small cell lung cancer (NSCLC). The drug has been approved for launch in India by the Drug Controller General of India (DCGI). It targets Desmocolin-3, a novel target.

4.6. Biocon & Mylan receive DCGI nod for biosimilar Trastuzumab Nov 25, 2013

- Biocon Ltd has received the Marketing Authorization from the Drugs Controller General of India (DCGI) for its biosimilar Trastuzumab being developed jointly with Mylan, for the treatment of Her 2+ metastatic breast cancer. The regulatory approval for biosimilar Trastuzumab in India is an extremely important milestone for Biocon as it is the world's first biosimilar version of Herceptin of Roche to be brought to the market. The biosimilar Trastuzumab will be marketed in India under the brand name of CANMAb by Biocon and is expected to be available to Indian patients in Q4 Fy14.

DRUGS DEVELOPMENT & CLINICAL TRIALS

5.1. Novartis scientists discover new drug for malaria treatment Nov 30, 2013

- Novartis scientists have discovered a new drug target for treating malaria, which identifies phosphatidylinositol-4 kinase (PfPI4K) as the target of the imidazopyrazines, a novel experimental antimalarial compound class that inhibits the development of multiple malaria-causing Plasmodium species at each stage of infection in the human host. The discovery is published in the journal Nature. The on-going research to develop imidazopyrazines as a new treatment for malaria is supported by the Welcome Trust and Medicines for Malaria Venture.

AGREEMENTS (MERGER/ACQUISITIONS/SETTLEMENTS)

6.1. GlaxoSmithKline (GSK) and Pfizer team up for melanoma trial Nov 23, 2013

- GSK and Pfizer have joined forces to test a combination of their respective melanoma compounds. A Phase I/II study will explore the efficacy and safety of Pfizer's investigational drug palbociclib with GlaxoSmithKline's already-marketed Mekinist (trametinib). The trials will also evaluate the effect of the combo on tumour biomarkers, safety and anti-cancer activity in patients with BRAFV600 wild type melanoma, including those with NRAS mutations. The two companies will collaborate on the study, which GSK will conduct. Financial terms of the agreement have not been disclosed.

6.2. Piramal partners with Ci-Co Healthcare for commercialisation of florbetaben F18 Nov 21, 2013

- Ci-Co Healthcare, Korea and Piramal Imaging, a division of Piramal Enterprises, Ltd., have entered into a strategic partnership and exclusive licensing agreement whereby Ci-Co Healthcare will obtain market authorisation from the Korean Health Authorities and commercialise the PET amyloid imaging agent, florbetaben F18, in South Korea. Ci-Co Healthcare has assigned the manufacturing and supply of florbetaben F18 to DuChemBio, a market leading radiopharmacy network in Korea. Florbetaben F18 is an investigational PET amyloid imaging agent currently under review by the US Food and Drug Administration and the European Medicines Agency.