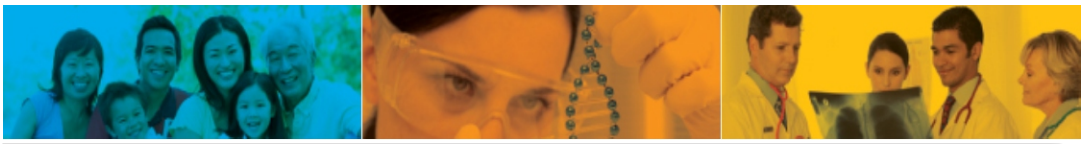

Clinical Research Newsletter Volume - 2, February 2014

LAMBDA

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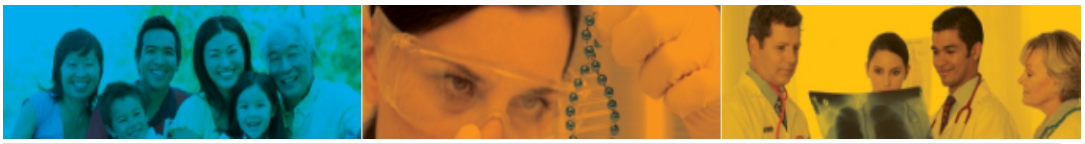

LAMBDA

GLOBAL NEWS

1.1. Sanofi to expand access to clinical trials data of Sanofi Group Jan 03, 2014

- Sanofi will be expanding access to information and data from clinical trials in January, sponsored by companies of the Sanofi group, in support of industry-wide efforts to promote a set of Principles for Responsible Sharing of Clinical Trial Data that the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) jointly released in July 13.

1.2. US-based Merit Medical Systems opens office in India Jan 23, 2014

- US based Merit Medical Systems, Inc., a leading manufacturer and marketer of proprietary medical disposable devices used primarily in cardiology, radiology and endoscopy, has kicked off operations in Bengaluru. At the opening of the India subsidiary office, Joe Wright, president, Merit Medical Systems, Inc. said that the key reason for our entry into the Indian market now with direct presence is due to the large need that has been generated for our products over the last 3-5 years."

1.3. Abbott Laboratories' net earnings dips by 44% in Q4 Jan 24, 2014

- Abbott Laboratories has suffered a setback during the fourth quarter ended December 2013 and its net earnings, after specified items related to separation of AbbVie, declined by 44 % to US$ 589 million from $1,053 million in the corresponding period of last year. The company shown earnings of $1575 million from discontinued operations in the last period as against nil in the current period.

1.4. Novartis net dips by 48% to Rs. 15.23 cr in Q3 Jan 24, 2014

- Novartis India, a Rs. 875 crore plus MNC from Mumbai, has suffered heavy setback during the third quarter ended December 2013 on account of reduction in the selling prices of some key products under new Drug Price Control Order. Its net profit declined sharply by 47.5 per cent to Rs. 15.23 crore from Rs. 29 crore in the corresponding period of last year.

1.5. Catalent files for IPO Jan 24, 2014

- Catalent, the parent company of Catalent Pharma Solutions, has publicly filed a registration statement with the U.S. Securities and Exchange Commission (SEC) for a proposed Initial Public Offering (IPO) of its common stock. The number of shares to be offered and the price range have not yet been determined.

DOMESTIC NEWS

2.1. CDSCO to strengthen PvPI & Haemovigilance Programme Jan 02, 2014

- To enable better healthcare services to all, the Central Drugs Standard Control Organisation (CDSCO) is planning to embark on a mission to strengthen its pharmacovigilance and haemovigilance programme across country to another level. This they are planning to do by bringing new adverse drug reaction centres under its fold and also by asking drug manufacturers to start patient safety monitoring units. With this agenda in mind, the Drugs Controller General of India (DCGI) recently inaugurated the haemovigilance cell at the Cuttack Medical College in Odisha.

2.2. ISCR releases Code of Conduct for Clinical Research in India — Jan 11, 2014

- Indian Society for Clinical Research (ISCR) has issued Code of Conduct for clinical research in India. A set of 12 norms were unveiled here at the 7th annual ISCR conference being held in Bengaluru from January 10 to 11. Dr Suresh Menon of ISCR said that the key objective of 12 rules, to be adhered by the clinical research industry, is that the 200 members of ISCR representing from across the clinical research spectrum are committed to ethical, scientific and regulatory compliance during the process of human studies.

2.3. DCGI not to approve BA/BE studies done at non approved facilities — Jan 20, 2014

- The Drug Controller General of India (DCGI) will not accept and approve the reports of bioavailability (BA) and bioequivalence (BE) studies which are conducted at clinical or bioanalytical facilities that are not approved by the Central Drugs Standard Control Organisation (CDSCO). Cautioning the industry about such malpractices, the DCGI has warned that there is a requirement of obtaining approval from the office of DCGI prior to initiation of activity of bioanalytical laboratory for the purpose of analysis of samples obtained from bioavailability (BA) and bioequivalence (BE) studies.

2.4. Indian pharma companies secure 154 ANDAs approval in 2013 — Jan 22, 2014

- The Indian pharmaceutical companies and their subsidiaries have established strong presence in the United States and other regulated markets with higher investment in research and development (R&D) during the last couple of years. Indian companies received final approval for 154 ANDAs during the year 2013 from US FDA and 38 tentative ANDAs approval during 2013.
- The US FDA has approved a total 400 final ANDAs (lowest in the last five years) during the year 2013 as against 476 in the previous year and it approved total 86 tentative ANDAs during 2013 as against 94 during 2012.

REGULATORY NEWS

3.1. Interim reporting guidance for outsourcing facilities - USFDA — Jan 04, 2014

- USFDA has issued guidance on Interim Product Reporting for Human Drug Compounding Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act. The guidance is intended for outsourcing facilities that compound human drugs. Now the outsourcing facilities may elect to register with FDA under section 503B. If an outsourcing facility registers, it must report to FDA information about the drugs compounded at the outsourcing facility.

3.2. US FDA issues draft norms on Post Marketing Surveillance — Jan 28, 2014

- US Food and Drugs Administration (FDA) has issued draft guidance on Post Marketing Surveillance (PMS) of promotional media for prescription human and animal drugs and biologics. The regulatory authority requires the industry comments on the same before March 31, 2014. The draft guidance is intended to fulfil regulatory requirements for post marketing submissions of interactive promotional media for FDA-approved products.

DRUGS APPROVAL AND LAUNCHES

4.1. US FDA grants fast track status to Peregrine's bavituximab Jan 08, 2014

- The US FDA have granted Fast Track designation to Peregrine Pharmaceuticals, Inc. for its lead investigational immunotherapy bavituximab for the potential treatment of second-line non-small cell lung cancer (NSCLC). Recently, the company initiated SUNRISE, a pivotal phase III clinical trial comparing bavituximab plus the chemotherapy docetaxel against placebo plus docetaxel in this indication.

4.2. US FDA grants breakthrough therapy designation to GSK's Tafinlar Jan 15, 2014

- The US FDA has granted Breakthrough Therapy designation to GlaxoSmithKline's Tafinlar (dabrafenib) for treatment of patients with metastatic BRAF V600E mutation-positive non-small cell lung cancer (NSCLC) who have received at least one prior line of platinum-containing chemotherapy. Dabrafenib is not approved or licensed anywhere in the world for use in this treatment setting.

4.3. Celltrion received approval of biosimilar trastuzumab in S. Korea Jan 18, 2014

- South Korean biotechnology company Celltrion announced on 15 January 2014 that it had received approval for its biosimilar monoclonal antibody Herzuma (trastuzumab) with the Korean Ministry of Food and Drug Safety (MFDS). Herzuma is a biosimilar of Roche's blockbuster breast cancer treatment Herceptin (trastuzumab).

4.4. Subcutaneous Rituximab Recommended in the EU Jan 27, 2014

- A subcutaneous formulation of rituximab (MabThera, Roche) could soon be available in Europe, now that the Committee for Medicinal Products for Human Use (CHMP) has recommended the product for approval by the European Commission. Rituximab is currently delivered by intravenous (IV) infusion, which takes approximately 2.5 hours. The subcutaneous formulation can be delivered in approximately 5 minutes and is available in ready-to-use fixed doses.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. AbbVie begins phase III study of veliparib for Breast Cancer Jan 17, 2014

- AbbVie, a global, research-based biopharmaceutical company, has started a phase III clinical trial evaluating the safety and efficacy of its investigational compound, veliparib (ABT-888) when added to carboplatin, a chemotherapy, in women with early-stage, triple-negative breast cancer. The three-arm trial will compare the addition of veliparib plus carboplatin or placebo plus carboplatin to standard neoadjuvant chemotherapy.

5.2. Starpharma begins dendrimer-docetaxel phase I trial Jan 27, 2014

- Starpharma has received approvals to commence a phase I human clinical trial for its dendrimer-enhanced docetaxel (Taxotere) chemotherapeutic product, referred to as DEP-Docetaxel. The trial will be conducted exclusively in Australia, at Nucleus Network's clinical facility at the AMREP/Alfred Hospital initially, with the plan to add one to two additional sites in the near future.

5.3. Pfizer reports +ve results from 2 phase III trials of dacomitinib Jan 29, 2014

- Pfizer Inc. has reported top-line results from two randomized phase III studies of the irreversible pan-HER kinase inhibitor dacomitinib in patients with advanced non-small cell lung cancer (NSCLC). Both trials evaluated dacomitinib in populations of previously treated patients with advanced NSCLC.

MERGER, ACQUISITION AND SETTLEMENTS

6.1. Kester Capital sells Chiltern Jan 02, 2014

- Kester Capital, the European private equity arm of Greenhill & Co., has sold its interest in Chiltern in a deal valuing the company at $223.4 million. The exit comes as Chiltern announces the consolidation of existing investors, led by Sir Douglas Myers. The transaction has generated a return of over two times capital and a 25% IRR for Kester Capital funds.

6.2. Santaris Pharma signs worldwide strategic alliance with Roche Jan 11, 2014

- Santaris Pharma A/S, a privately held biopharmaceutical company, has signed a worldwide strategic alliance with Roche to discover and develop novel RNA targeted medicines using Santaris Pharma's proprietary Locked Nucleic Acid (LNA) drug platform. Under the terms of the agreement, Santaris Pharma and Roche will collaborate on the discovery of LNA drugs against a multitude of targets across several disease areas.

6.3. Dr Reddy's and Galena ink partnership to develop NeuVax Jan 15, 2014

- Dr Reddy's Laboratories Ltd., an integrated global pharmaceutical company, and Oregon based, Galena Biopharma have signed a strategic partnership to develop and commercialize NeuVax (nelipepimut-S) in India. NeuVax is a vaccine aimed at preventing the recurrence of breast cancer in patients under remission.

6.4. GVK BIO to acquire Aragen Bioscience, Inc. Jan 30, 2014

- Asia's leading small-molecule contract research organization (CRO), GVK BIO and Aragen Bioscience, Inc., a privately held US based, pre-clinical CRO specializing in high-value biologics services, have entered into an agreement to acquire the capital stock of Aragen Bioscience. GVK BIO has established itself as a pre-eminent small molecule service provider. This is GVK BIO's first international acquisition; the financial details were not disclosed.

TECHNOLOGY NEWS

7.1. Samsung launches first ultrasound with 5D technology in India Jan 07, 2014

- Samsung Electronics, a global leader in technology, has launched the UGEO WS80A, its first premium ultrasound with 5D technology in India. The new UGEO WS80A combines Samsung's latest technology in display to deliver faster and more accurate diagnoses in the field of women's health. With new Samsung design and innovative features including the 5D technologies, MPI and ElastoScan that provides superior image performance, the UGEO WS80A redefines premium ultrasound for women's health.