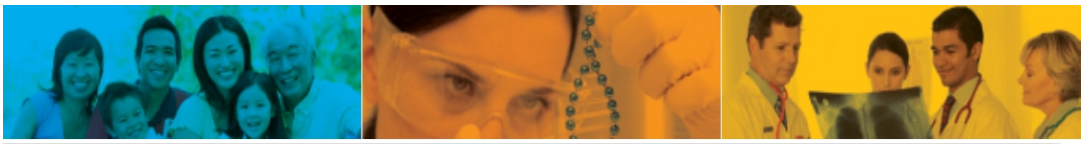

Clinical Research Newsletter Volume - 9, September 2014

LAMBDA

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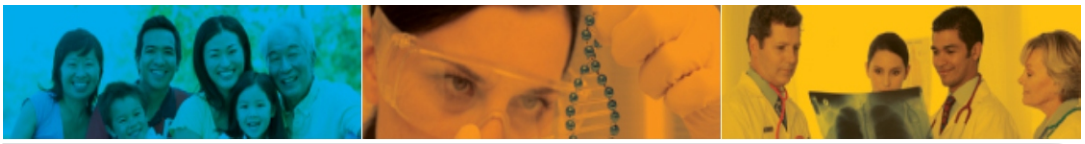


GLOBAL NEWS

1.1. Baxter opens state-of-the-art biologics facility in Singapore Aug 09, 2014

- Baxter International has recently announced the formal opening of its first advanced recombinant biologic facility in Singapore, and expansion plans for a new recombinant protein processing suite. The current suite supports the processing of ADVATE [Antihemophilic Factor (Recombinant)], the market leading full-length recombinant factor VIII (rFVIII) worldwide for the treatment of patients with haemophilia A.

1.2. FAPA sees Indian pharma to make mark in South East Asia Aug 11, 2014

- Indian pharma companies will be able to make a mark in the South East Asia region for manufacture of biologicals and biosimilars over the generics. This is because in the case of generic drugs, the countries such as Malaysia, Vietnam, Philippines and Korea apart from Japan are looking for differentiated products and therefore Indian pharma will need to enhance its brand building exercise to compete in these markets, said John CP Chang, president, Federation of Asian Pharmaceuticals Associations.

1.3. Argentina govt allows imports formulations from India Aug 25, 2014

- Argentinian government issued a notification permitting import of generic formulations from Indian pharmaceutical exporters. With this India becomes the 27th country to supply generic formulations to Argentina, a highly regulated market, further establishing India's expertise in this field and proving the capabilities of Indian manufacturers as a supplier of high quality raw materials at the global platform. This move comes as an outcome of the huge effort put by the commerce ministry.

1.4. Ebola vaccine proves highly efficacious in non-human primate study Aug 26, 2014

- Immunovaccine Inc., a clinical stage vaccine company, announced positive results for a vaccine formulated in its DepoVax technology in an Ebola virus challenge study performed by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). In a preliminary study using cynomolgus monkeys, which are particularly sensitive to the Ebola virus, all vaccinated subjects survived exposure to a lethal dose of the wild type Zaire strain of the virus. All unvaccinated control animals succumbed to the disease.

DOMESTIC NEWS

2.1. IPC launches medicines adverse effect reporting form for patients Aug 18, 2014

- In a strategic move that involves direct participation of patients in the Pharmacovigilance Programme of India (PvPI), the Indian Pharmacopoeia Commission (IPC) has recently launched the ambitious medicines adverse effect reporting form for consumers i.e. the patients. Interestingly, this will be first done on pilot basis across all the 150 adverse drug reaction (ADR) centres to gauge the impact it creates among the patients and on whether they are comfortable with the module prepared by them for reporting of ADRs in future.

2.2. NPPA fixes/revises ceiling and retail prices of 56 formulation packs Aug 23, 2014

- The National Pharmaceutical Pricing Authority (NPPA) has fixed or revised the prices in respect of 56 formulation packs both ceiling and retail price packs under Drugs Prices Control Order (DPCO), 2013. The manufacturers of various formulations having maximum retail price higher than the ceiling price shall revise the MRP to an amount not exceeding the ceiling price plus local taxes, wherever applicable in accordance with paragraph 13 (1) and 24 of the DPCO,2013, the NPPA further said in its order.

2.3. Metropolis launches Multiplex PCR test to detect disease causing fever Aug 28, 2014

- Metropolis Healthcare Ltd, a leading multinational chain of diagnostic centres, has launched India's first single test for seven diseases which cause fever. The Multiplex PCR test helps diagnose seven common diseases causing fevers Malaria, Dengue, Typhoid, Leptospirosis, Chikungunya, West Nile Fever and Rickettsia. The test is seen to save cost and provide doctors to help faster diagnosis. The Multiple PCR is done in real-time which extract nucleic acid of pathogens from whole blood.

REGULATORY NEWS

3.1. ISCR notes positive response of regulatory authorities Aug 05, 2014

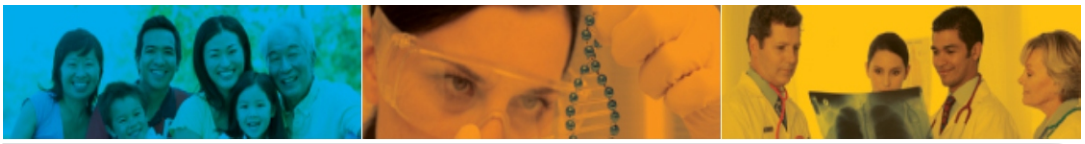
- Indian Society for Clinical Research (ISCR) views that the response of the regulatory authorities on the concerns raised by clinical research organisations (CROs) about some of the challenging guidelines makes it hopeful that issues will be ironed out and India could be back-in-business for human studies. “However, winning back the confidence of the CROs will be a challenging and uphill task. It will take several months before we see clinical research back in India on track,” Suneela Thatte, president ISCR.

3.2. ABLE & ACRO request DCGI to maintain patient confidentiality in clinical trials Aug 25, 2014

- The Association of Biotechnology Led Enterprises (ABLE), and the Association of Contract Research Organisations (ACRO) India have cautioned the DCGI to preserve confidentiality of the patients. The industry bodies have also requested to retain the existing Clinical Trial Registry of India (CTRI) website for clear visibility of human studies in the country. The request follows the need for suggestions from CDSCO on its notification issued on July 28, 2014 to improve its clinical trials management.

3.3. DCGI renames new drug advisory committees as subject expert committees Aug 26, 2014

- As per the recommendations of the Prof Ranjit Roy Choudhury committee, the Drugs Controller General of India (DCGI) has renamed new drug advisory committees (NDACs) as subject expert committees (SECs). As per the action on the committee recommendations, all the 12 NDACs will be renamed as subject expert committees (SECs). The members for their meetings will be drawn randomly from a large pool of experts. Applications of clinical trials and new drugs will initially be evaluated by the SECs and their recommendations will be reviewed by Technical Review Committee (TRC).



LAMBDA

DRUG APPROVALS AND LAUNCHES

4.1. New EU plan to fast-track next-generation drugs launches Aug 01, 2014

- Jardiance (empagliflozin) has been approved by the U.S. Food and Drug Administration to treat type 2 diabetes, which accounts for some 90 percent of diabetes cases in the United States. Jardiance, from a class of drugs called "sodium glucose co-transporter 2 inhibitors," is designed to block re-absorption of blood sugar by the kidneys. Its safety and effectiveness were evaluated in clinical studies involving 4,480 people with type 2 diabetes.

4.2. Roche's Avastin receives European approval to treat recurrent ovarian cancer Aug 07, 2014

- The European Commission (EU) has approved the use of Roche's Avastin (bevacizumab) in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin chemotherapy as a treatment for women with recurrent ovarian cancer that is resistant to platinum-containing chemotherapy. The EU approval was based on results of the phase III AURELIA study which involved women with recurrent, platinum-resistant ovarian cancer who received either chemotherapy or Avastin in combination with chemotherapy.

4.3. Mylan launches capecitabine tablets in US market Aug 12, 2014

- Mylan Inc., a global pharmaceutical company committed to setting new standards in health care, has launched capecitabine tablets USP, 150 mg and 500 mg, the generic version of Genentech's Xeloda tablets. Mylan received final approval from the US Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated as monotherapy, adjuvant therapy and combination therapy for certain types of breast, colon and colorectal cancers.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Eli Lilly's ixekizumab superior to etanercept and placebo in phase 3 psoriasis study Aug 22, 2014

- Eli Lilly and Company's investigational medicine ixekizumab was statistically superior to etanercept and placebo on all skin clearance measures in phase 3 studies, the company said in disclosing top-line results from its pivotal UNCOVER studies in moderate-to-severe plaque psoriasis. "These data are important for people suffering from moderate-to-severe plaque psoriasis, as up to 41 percent of those treated with ixekizumab were able to achieve clear skin at week 12, with just one injection per dose.

5.2. Baxter's phase 3 study of BAX 855 meets primary endpoint Aug 23, 2014

- Baxter International Inc., a global, diversified healthcare company, announced positive results from its phase 3 pivotal clinical trial of BAX 855, an investigational, extended half-life recombinant factor VIII (rFVIII) treatment for haemophilia A based on ADVATE [Antihemophilic Factor (Recombinant)], which met its primary endpoint in reducing annualized bleed rates (ABR) in the prophylaxis arm compared to the on-demand arm. The positive results of the BAX 855 study reflect ongoing, long-term commitment to drive innovation and expand treatment options for patients with haemophilia.

5.3. Apex committee on clinical trials gives clearance to 9 new trial proposals Aug 27, 2014

- The apex committee on clinical trials, constituted by the Union health ministry has cleared 9 new clinical trial proposals, 5 proposals of global clinical trials (GCTs) and 4 in other areas. These trials were earlier approved by new drug advisory committees (NDACs) and thereafter the technical committee. As per the direction of the Supreme Court made in its order April 21, 2014, the proposals of global clinical trials/clinical trials of NCEs are required to be evaluated with regard to three parameters like the assessment of risk versus benefit to the patients; innovation vis-à-vis existing therapeutic option; and unmet medical need in the country.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Pfizer to buy Baxter's portfolio of marketed vaccines for $635 million Aug 01, 2014

- Pfizer has entered into a definitive agreement to acquire Baxter International Inc.'s portfolio of marketed vaccines for $635 million. As part of the transaction, Pfizer will also acquire a portion of Baxter's facility in Orth, Austria, where these vaccines are manufactured. Baxter's portfolio of marketed vaccines consists of NeisVac-C and FSME-IMMUN/TicoVac. NeisVac-C is a vaccine that helps protect against meningitis caused by group C meningococcal meningitis (MenC).

6.2. Roche to buy Denmark-based biotech firm Santaris Pharma for US$ 450 mn Aug 05, 2014

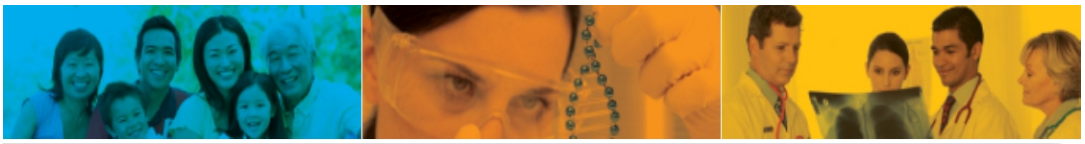
- Roche has agreed to acquire Santaris Pharma, a privately held bio-pharmaceutical company based near Copenhagen, Denmark. Santaris Pharma has pioneered its proprietary Locked Nucleic Acid (LNA) platform that has contributed to an emerging era of RNA-targeting therapeutics. “The acquisition combines Santaris Pharma's next-generation antisense technology and LNA expertise with Roche's deep experience in disease biology, chemistry, drug safety, drug formulation, delivery, and development.”

6.3. Sanofi ties up with Emcure Pharma to market oncology portfolio in India Aug 06, 2014

- Sanofi has entered into a marketing and distribution agreement with Emcure Pharmaceuticals for its oncology portfolio in India. As per the agreement, while Sanofi will continue to own its oncology range comprising 4 brands namely Taxotere, Jevtana, Fludara and Fasturtec. Emcure will market and distribute these brands through its specialty unit.

6.4. Roche to acquire US biotech company, InterMune for US$ 8.3 billion Aug 26, 2014

- Roche, a leader in research-focused healthcare and biotechnology company, InterMune have entered into a definitive merger agreement for Roche to fully acquire InterMune at a price of US$ 74.00 per share in an all-cash transaction. The merger agreement has been approved by the boards of InterMune and Roche. Under the terms of the merger agreement, Roche will commence a tender offer no later than 29 August 2014, to acquire all outstanding shares of InterMune common stock.



LAMBDA

TECHNOLOGY NEWS

7.1. PET-CT may help in detecting infection in patients with acute pancreatitis Aug 06, 2014

- A new study diagnosing infection in patients with pancreatic fluid collections may swiftly and accurately rule out active infection in the body. In the study, Leucocytes were separated from the patient's venous blood, labeled with 18F-fluorodeoxyglucose (FDG) and re-injected intravenously, followed by PET/CT imaging two hours later. A final diagnosis of infection was based on microbiological culture of fluid aspirated from the collection. Patients were managed with supportive care and antibiotics; percutaneous drainage/laparotomy were performed when indicated.

7.2. New digital x-ray imaging delivers results in 5 seconds Aug 08, 2014

- Wanting to replace the medical equipment for taking X-rays, the Mexican Society of Radiology (CMR) created a system of digital x-ray imaging, which replaces the traditional plaque by a solid detector, which delivers results in five seconds. Analog equipment take six minutes to develop the traditional film. The system called ARiX RAD obtains X-ray images that aid in the diagnosis of various diseases, like identifying bone fractures, kidney stones or tumors.