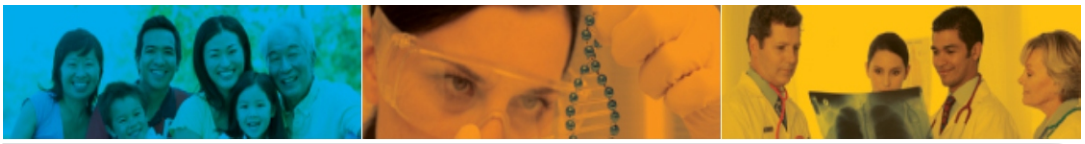

Clinical Research Newsletter Volume - 08, August 2013

LAMBDA

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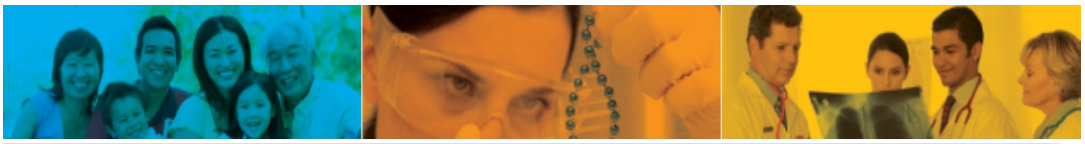
Contact Us

Dr. Mrinal Kammili, Director Global Head - BD
mrinal@lambda-cro.com

Dr. Manish Sharma, AVP, Medical Affairs
manishsharma@lambda-cro.com



LAMBDA

BIOANALYTICAL METHOD - LAMBDA SPOTLIGHT

A Developed Method for the Quantification of Telaprevir in Human Plasma

Telaprevir	PRECISION & ACCURACY			
	LOQ QC	LQC	MQC	HQC
Method Summary - Rapid LLE - 250 µL Plasma - 2.50 ng/mL LLOQ - Run Time: 6.2 mins - No Carry Over	2.5442	7.1261	737.0932	1142.6014
	± 0.09009	± 0.26584	± 11.83593	± 25.57320
	3.5% CV	3.7 % CV	1.6%CV	2.2% CV
	98.9% THR	95.6% THR	97.8 % THR	98.6% THR
	n=18	n=18	n=18	n=18

GLOBAL NEWS

2.1. South Africa's pharmaceutical market is one of the most attractive markets in Africa Jul 10, 2013

- As per new report, "Emerging Pharmaceutical Market in South Africa - Proposed Introduction of New Drug Regulatory Agency (SAHPRA) to Accelerate Drug Registration Process" revealed South Africa's pharmaceutical market is one of the most attractive markets in Africa and some of the main reasons are availability of cost-effective and skilled labor, high quality infrastructure, and the introduction of the South African Health Products Regulatory Authority (SAHPRA).
- The report valued the South African pharmaceutical market at $3.8 billion in 2011, and expects it to reach $7 billion in 2018 at a Compound Annual Growth Rate (CAGR) of 9.2%. It also shows that generics accounted for over 60% of the volume of the pharmaceutical market in 2011.

2.2. Ranbaxy drugs safe says Australian drug regulator Jul 03, 2013

- Just after the UK drug regulator (MHRA) clarification on the Ranbaxy issue, the Australian drug regulator (TGA) has also said that the drugs marketed by Ranbaxy Labs are safe. As stated by the TGA authorities, so far there has been no evidence of any products in the Australian market manufactured by Ranbaxy to be of unacceptable quality or that it can cause danger to consumers in Australia.

2.3. GlaxoSmithKline launches Eno digestive antacid in tablet, liquid forms Jul 04, 2013

- UK-based GlaxoSmithKline's consumer healthcare unit has launched its Eno brand in chewy tablet and liquid forms to expand offering in digestive antacid market in India. With the transition from powder form into tablet, liquid forms, Eno will now compete with brands such as Abott's Digene, Pfizer's Gelusil and Piramal's Polycrol Gel. The competitor brands are sold as tablets and syrups.

2.4. Mylan Launches Generic Version of Viagra in 11 European Countries Jul 08, 2013

- Mylan Inc. announced that it has launched Sildenafil Citrate Tablets, 25 mg, 50 mg, and 100 mg in France, the United Kingdom, Ireland, Italy, Belgium, Slovakia, Germany, Denmark, Czech Republic, Spain, and the Netherlands.
- Mylan has received marketing authorization from each country's respective health authority to begin selling its product immediately.

2.5. Sanofi to launch first dengue vaccine this year Jul 22, 2013

- Sanofi Pasteur is in the process of finalizing tests for its first vaccine against dengue in Africa and Asia. The company has announced that it plans to start production of the vaccine by the end of the year.
- Dengue, which is a mosquito-borne disease, affects about 100 million people every year worldwide and if the first dengue vaccine is approved for release, it could be avaibale in the market in 2015.

DOMESTIC NEWS

3.1. Indian Government approves 50 clinical trials Jul 03, 2013

- Six months after the Supreme Court banned clinical trials for new chemical entities (or molecules) unless these were personally vetted and cleared by the Union health secretary, the health ministry's apex committee on clinical trials approved 50 clinical trials in a move that will bring some relief to an industry that is worth $500 million in revenue and employs around 15,000 people.

3.2. IPC to add another 150 ADR centres by 2014 end to strengthen PvPI programme Jul 04, 2013

- Indian Pharmacopoeia Commission (IPC) will be adding 150 new Adverse Drug Reaction (ADR) monitoring centres across the country by end of 2014 in order to further strengthen the Pharmacovigilance Programme of India (PvPI).
- Through this initiative, IPC which acts as the National Coordinating Centre (NCC) for PvPI, plans to make the Indian pharmacovigilance programme as one of the most established and elaborate programmes in the world.

3.3. DTAB recommends no compensation if drug under CT fails to deliver desired results

Jul 05, 2013

- A person undergoing clinical trial would not become eligible for financial compensation just because a new investigational potential drug fails to deliver the desired results, the Drug Technical Advisory Board, the apex decision-making body on drugs safety has recommended in a recent meeting.
- It has also suggested, that if the subject is put under a placebo in a clinical trial, but is not taken off his standard medical regimen, he cannot claim financial compensation for an adverse event.

3.4. Govt. to further modify rule on timeline, compensation for injury during clinical trials Jul 11, 2013

- The Centre is planning to further modify the newly added clause 122 DAB of the Drugs and Cosmetic (D&C) Rules, 1945 to further relax the norms on compensation in the case of injury or death during the clinical trials. The timeline for reporting the serious adverse events will also be modified in line with the international practices.

3.5. Nearly 500 ethics committees registered after CDSCO made it mandatory in Feb, 2013

Jul 15, 2013

- Evoking a very good response to the steps by the regulatory authorities to streamline the clinical trials sector, nearly 500 ethics committees of hospitals and clinical trial organisations have secured registration within just five months since it was made mandatory.
- Leading hospitals from all across the country, both from the public and private sectors, were among those applied and got the institutional ethics committees registered for trials after the Government had recently tightened the norms for trials through various steps.

3.6. Indian Pharma cos secure final approval for 87 ANDAs from US FDA in Jan-June 2013

Jul 19, 2013

- Indian pharmaceutical companies and their subsidiaries maintained the momentum in respect of securing ANDA approvals from USFDA during the first half ended June 2013. These companies received 87 final approvals for ANDAs as well as 25 tentative approvals.
- The total number of ANDAs approved by US FDA during the first half stood at 211 and total tentative approvals are 47.

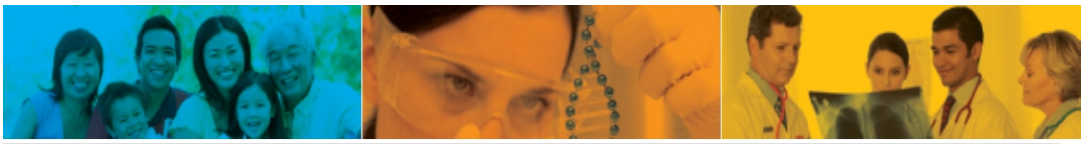
3.7. Dr. Reddy's working on six innovative drugs in clinical development stage Jul 22, 2013

- Dr. Reddy's had 21 active products in the proprietary products pipeline, out of which six are in clinical development stage.
- The medicines which are presently in the clinical development stage are targeted in areas including migraine, anti-infective atopic dermatitis/psoriasis, cardiovascular disorders, psoriasis and pain. The new drug research on metabolic disorders/cardiovascular disorders is in phase II and the remaining five medicines are in clinical stage.

REGULATORY NEWS

4.1. FDA report casts doubt on Chinese Trial Data Jul 15, 2013

- FDA found irregularities, fraudulent data, and unreported adverse events in a Chinese trial of Eliquis, a drug designed to prevent strokes in patients with atrial fibrillation. The errors held up the drug's approval for 9 months, according to the agency, requiring all three companies to correct mistakes and resubmit data to the FDA.



DRUG APPROVALS AND LAUNCHES

5.1. EU committee recommends approval of Roche's subcutaneous Herceptin Jul 01, 2013

- European Union's Committee for Medicinal Products for Human Use (CHMP) has today recommended EU approval of a subcutaneous formulation of Herceptin® (trastuzumab) for the treatment of patients with HER2-positive breast cancer.
- At present, Herceptin is given to patients intravenously, which takes 30 to 90 minutes per dose. By contrast, the new subcutaneous formulation of Herceptin can be administered in two to five minutes by a simple injection under the skin.
- Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche.

5.2. Novartis' Lucentis gets its fourth approval in EU Jul 05, 2013

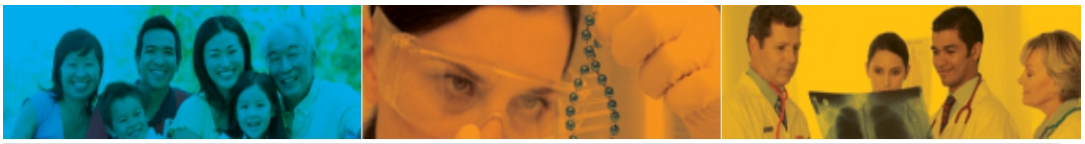
- Novartis' eye drug Lucentis has gained a new edge in its battle for market share with Regeneron's Eylea. Lucentis has been granted approval in Europe for a new indication, its fourth there.
- The company said that the EU has approved Lucentis for treatment of sight problems caused by choroidal neovascularization (CNV) secondary to pathologic myopia (myopic CNV). The condition often strikes people under the age of 50, and 9 out of 10 times it will lead to severe vision loss within 5 years if not treated.

5.3. SIMPONI ARIA (golimumab) for infusion Receives FDA Approval Jul 22, 2013

- Janssen Biotech, Inc. announced the USFDA approval of SIMPONI ARIA (golimumab) for infusion for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate.
- SIMPONI ARIA, the only fully-human anti-tumor necrosis factor (TNF)-alpha infusible therapy, has been shown to significantly improve signs and symptoms and physical function, and inhibit the progression of structural damage.

5.4. Dr. Reddy's introduces Alzheimer's drug Aricept generic equivalent in US Jul 29, 2013

- Dr. Reddy's Laboratories, an India-based pharmaceutical company, has introduced Donepezil Hydrochloride tablets 23mg in the US on 26 July 2013. The launch follows the approval of an abbreviated new drug application (ANDA) for the drug by the US Food and Drug Administration (USFDA).
- Donepezil Hydrochloride, a therapeutic equivalent generic version of Aricept, is indicated for the treatment of Alzheimer's disease.



MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. AstraZeneca takes over Pearl Therapeutics Jul 01, 2013

- AstraZeneca, a biopharmaceutical business focused on the discovery, development and commercialisation of prescription medicines, has announced the completion of its acquisition of the California-based privately held Pearl Therapeutics.
- The completion of the transaction involved AstraZeneca to acquire 100% of Pearl's shares and provides access to PT003, a probable new treatment for chronic obstructive pulmonary disease (COPD), and inhaler and formulation technology that provides a platform for future combination products.

6.2. Cipla completes acquisition of Cipla Medpro South Africa Jul 17, 2013

- Indian based pharmaceutical company Cipla has completed the acquisition of Cipla Medpro South Africa. In a filing to the exchanges, Cipla said that it has completed the $512 million takeover deal and acquired 100% of the shares issued by Medpro.
- Majority of Cipla Medpro's drugs were supplied by Cipla even though the company had never owned a stake in Medpro. Post this acquisition, the Indian drug-maker hopes to strengthen its African operations.