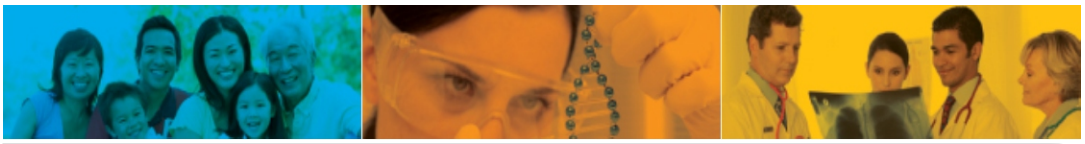


Clinical Research Update Volume - 02, February 2013

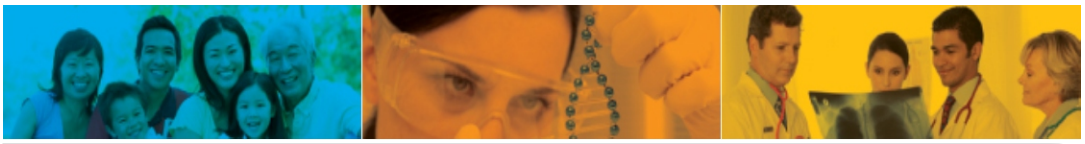
LAMBDA

CONTENTS

Contact Us

Dr. Mrinal Kammili, Sr. VP, Business Development
mrinal@lambda-cro.com

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



LAMBDA

GLOBAL NEWS

1.1. First TB drug in 40 years approved in the USA Jan 02, 2013

- Regulators in the USA have granted accelerated approval of the first new tuberculosis treatment in 40 years, with the thumbs up to Janssen's Sirturo.
- The drug, which will treat pulmonary multi-drug resistant tuberculosis as part of combination therapy in adults, was granted accelerated approval by the US Food and Drug Administration based on the surrogate endpoint of time to sputum culture conversion from two Phase II trials.

1.2. New Technique to predict Drug Adverse Events without Clinical Trials Jan 04, 2013

- A team of Japanese and French scientists developed a new technique to predict the adverse events of drugs before the drug reach the market.
- The technique is based on several extensions of Kernel regression models that calculate the target protein and drug molecule interactions in biological space and its associated adverse events. The technique can save a lot of time and money of drug manufacturer and the patient from adverse events.

1.3. 39 drugs approved in the USA in 2012 Jan 04, 2013

- US Drug approvals in 2012 have reached a 15-year high with regulators giving the thumbs up to 39 new drugs.
- The figures from the US Food and Drug Administration show approved drugs were up on 2011, when 30 new medicines were given marketing authorisations. Of the 39 approved in 2012, 11 were for cancer treatments and almost 20 were designated orphan drug status.

1.4. South Korea will be biosimilars leader by 2020 Jan 08, 2013

- Since South Korea introduced a regulatory pathway for manufacturing biologics in 2009, the government has raised its stakes in the biosimilars market. It is providing both financial and institutional support to help the market emerge as a global leader by 2020.
- The market is expected to witness substantial growth during 2013-16, when new products and segments will be launched. Frost & Sullivan estimates the market to earn revenues $89.8 million in 2017, with erythropoietin being the biggest revenue generator.

DOMESTIC NEWS

2.1. India Group wants Change in Clinical Trial Regulations for Children Jan 02, 2013

- India's clinical trial regulations (or lack thereof) have long been the subject of international debate, and now the country's National Commission for Protection of Child Rights (NCPCR) is looking to enact standardized rules for trials on children, saying many are subjected to studies without their parents being made aware.

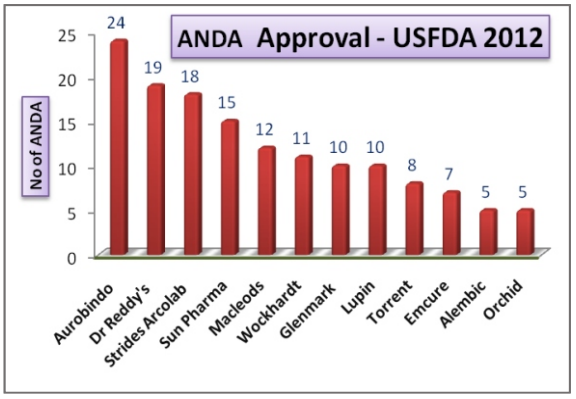
2.2. Indian Pharma Companies secure 178 ANDA Approvals from US FDA in 2012

Jan 08, 2013

- The Indian companies have received higher number of US FDA approvals for 178 ANDAs during 2012 as compared to 144 in the previous year despite stringent approval norms.
- The US FDA granted total 476 ANDAs approvals during the year 2012 as against 431 approvals in the previous year. Of these total US FDA approvals, Indian companies grabbed 37.4 % approvals in 2012 as against 33.4 % in the last year. The total number of tentative approvals stood at 94 during 2012 as compared to 117 in the previous year.

2.3 DCGI takes tougher stand on FDCs; asks Manufacturers to prove Efficacy and Safety

Jan 18, 2013



- The drug authorities have asked the manufacturers to prove the safety and efficacy of the FDCs approved before October 1, 2012 and made it clear that those FDCs approved by the State licencing authorities from October without the permission of the DCGI will be considered for ban.
- DCGI has directed the State drug controllers to ask the concerned manufacturers to prove the safety and efficacy within 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

REGULATORY UPDATES

3.1. US FDA issues Guidance for Clinical Site Data for Inspection of New Drug Applications

Jan 02, 2013

- US FDA has issued specifications to prepare and submit summary level clinical site dataset in electronic form for new drug applications (NDAs), biologics licensing applications (BLAs), and NDA or BLA supplemental applications submitted to the Centre for Drug Evaluation and Research (CDER).
- In this regard, the regulatory authority has called to submit a single summary level clinical site dataset that contains data from all major studies used to support safety and efficacy in the application, including studies with different treatment indications.

DRUG APPROVALS AND LAUNCHES

4.1. Mylan's partner Famy Care receives FDA approval for Contraceptive Drug

Jan 04, 2013

- Mylan Inc., a generic pharmaceutical company, has announced that its partner Famy Care Ltd. has received final approval from the FDA for its abbreviated new drug application, or ANDA, for Levonorgestrel and Ethinyl Estradiol tablets USP, 0.15mg/0.03mg.

4.2. Janssen Therapeutics receives FDA approval for MDR-TB Treatment Jan 07, 2013

- Janssen Therapeutics, has received FDA accelerated approval to SIRTURO tablets for the treatment of pulmonary multi-drug resistant tuberculosis, or MDR-TB, as part of combination therapy in adults. The accelerated approval is based on the surrogate endpoint of time to sputum culture conversion.

4.3. BOTOX wins FDA Approval for Treatment of Overactive Bladder for Adults Jan 18, 2013

- Allergan, Inc. announced that the U.S. FDA has approved BOTOX (onabotulinumtoxinA) for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

4.4. EU approves Novo diabetes drugs Tresiba and Ryzodeq Jan 22, 2013

- European regulators gave the green light to Tresiba and Ryzodeg, of Novo Nordisk. The European Commission has granted marketing authorisations for Tresiba (insulin degludec) and Ryzodeg (insulin degludec/insulin aspart) for the treatment of diabetes in adults. Tresiba is a once-daily new-generation basal insulin analogue with an ultra-long duration of action.

4.5. FDA approves Gleevec for children with Acute Lymphoblastic Leukemia Jan 28, 2013

- The U.S. FDA approved a new use of Gleevec (imatinib) to treat children newly diagnosed with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL).
- ALL is the most common type of pediatric cancer, affecting approximately 2,900 children annually, and progresses quickly if untreated.

DRUGS IN DEVELOPMENT

5.1. Biocon gets DCGI nod for Psoriasis drug Itolizumab Jan 09, 2013

- Biocon received marketing authorization from the Drugs Controller General of India (DCGI) for its novel biologic Itolizumab, which is an anti-CD6 molecule used for the treatment of chronic plaque psoriasis.

5.2. Oramed submits U.S. IND for Oral Insulin Phase II Jan 09, 2013

- Oramed Pharmaceuticals has moved onto the next stage of development of its oral insulin, ORMD-0801, with an IND submission to begin a Phase II clinical trial in the U.S. in 147 people with Type 2 diabetes.
- Oramed's oral formulations, delivered in enteric-coated capsules, protect peptides and proteins from digestion and help them to pass across the gut wall into the bloodstream.
- ORMD-0801 could also have potential in Type 1 diabetes, improving blood glucose control and cutting the number of daily insulin injections.

5.3. Clinical Trials for Onco Therapy's cancer vaccine approved in S. Korea Jan 28, 2013

- Onco Therapy Science Inc. has obtained South Korea's approval for clinical trials on its vaccine against stomach cancer to be conducted there.
- The cancer research firm said the vaccine, whose clinical tests have been approved by the Korean Food and Drug Administration, is currently undergoing similar trials in Japan and Singapore.

5.4. Teva's Phase III Depression Trial fails to meet Endpoints Jan 28, 2013

- Teva Pharmaceutical Industries Ltd., has announced results of its Phase III clinical program for armodafinil as adjunct therapy in adults with major depression associated with bipolar 1 disorder.

5.5. Mesoblast receives FDA clearance for Phase II trial of Arthritis Treatment Jan 31, 2013

- Teva Pharmaceutical Industries Ltd., has announced results of its Phase III clinical program for armodafinil as adjunct therapy in adults with major depression associated with bipolar 1 disorder.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Parexel acquires Liquent Jan 02, 2013

- Parexel International has acquired all of the outstanding equity securities of Liquent, a global provider of Regulatory Information Management (RIM) solutions. Liquent provides an integrated platform of software solutions for regulatory submissions and product registration management, as well as a range of complementary business process outsourcing capabilities.

6.2. Glenmark signs Agreement with Forest Labs Jan 04, 2013

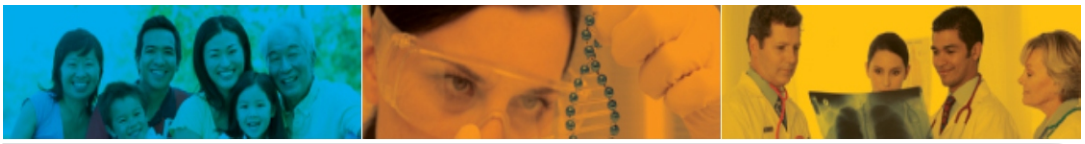
- Glenmark Pharmaceuticals, a leading Indian multinational pharmaceutical company, has entered into a collaboration agreement with Forest Laboratories, an international healthcare leader, for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain.

6.3. GVK Bio & US-based Onconova partner to advance new drugs for Cancer Jan 09, 2013

- GVK Bio, and Onconova Therapeutics, a US based biopharmaceutical company primarily focused on discovery and development of novel small molecules for oncology, have entered into a novel joint partnership to develop new drugs for cancer.
- The joint partnership will be based in the US and will align research priorities and technological expertise from both companies to facilitate moving certain Onconova oncology assets from early discovery to clinical development stage.

6.4. Watson Pharmaceuticals now becames Actavis Jan 25, 2013

- Watson Pharmaceuticals, Inc. has adopted Actavis, Inc., as its new global name and begin trading under a new symbol - ACT - on the New York Stock Exchange. The company first announced its intention to change its name last year, following its acquisition of the Actavis Group. The combination created the world's third largest generic pharmaceutical company, with anticipated pro forma combined 2012 revenues in excess of $8 billion.



LAMBDA

LAMBDA CAPABILITIES

Early Phase Trials

- One of the best State-of-the-art facilities with global access to more than 640 clinical beds
- Excellent scientific expertise with capabilities for handling challenging studies
- Excellent recruitment & housing options customizable to sponsor / study requirements
- > 50 Global inspections by all leading regulatory agencies from across the world

Bioanalytical

- Experienced Team comprised of more than 100 research professionals and more than 50% professionals having immense experience ranging from 5 to 19 years
- Global Presence having GLP certified Bioanalytical labs in India, Canada and UK
- Capability to analyze more than 70,000 samples per month on 43 LC-MS
- Develop 7-8 new methods/month with expertise in different matrix handling such as plasma, serum, urine, whole blood, milk, food, bone, stool and animal tissues

Phase II - IV Clinical Trials

- Global presence with capabilities in Indian subcontinent, Europe, and North America
- Immensely experienced global team with full life cycle Clinical Trial Managemen
- Huge investigator database for highly competitive recruitment potential in all therapeutic areas
- Data submitted to all Leading Agencies: US FDA, EMA, DCGI, ANVISA

PharmacoVigilance

- Robust and Compliant Systems and Processes
- PvNET an advanced software solution that offers complex data analysis and querying of safety data sets, proactively meeting all risk management requirements, while ensuring global regulatory compliance
- A total of 11 successful PV regulatory inspections in last three years
- End-to-End pharmacovigilance services for 4000+ authorizations globally

Medical Imaging

- End-to-End Imaging Review Services for extensive range of therapeutic categories
- Cent-Re-View - A 21 CFR Part 11 compliant Central Imaging Review Platform for performing central independent review in all therapeutic segments
- Web-based Image upload from sites anywhere across the globe in compliance of HIPAA & local regulations
- One of the quickest turnaround time in the industry for Application customization & real-time reviews

Clinical Data Management (CDM)

- Accurate, accessible, and reproducible high quality data
- State-of-the-art technologies compliant with regulatory requirements includes Clintrial®, BizNet®, MedDRA®, WinNonlin® / Phoenix®, SAS®, WHO-DD systems
- BizNet®- Excellent regulatory complaint eCRF / EDC platform for paperless execution & efficient execution of projects
- Highly skilled team of data managers, biostatistician and statistical programmers with extensive experience for various regulatory submissions