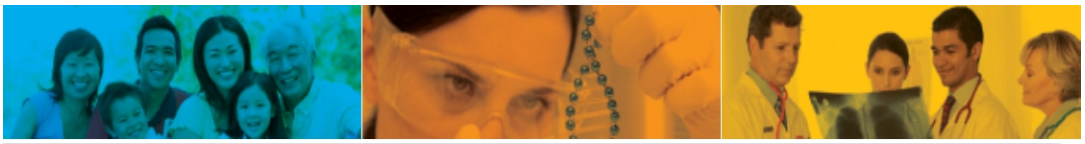

Clinical Research Newsletter Volume - 6, June 2014

LAMBDA

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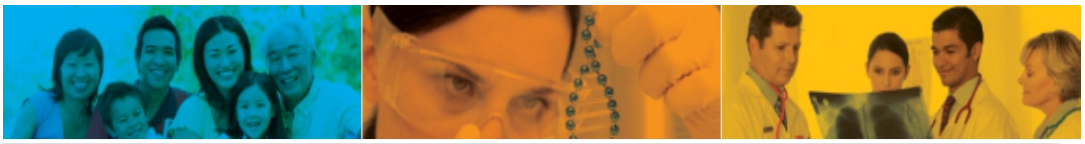
Contact Us

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

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



LAMBDA

GLOBAL NEWS

1.1. Bayer inaugurates its second research incubator in Berlin May 14, 2014

- Bayer HealthCare has officially inaugurated its second research incubator for young life sciences companies at its Berlin location, dubbed 'CoLaborator'. The aim of the global CoLaborator concept is to offer young companies in the area of chemistry and biosciences ready-to-use laboratory and office infrastructure in the immediate vicinity of Bayer's own research facilities. In this way, the 'CoLaborator' creates an ideal environment in which to advance research and innovation.

1.2. ImaginAb launches Japanese subsidiary May 22, 2014

- Los Angeles-based ImaginAb, focused on antibody technology for in vivo imaging, has launched ImaginAb Japan. ImaginAb Japan, headquartered in Tokyo, has been established to better meet the commercial needs of several significant clinical development and partnering opportunities for the company.

DOMESTIC NEWS

2.1. Health ministry issues draft formula for compensation in trial related injury May 01, 2014

- The Union health ministry has issued the draft formula to determine the quantum of compensation in case of clinical trial related injury (other than death) as per which the quantum of compensation in case of 100% disability should be 80 per cent of the compensation which would have been due for payment to the nominees in case of death of the subject. The quantum for less than 100% disability will be proportional to the actual percentage disability the subject has suffered.
- In case of birth defect leading to no death but deformity which can be fully corrected through appropriate intervention, and permanent disability (mental or physical) to any child, the medical management as long as required should be provided by the sponsor or his representative which will be over and above the financial compensation.

2.2. HSI applauds DCGI's decision regarding modern non-animal alternatives May 07, 2014

- Humane Society International (HSI) India expressed relief and hopes over the Drugs Controller General of India (DCGI) decision to contemplate over possibilities of replacing drug testing on animals with alternative no animal testing methods. It is understood that the Central Drugs Control Organisation (CDSCO) is giving serious thought on modernising India's pharmaceutical safety assessment by replacing old-fashioned animal testing with modern non-animal alternatives.

2.3. Health ministry amends D&C Rules to fix responsibilities May 12, 2014

- The Union health ministry has amended the Drugs and Cosmetics Rules, 1945 under which the ministry has fixed the responsibilities of sponsors, investigators and the ethics committees (EC) in clinical trials. As per the amendment, in Schedule Y of the Drugs and Cosmetics Rules, 1945, in

paragraph 2 relating to 'Clinical Trial', in sub-paragraph (2), relating to responsibilities of Sponsor, for clause (iv), the clause shall be substituted, by "(iv) Any report of the serious adverse event, after due analysis shall be forwarded by the sponsor to the Licensing Authority as referred to in clause (b) of rule 21, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen calendar days of the occurrence of the serious adverse event."

2.4. International patients storm into India for cancer care May 15, 2014

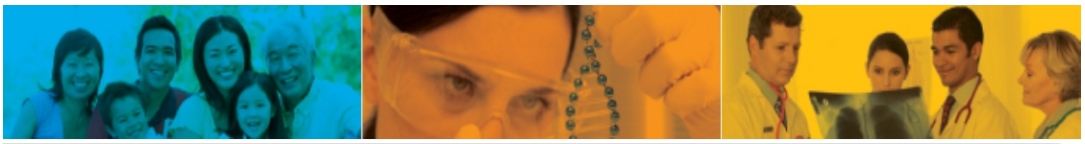
- International patients are accessing Indian medical centres for cancer care driven by the positive outcome from oncologists expertise followed by dependable access to technology at a reasonable cost. From HCG to Apollo Hospital Group, Fortis, Medanta-The Medicity, Max Healthcare Artemis Hospital, Tata Memorial Cancer Centre, Mazumdar-Shaw Cancer Centre, to name a few are a hot bed for international patients to access treatment for cancer and related complicated and chronic conditions. These hospitals are accredited by international agencies and recognised by patients and are offering world-class care.
- According to Dr B S Ajaikumar, founder, chairman, HCG Enterprise, foreign patients usually say that it is an Indian oncologist at the hospitals in the US and UK seen to have the expertise. This led many such patients to come to India for the treatment. In fact, the patient care for cancer in India is on par and can be accessed at one-tenth the cost.

2.5. Apex panel on clinical trials gives nod to 21 fresh proposals May 20, 2014

- The apex committee set up by the Union health ministry to monitor the clinical trials sector and headed by the health secretary has cleared 21 out of the 22 fresh proposals for clinical trials, after they were recommended by new drug advisory committees and thereafter the technical committee, another high-level panel formed by the ministry.
- In a recent meeting of the apex committee, 22 applications were taken for ratification after the clearance by the technical panel and the panel evaluated the cases in view of risk versus benefit to the patients, innovation vis-à-vis exiting therapeutic option and unmet medical need in the country. The committee then ratified the recommendations by the technical committee in this regard.

2.6. CDSCO in the process of constituting 38 more new drug advisory committees May 26, 2014

- With a view to further beef up the process of approvals to clinical trials, the health ministry has begun the process of increasing the number of new drug advisory committees (NDACs) from the current 12 to 50. The Central Drugs Standard Control Organization (CDSCO) has already in principle finalized the composition of the new NDACs. The members for the new panels have already been contacted and many of them had given consents verbally and through mails.
- Following the recommendations by the Parliamentary committee on the functioning of the regulatory mechanism and under pressure from the judiciary, the Health Ministry had formed 12 NDACs to advise on matters related to review and regulatory approval of clinical trials and new drugs (except for Investigational New Drugs).



LAMBDA

DRUG APPROVALS AND LAUNCHES

3.1. US FDA approves Novartis' Zykadia for NSCLC — May 02, 2014

- The US Food and Drug Administration (FDA) has approved Novartis' Zykadia (ceritinib, previously known as LDK378) for the treatment of patients with anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. The approval of Zykadia addresses an unmet medical need for patients with this type of lung cancer who have progressed on prior therapy.

3.2. US FDA approves Merck's Zontivity — May 10, 2014

- The US Food and Drug Administration (FDA) approved Zontivity (vorapaxar) tablets to reduce the risk of heart attack, stroke, cardiovascular death, and need for procedures to restore the blood flow to the heart in patients with a previous heart attack or blockages in the arteries to the legs.
- Zontivity is the first in a new class of drug, called a protease-activated receptor-1 (PAR-1) antagonist. It is an anti-platelet agent, designed to decrease the tendency of platelets to clump together to form a blood clot. By decreasing the formation of blood clots, Zontivity decreases the risk of heart attack and stroke.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

4.1. Novartis phase III study Ultibro shows superior efficacy — May 02, 2014

- Novartis announced positive first results from the phase III head-to-head LANTERN study, which showed the superiority of once-daily Ultibro Breezhaler (indacaterol/ glycopyrronium) 110/50 mcg in improving lung function compared to twice-daily Seretide Accuhaler (salmeterol/fluticasone (SFC) 50/500 mcg in COPD patients with or without a history of moderate-to-severe exacerbations in the previous year. Ultibro Breezhaler met both the primary and key secondary objectives.

4.2. GSK begins phase III programme for mepolizumab — May 02, 2014

- GlaxoSmithKline plc has started a phase III programme to evaluate the efficacy and safety of mepolizumab as an adjunctive therapy for adults who have severe chronic obstructive pulmonary disease (COPD). The programme will enrol approximately 1500 patients who are at high risk of COPD exacerbations despite the use of standard background therapy.

4.3. Zydus begins phase III trial of its breakthrough drug Lipaglyn — May 29, 2014

- With a view to explore new therapeutic usage of its breakthrough drug Lipaglyn (saroglitazar), the Zydus Group has commenced phase III trials of the molecule for patients suffering from lipodystrophy. The goal of this trial is to evaluate the safety and efficacy of Lipaglyn 4 mg versus standard-of-care with placebo in the treatment of lipodystrophy. Patients with lipodystrophy suffer from metabolic disorders including lipid disorder and insulin resistance that leads to diabetes. These disorders can also increase the risk for other problems such as heart or liver disease.

MERGER, ACQUISITIONS AND SETTLEMENTS

5.1. AstraZeneca board rejects Pfizer proposal May 02, 2014

- The Board of AstraZeneca Plc has rejected Pfizer's fresh proposal which raised an indicative value of £50 ($84.47) per AstraZeneca share, as against earlier offer of £46.61 ($76.62). The financial and other terms described in the Proposal are inadequate, substantially undervalue AstraZeneca and are not a basis on which to engage with Pfizer. The large proportion of the consideration payable in Pfizer shares and the tax-driven inversion structure remain unchanged. Accordingly, the Board has rejected the Proposal.

5.2. ICON completes acquisition of Aptiv Solutions May 10, 2014

- ICON plc, a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, has completed the previously announced acquisition of Aptiv Solutions.
- Aptiv Solutions is a recognised leader in the design and execution of adaptive clinical trials for pharmaceutical and biotech customers. The company also has in-depth experience in the management of medical device trials and its Japanese subsidiary, Niphix, is a full-service, oncology-focused CRO serving both Japanese and international customers.

5.3. Cipla to acquires 14.6% stake in US based Chase Pharmaceuticals May 12, 2014

- Cipla Ltd, a Rs. 8,000 crore plus fifth largest Indian pharmaceutical company, has signed a definitive agreement to invest US$ 1.5 million to acquire 14.6 per cent stake in Chase Pharmaceuticals Corporation Inc, US through its UK based wholly owned subsidiary Cipla (EU) Ltd. Cipla will make an additional $4.5 million investment in Chase upon achievement of certain milestones.
- Chase is an early stage drug development company developing novel approaches to improve treatments for Alzheimer's disease. It has a unique patented approach and is focused on improving the efficacy, safety and tolerability of existing Alzheimer medications.

5.4. Abbott to buy Latin American company, CFR pharma for $2.9 billion May 19, 2014

- Abbott, a global healthcare company, has entered into a definitive agreement to acquire Latin American pharmaceutical company CFR Pharmaceuticals, more than doubling its Latin American branded generics pharmaceutical presence and further expanding Abbott's presence in fast-growing markets.
- Under the terms of the agreement, Abbott will acquire the holding company that indirectly owns approximately 73 per cent of CFR Pharmaceuticals and will conduct a public cash tender offer for all of the outstanding shares of CFR. Assuming all publicly-held shares are tendered, the total purchase price would be approximately $2.9 billion, plus the assumption of net debt of approximately $430 million.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

6.1. Sun Pharma and Novartis settle litigation for generic Gleevec in US May 15, 2014

- Sun Pharmaceutical Industries' subsidiary has executed a settlement agreement with Novartis Pharmaceuticals Corporation stipulating a dismissal of the lawsuits filed in the United States against the company regarding submission of an ANDA for a generic version of Gleevec, imatinib mesylate tablets. These tablets are indicated for the treatment of chronic myeloid leukaemia.

TECHNOLOGY NEWS

7.1. Parexel launches Perceptive MyTrials Data-Driven Monitoring May 21, 2014

- Parexel International, a global biopharmaceutical services organization, has launched its Perceptive MyTrials Data-Driven Monitoring solution. Developed by Parexel Informatics, it is a key component of the Perceptive MyTrials eClinical platform, an integrated suite of applications for managing clinical trials.