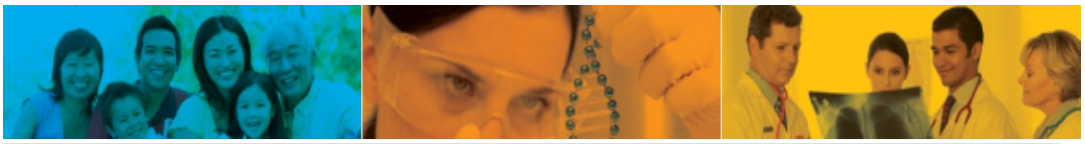

Clinical Research Newsletter Volume - 05, May 2013

LAMBDA

CONTENTS

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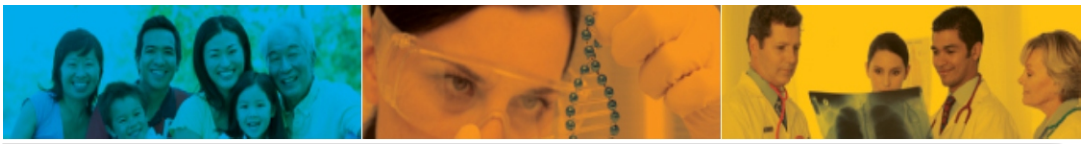

LAMBDA

GLOBAL NEWS

1.1. Perceptive Informatics launches upgraded Impact CTMS solution Apr 05, 2013

- Perceptive Informatics, an eClinical solutions provider, has launched an enhanced version of its comprehensive Impact clinical trial management system (CTMS). Notable features include improved data entry as well as site management and monitoring capabilities.
- The solution is used to plan, track and report on clinical trials and is available as a hosted, software-as-a-service (SaaS) application.

1.2. Ibrutinib receives 3rd Oncology Breakthrough Therapy Designation from US FDA Apr 08, 2013

- Janssen Research & Development announced that US FDA has granted a Third Breakthrough Therapy Designation for the investigational oral Bruton's tyrosine kinase (BTK) inhibitor ibrutinib. It has been granted Breakthrough Therapy Designation as a monotherapy in the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma with deletion of the short arm of chromosome 17 (del17p).
- Ibrutinib is jointly being developed by Janssen and Pharmacyclics Inc.

1.3. Dr. Reddy's to establish R&D Center in New Jersey Apr 10, 2013

- India-based Dr. Reddy's Laboratories is planning to relocate North America headquarters and establish R&D Center in Princeton, New Jersey, US.
- The new North America headquarters will house generic, biologic, PSAI (pharmaceutical services and active ingredients) and proprietary product businesses as well as the corporate support functions within North America.

1.4. Clinical Trial Ethics Are Revised In The Helsinki Declaration Apr 18, 2013

- The World Medical Association has revised various principles found in the Helsinki Declaration on medical research and the revisions include adding protection for vulnerable patient groups, a more systematic approach to using placebos and, for the first time, providing compensation and treatment for study subjects who suffer harm.

DOMESTIC NEWS

2.1. WHO approves India's vaccine regulatory system Apr 10, 2013

- The WHO has approved India's vaccine regulatory system for maintaining international standards and found that the country's vaccine production lines are efficacious and safe and can easily be trusted.
- This step opens the way for easy export of vaccines produced in the country.

2.2. CDSCO to give priority to approval of new drugs having impact on public health Apr 16, 2013

- The Central Drugs Standard Control Organisation (CDSCO) will give the first priority to giving approval of new drugs having direct impact on public health and of special relevance to Indian health scenario.
- Registration of ethics committees, monitoring of clinical trials in the country, examination of reports of serious adverse events occurring during the clinical trials and protecting rights, safety and well-being of the participant subjects in the clinical trials are the other important responsibilities to be carried out on priority basis along with approval of new drugs having impact on public health according to a notice by the DCGI.

2.3. Over 200 ethics committees got registered with DCGI after making it mandatory Apr 23, 2013

- After the authorities made registration of ethics committees mandatory for the clinical trial organisations to conduct trials, over 200 ethics committees secured registration as the Central Drugs Standard Control Organisation (CDSCO) witnessed a flurry of applications.
- The Government had issued the notification on February 8 this year to make it mandatory the registration of ECs and so far, the Drugs Controller General of India (DCGI) has given registration to 214 panels during this brief period.

REGULATORY NEWS

3.1. FDA says no to generic versions of older OxyContin Apr 17, 2013

- The Food and Drug Administration halted plans of some generic drug companies to sell their versions of the brand-name painkiller OxyContin because More than 16,000 people died from overdoses of prescription opioid painkillers in 2010. Applications to sell generic versions were based on the older, non-tamper resistant version of OxyContin, which some abusers have crushed, liquefied, smoked, inhaled or injected in order to get high.
- The newer, crush-resistant version of OxyContin was approved by the FDA. Generic drugs must follow the official label of the brand-name drug, so the FDA said it would not approve generic versions based on the old formulation.

3.2. European Medicines Agency approved 59 new medicines in 2012 Apr 26, 2013

- The European Medicines Agency (EMA) has received a stable number of initial marketing authorisation applications (MAAs) for human medicines, with a total of 96 applications received in 2012.
- The Committee for Medicinal Products for Human Use (CHMP) issued 59 positive opinions for the approval of new medicines, including a positive opinion for the first gene therapy in Europe.

DRUG APPROVALS

4.1. FDA OKs Biogen Idec's Tecfidera as First-Line Oral Treatment for Multiple Sclerosis Apr 01, 2013

- Biogen Idec has announced that the US FDA has approved Tecfidera (dimethyl fumarate), a new first-line oral treatment for people with relapsing forms of multiple sclerosis (MS).
- The biotech drugmaker already sells the once-a-week multiple sclerosis injection Avonex. It also markets the once-a-month injection Tysabri through a partnership with Elan Corp. PLC of Ireland. However, Tysabri's severe side effects have curtailed its use. The twice-a-day capsules, called Tecfidera is designed to be taken orally, offer a new option for multiple sclerosis.

4.2. Mylan Launches First Generic Version of Zovirax Ointment Apr 03, 2013

- Mylan Inc. announced that it received final approval from the US FDA for its Abbreviated New Drug Application for Acyclovir Ointment USP, 5%.
- This product is the first generic version of Valeant International's Zovirax Ointment, which is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous herpes simplex virus infections in immunocompromised patients.

4.3. Dr. Reddy's launches osteoporosis injection in US Apr 04, 2013

- Dr. Reddy's Laboratories (DRL) has launched zoledronic acid injection in the US market following approval by the United States Food & Drug Administration (USFDA).
- The medicine, used to treat osteoporosis in women after menopause, is a therapeutic equivalent generic version of Reclast (zoledronic acid) injection, DRL.

4.4. Sun Pharma gets FDA nod for generic version of Januvia Apr 16, 2013

- Indian drugmaker Sun Pharma received a tentative approval from the US drug regulator for generic version of Januvia. The company noted that Januvia, which is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes, have annual sales of approximately $2.7 billion in the US.

4.5. Cipla launches first Rheumatic drug biosimilar in India Apr 18, 2013

- Cipla launched the first biosimilar of Etanercept in India under the brand name, Etacept, indicated for the treatment of rheumatic disorders. Etacept is manufactured by China-based Shanghai CP Guojian Pharmaceutical and will be marketed in India by Cipla. Clinical efficacy and the safety of the drug have been well established in Indian patients.

4.6. FDA Approves ACTEMRA for Children Living with a Rare Form of Arthritis Apr 30, 2013

- Genentech, a member of the Roche Group announced that the U.S. FDA has approved ACTEMRA (tocilizumab) for the treatment of polyarticular juvenile idiopathic arthritis (PJIA). The medicine can be used in children two years of age and older with active disease.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. ERYTECH Pharma receives USFDA IND Clearance to Initiate a Clinical Study in ALL Apr 03, 2013

- ERYTECH Pharma SA announced that it has received clearance of its Investigational New Drug (IND) Application from the United States Food and Drug Administration (FDA) to initiate a Phase I clinical trial of its product ERYASP, L-asparaginase loaded erythrocytes, in patients 40 years or older with newly diagnosed Acute Lymphoblastic Leukemia (ALL).

5.2. OncoGenex to initiate phase II trial of OGX-427 in Non-Squamous NSCLC Apr 12, 2013

- OncoGenex Pharmaceuticals, plans to initiate an investigator-sponsored, randomized, double-blind, placebo-controlled phase II study, Spruce, evaluating OGX-427 in patients with previously untreated advanced Non-Squamous Non-Small cell lung cancer (NSCLC).
- The trial will investigate whether adding OGX-427 to carboplatin and pemetrexed therapy can extend progression-free survival (PFS) outcomes.

MERGER, ACQUISITIONS AND COLLABORATIONS

6.1. Astrazeneca's Medimmune Biologics Unit Acquires Alphacore Pharma Apr 03, 2013

- AstraZeneca announced that MedImmune, its global biologics research and development unit, has acquired AlphaCore Pharma, an Ann Arbor, Michigan-based biotechnology company focused on the development of ACP-501, a recombinant human lecithin-cholesterol acyltransferase (LCAT) enzyme.

6.2. Pfizer signs deal with Bind Therapeutics Apr 03, 2013

- Pfizer will pay Bind Therapeutics, a US-based clinical-stage biopharmaceutical company, at least US$200m in a global collaboration to develop and commercialise Accurins using small molecule targeted therapies. The collaboration aims to use Bind's Medicinal Nanoengineering technology to impart tissue and cellular targeting capabilities to molecularly targeted drugs.

6.3. Merck, Pfizer to jointly develop investigational Type 2 Diabetes drug Apr 29, 2013

- Merck, referred to as MSD outside the US and Canada, has collaborated with Pfizer for the development and commercialization of an investigational Type 2 Diabetes drug ertugliflozin (PF-04971729). According to the deal, Merck, through a subsidiary, and Pfizer will work on the development and marketing of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and Januvia (sitagliptin) tablets.

6.4. Bayer to acquire Conceptus Apr 29, 2013

- Bayer HealthCare has signed a merger agreement with Conceptus, Calif.-based developer of the Essure procedure, a non-surgical permanent birth control method.
- With this acquisition, Bayer will be able to offer a complete range of short-term, long-term and permanent contraceptive choices for women.