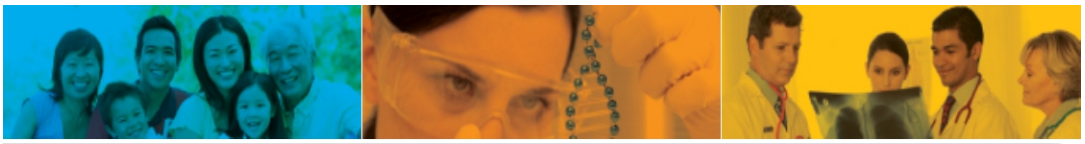

Clinical Research Newsletter Volume - 03, March 2013

LAMBDA

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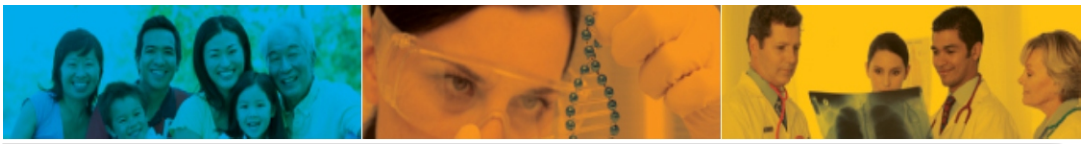


LAMBDA

GLOBAL NEWS

1.1. EU's biggest drug makers team up in €196M discovery effort Feb 07, 2013

- Seven major European drug makers including AstraZeneca, Bayer, Lundbeck, Janssen, Merck KGaA, Sanofi and UCB Pharma-joined with other pharma companies, academics and other collaborators in a €196 million ($262.6 million) project to share and screen hundreds of thousands of compounds.

1.2. Amgen highlights late-stage pipeline, biosimilars in growth plan Feb 07, 2013

- Amgen plans to develop a copycat versions of blockbuster biologics from other pharmas such as Roche's Herceptin, Eli Lilly's Erbitux and AbbVie's best-seller Humira. Between this year and 2016 the biotech company expects to reveal data from 8 late-stage R&D efforts. This year the company aims to unveil Phase III results for talimogene laherparepvec in melanoma and trebananib or AMG 386 for patients with ovarian cancer. Yet the biggest program on tap is Amgen's AMG 145, a PCSK9 drug for lowering cholesterol that the company plans to test in 26,000 patients, with results from four Phase III studies due out in 2014.

1.3. Lentigen receives Orphan Drug status for glioblastoma multiforme Feb 14, 2013

- Lentigen, a biotechnology company specializing in the development and manufacture of lentiviral gene delivery products, announced that the FDA has granted orphan drug status to LG631-CD34, P140K methylguanine methyltransferase (MGMT) transduced human CD34 cells, for bone marrow protection in the treatment of glioblastoma multiforme. The designation qualifies Lentigen for seven years of market exclusivity following marketing approval by the FDA and provides other development-related incentives.

1.4. Roche follows GSK in move to unlock its data vault on drugs Feb 26, 2013

- GlaxoSmithKline encountered some stiff industry headwinds when it pledged to open up its data vault to outside investigators. But as of today it has a high-profile convert on its side. The biopharma giant Roche has agreed to follow in GSK's footsteps, saying that it will work with an independent group which will be charged with sorting out and approving requests for access to anonymized clinical trial data for all approved products. If regulators can't provide the data then company will make it available.

DOMESTIC NEWS

2.1. DCGI - a final authority to take the decision about compensation during clinical trials Feb 03, 2013

- The Union Health Ministry has notified rules for grant of compensation in case of Serious Adverse Events (SAEs) like death and injuries on account of participation in clinical trial of drugs including biologicals and medical devices. Drug Controller General of India (DCGI), the apex drug regulator, will be the final authority for deciding the causes of injuries or death in clinical trials and also approving the final compensation amount in each case. The DCGI would recommend the final payment based on the independent probe panel's report, thus ruling out bias and unfairness.

2.2. Glenmark discovers IND enabling studies of a novel monoclonal antibody Feb 04, 2013

- Glenmark Pharmaceuticals SA (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), announced the discovery and initiation of IND enabling studies of a novel clinical development candidate, GBR 830, an anti-OX40 monoclonal antibody. GBR 830, an anti-OX40 monoclonal antibody, is a potential global first-in-class molecule. OX40, also known as CD134, plays a key role in T-cell mediated autoimmune disorders.

2.3. CDSCO introduces pre-screening of SAEs to streamline submission of reports Feb 19, 2013

- The Central Drugs Standard Control Organisation (CDSCO) has introduced a system of pre-screening of Serious Adverse Events (SAEs) reports at the time of receiving these reports with main objective to streamline the submission of reports of SAEs. This system of preliminary screening to determine the acceptability of the SAE report has come into effect from February 18, 2013.

2.4. CDSCO introduces pre-screening of applications for registration of ECs Feb 21, 2013

- The Central Drugs Standard Control Organization (CDSCO) has introduced a system for the pre-screening of the applications for registration of Ethics Committee. This system of preliminary scrutiny to determine the acceptability of the application for registration of ethics committee is expected to come into effect from February 25, 2013. This system is being introduced by the CDSCO to streamline the submission of application for registration of Ethics Committee and their examination as per Rule 122DD. This preliminary scrutiny of applications at the time of receipt will determine their acceptability for examination by the CDSCO.

2.5. Indian bio-pharma industry divided on US FDA draft guidance Feb 26, 2013

- India's bio-pharmaceutical companies are divided in their response to the recently issued draft US Food and Drug Administration (FDA) guidelines on 'Immunogenicity Assessment for Therapeutic Protein Products'. The guidelines are intended to assist manufacturers and clinical investigators involved in the development of therapeutic protein products for human use.
- Indian companies engaged in the development of therapeutic protein products include Biocon, Panacea Biotech, Serum Institute of India, Reliance Life Sciences, Shantha Biotechniques, Indian Immunologicals, Bharat Biotech, Cadila Health Care, Intervet India and Intas Biopharma.

DRUG APPROVALS AND LAUNCHES

3.1. Sun Pharma announces US FDA approval for generic Doxil Feb 05, 2013

- Sun Pharmaceutical Industries Ltd. announced that US FDA has granted its subsidiary an approval for its Abbreviated New Drug Application for generic version of Doxil, Doxorubicin HCl liposome injection, used to treat patients with ovarian cancer that has progressed or recurred after platinum-based chemotherapy. This generic Doxorubicin HCl Liposome injection USP, 2 mg/mL is therapeutically equivalent to Doxil Liposome Injection, 2 mg/mL of Janssen Research and Development, LLC.

3.2. J&J scores 'breakthrough' status at FDA Feb 13, 2013

- Johnson & Johnson and Pharmacyclics nabbed the FDA's new breakthrough designation for their cancer drug ibrutinib, a promising late-stage therapy that will be put in the hands of regulators later this year.

3.3. FDA promises swift review of GSK's blockbuster dolutegravir Feb 15, 2013

- Based on the big promise of GlaxoSmithKline's dolutegravir, the FDA has granted the potential HIV drug a priority review of 6 months rather than the standard 10 months. The agency gave an Aug. 17 action date for its review of the drug. London-based GSK controls a majority stake in the product, which is owned by its ViiV Healthcare joint venture with Pfizer.

3.4. Gilead races to FDA after Hep C blockbuster hopeful scores 4th win in PhIII Feb 19, 2013

- Gilead announced that it has successfully wrapped up positive top-line data from its fourth and last Phase III study for sofosbuvir, putting the biotech on a short path to the FDA with what promises to be the first oral drug for hepatitis C. This study demonstrates that all-oral therapy with sofosbuvir provides significant efficacy among difficult-to-treat hepatitis C patients who could not be cured by prior regimens containing pegylated interferon and now have limited treatment options. With positive results from all four Phase III trials now in hand, Gilead is on track to meet its goal of filing regulatory applications in the United States and Europe in the second quarter.

3.5. Roche / Genentech's breakthrough T-DM1 Feb 22, 2013

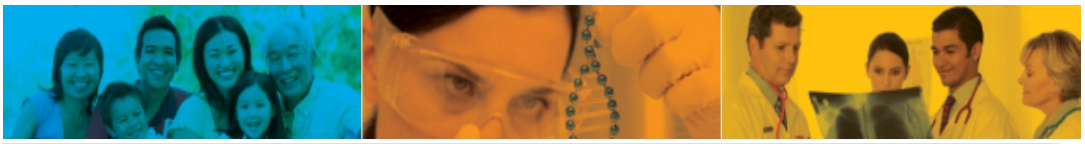
- The FDA today approved T-DM1, a breakthrough antibody drug conjugate from Roche / Genentech's widely expected to quickly become a new blockbuster treatment for breast cancer. Roche will market the newly approved drug as Kadcyla. The drug will cost $9,800 a month,or about $94,000 for a 9.5-month course of therapy.

3.6. Bayer's Stivarga® (regorafenib) Tablets Approved by US FDA Feb 25, 2013

- Bayer HealthCare and Onyx Pharmaceuticals, Inc. announced that the US FDA approved Bayer's Stivarga® (regorafenib) tablets to treat patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

3.7. Gentium shares wrecked by fresh round of regulatory woes for lead drug Feb 21, 2013

- Shares of Italy's Gentium plunged more than 40% this morning after the biotech announced a fresh round of woes with regulators-this time in Europe-for its vascular drug defibrotide. The drug is designed to treat rare cases of veno-occlusive disease, a blockage of small veins that can occur after stem cell transplants. There is no approved therapy.



DRUGS IN DEVELOPMENT

4.1. Bayer spotlights positive PhIII data for fat-busting drug Feb 01, 2013

- Bayer Healthcare touted upbeat data from a pair of late-stage studies of an investigational drug targeting chin fat, setting the stage for the giant to step into growing aesthetic treatment market. The results provide a victory from Kythera, which licensed the injected drug to Bayer for markets outside the U.S. and Canada.

4.2. Daiichi Sankyo, ArQule begin enrollment in phase 3 trial with hepatocellular carcinoma Feb 02, 2013

- Daiichi Sankyo Company Limited, and ArQule, Inc., a biotechnology company engaged in the research and development of next-generation, small-molecule cancer therapeutics, have enrolled the first patient in the pivotal phase 3 METIV-HCC (MET-high patients with tivantinib in HCC) trial of tivantinib (ARQ 197). Tivantinib, an investigational selective inhibitor of MET, a receptor tyrosine kinase, is being evaluated for the treatment of patients diagnosed with hepatocellular carcinoma (HCC) who have received one or two prior systemic anti-cancer therapies.

4.3. Vertex plots a race through PhIII for 'breakthrough' combo CF therapy Feb 26, 2013

- Vertex Pharmaceuticals has set the stage for an ambitious Phase III program for its combo approach matching the experimental VX-809 and Kalydeco for cystic fibrosis. If it can stick with the plan, Vertex will cut a short path directly to an approval for the groundbreaking combo.

MERGER, ACQUISITIONS AND COLLABORATIONS

5.1. Icon buys Cross Country's clinical trials biz for $52M Feb 04, 2013

- Icon, a Irish CRO, has agreed to trade $52 million for Cross Country Healthcare's clinical trials operation, looking to expand its contract staffing, functional service and pharmacovigilance offerings. Under the deal, Icon receives three Cross Country subdivisions: ClinForce and Assent Consulting, which offer contract staffing, permanent placement and functional service provision services; and AKOS, which provides pharmacovigilance and drug safety consulting.

5.2. Gilead Sciences acquires YM BioSciences Feb 06, 2013

- The Supreme Court of Nova Scotia has issued a final order approving the previously announced plan involving YM BioSciences, Gilead Sciences and Nova Scotia Limited, a wholly-owned subsidiary of Gilead. Nova Scotia Limited will acquire all of the issued and outstanding common shares of YM BioSciences for cash consideration of $2.95 per common share.

5.3. Sun Pharma, Taro terminate proposed merger Feb 08, 2013

- Sun Pharmaceutical Industries, an India-based specialty pharmaceutical company, and Taro Pharmaceutical Industries, a multinational, science-based pharmaceutical company, have mutually agreed to terminate their merger agreement, announced in August 2012, pursuant to which all shareholders of Taro (other than Sun Pharma and its affiliates) would have received a cash payment of $39.50 per share upon the closing of the merger.

5.4. Biocon, Mylan enhance partnership with insulin products collaboration Feb 15, 2013

- Biocon, a biotechnology company based in India, has formed a strategic collaboration with Mylan, a global pharmaceutical company, for the global development and commercialization of generic versions of its three insulin analog products. Mylan will have the rights to develop and market Biocon's Glargine (the generic version of Sanofi's Lantus), Lispro (the generic version of Eli Lilly's Humalog) and Aspart (the generic version of Novo Nordisk's NovoLog).

LAMBDA - KEY DIFFERENTIATORS

- Immense experience of Clinical Trial Management with commitment to always deliver within projected timelines and budget
- Vast experience of performing supporting studies for ANDA
- Helped many of our clients in achieving first to file opportunity US FDA ANDA submissions
- Ability to implement Electronic Data Capture Technology at Participating Sites
- Regulatory Affairs professionals with proven domain expertise
- Clinical Data Management Services with internationally acceptable platform
- Dedicated Pharmacy to store Investigational Product at desired temperature
- Dedicated Independent Audit team
- In house QC team which has added value to the clinical trial data management team and in turn has resulted in minimizing data queries.
- Central Clinical Lab - Accreditated by CAP and National Accreditation Board for Testing Laboratories, Government of India
- Central Imaging Review Platform – 21CFR Part11 and HIPAA compliant

COMMITMENT OF LAMBDA

To deliver Competitive, Accurate and Timely Solutions

BENEFITS TO SPONSOR

To make sound and cost effective decisions for Clinical Trials