Clinical Research Newsletter
Volume - 10, October 2015

LAMBDA

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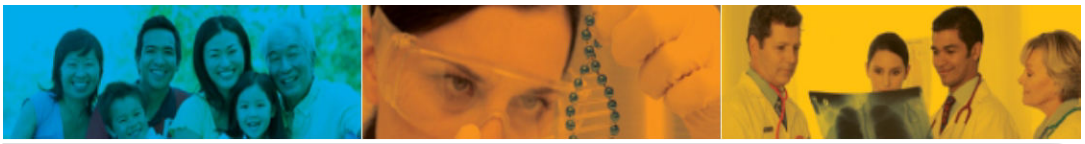


GLOBAL NEWS

1.1. US FDA grants breakthrough therapy designation for Roche's investigational medicine ACE910 for people with haemophilia A with factor VIII inhibitors

September 4, 2015

- US FDA has granted breakthrough therapy designation to Roche's ACE910 (RG6013, RO5534262) for the prophylactic treatment of people who are 12 years or older with haemophilia A with factor VIII inhibitors.
- Breakthrough therapy designation is designed to accelerate the development and review of medicines that demonstrate early clinical evidence of a substantial improvement over current treatment options for serious diseases.
- In a Phase I study, ACE910 showed promising results as a prophylactic treatment administered as a weekly subcutaneous injection in people with severe haemophilia A with and without inhibitors to factor VIII.

1.2. Pfizer says it Could be Leader in Cancer with Many New Drugs

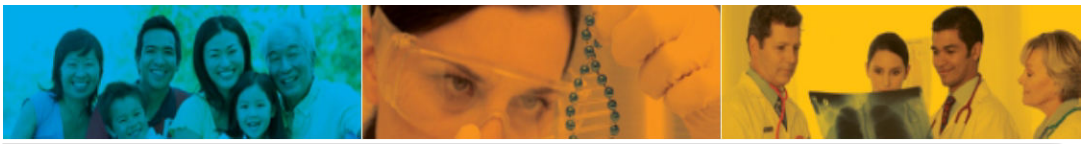
September 15, 2015

- Drug giant Pfizer is starting 20 clinical trials this year and more soon after on treatments to conquer cancer as it also seeks to gain leadership in one of the hottest and most lucrative areas of medicine.
- A decade ago, the world's second-biggest drugmaker by revenue wasn't even a player in cancer medicine. Instead, it was known for erectile dysfunction treatment Viagra and blockbuster cholesterol fighter Lipitor. New York-based Pfizer Inc. then chose to make cancer one of its core research areas, pitting it against cancer powerhouses including Novartis AG, Roche Holding AG, Bristol-Myers Squibb Co. and Merck & Co.
- Today, Pfizer has eight approved cancer medicines, four of them launched in the last four years. It's running late-stage patient tests on five of those drugs for additional uses, has three other drugs in late-stage testing - usually the last round before seeking approval from regulators- and has 14 other cancer drug development programs in early stages.

1.3. President Obama Nominates Califf as Next FDA Commissioner

September 15, 2015

- President Barack Obama has nominated Robert Califf, the current deputy commissioner for medical products and tobacco at the US Food and Drug Administration (FDA), as the next commissioner of the agency. Califf joined the FDA back in February following a stint as vice chancellor of clinical and translational research at Duke University.
- Other prominent roles during his tenure at Duke include director of the Duke Translational Medicine Institute (DTMI), and professor of medicine in the Division of Cardiology at the Duke University Medical Center in Durham North Carolina. Before serving as director of DTMI, he was the founding director of the Duke Clinical Research Institute, the world's largest academic research organization.



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DOMESTIC NEWS

2.1. Glenmark's novel antibody to enter clinical trials

September 15, 2015

- Glenmark Pharmaceuticals has completed the pre-clinical evaluation for its novel bi-specific antibody GBR 1302 and filed the phase I trial application for the same with German regulatory authorities. It has submitted a clinical trial application for GBR 1302 to the Paul-Ehrlich Institute in Germany.
- Glenmark Pharmaceuticals said in a statement "GBR 1302 has the potential to be used in the treatment of a broad array of cancers, including breast cancer and the company expects to obtain approval for the initiation of clinical studies during this financial year, it added.."

2.2. Intas Pharma expects US approval for Neulasta biosimilar this year

September 18, 2015

- India's Intas Pharmaceuticals could get approval this year to launch a version of Amgen Inc's white blood cell boosting Neulasta drug in the United States, chief financial officer Jayesh Shah said. That would make it the first Indian drugmaker to secure a green light to sell a biosimilar in the United States, the world's biggest healthcare market. Until recently, the regulatory pathway for such medicines was unclear and the first biosimilar was approved there only in March.

2.3. Health ministry of India releases National Health Profile-2015

September 23, 2015

- The Union minister for health and family welfare of India J P Nadda has released the National Health Profile (NHP)-2015 to navigate, to decide goals and chart the government policies on health. The data was prepared by the Central Bureau of Health Intelligence (CBHI).
- The e-book (digital version) of the annual document has been prepared for the first time, was also released. It covers demographic, socio-economic, health status and health finance indicators, along with comprehensive information on health infrastructure and human resources in health.

REGULATORY NEWS

3.1. NICE recommends Chugai's RoACTEMRA monotherapy to treat severe rheumatoid arthritis

September 19, 2015

- Chugai Pharmaceutical Co., Ltd. (Chugai) announced that National Institute for Health and Clinical Excellence(NICE) issued a positive Final Appraisal Determination (FAD), recommending RoACTEMRA (tocilizumab) monotherapy for use on the National Health Services (NHS) on September 3, 2015. The decision is based on a dossier of data that included results which show RoACTEMRA helps almost four times as many patients achieve remission than those treated with a leading anti-TNF monotherapy. As many as 20,000 patients in England and Wales with severe rheumatoid arthritis (RA) could soon benefit from RoACTEMRA monotherapy. The guidance brings England and Wales in line with Scotland, where RoACTEMRA has been available as monotherapy to Scottish patients for a year. This recommendation indicates the high medical need of RoACTEMRA in monotherapy which is equivalent to outcomes of RoACTEMRA in combination with methotrexate.

3.2. India mulls reclassifying vitamins as drugs if they come with health claims

September 22, 2015

- India may classify vitamin supplements as drugs rather than foods if the manufacturers of such products explain they can treat or prevent disease. The proposal which was put forward by CDSCO this week, is based on the recommendations of its Drugs Technical Advisory Board (DTAB).
- The board that enclosed regulators and attention representatives said vitamins should be reclassified "if there is a claim for treatment, mitigation or prevention of any diseases or disorder."They also concluded that supplements containing vitamins already found in schedule V products should be labelled as drugs even if the ingredient is below recommended daily allowance (RDA) limits.
- The committee also done transparent that: "Fortified powders that are presumably exempted underneath report K [of the D&C Rules 1945] and for Special Medicinal products (SMP) to be used as substitute for food shall not be deliberate as food if a tag of a product indicates name of disease."

3.3. Lack of regulatory clarity dominates US biosimilar debate post Zarxio

September 22, 2015

- Sandoz has reiterated its call for US FDA guidance on biosimilar interchangeability arguing that the lack of clarity makes it hard to gauge what impact switching rules will have on pricing. Industry demands for guidelines is strong with Sandoz, Pfenex and Hospira being just three examples of firms waiting for agency clarification.

DRUG APPROVALS AND LAUNCHES

4.1. FDA Approves Second PCSK9 Inhibitor for High Cholesterol

September 1, 2015

- The Food and Drug Administration (FDA) has approved Repatha (evolocumab; Amgen) for use in addition to diet and maximally-tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or clinical atherosclerotic cardiovascular disease, such as heart attacks or strokes, who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

4.2. Unique Aspirin Formulation Gets FDA Nod for Secondary Prevention of Stroke, Cardiac Events

September 8, 2015

- New Haven Pharmaceuticals announced that the Food and Drug Administration (FDA) has approved Durlaza, the first and only once-daily 24-hour extended-release aspirin for the secondary prevention of stroke and acute cardiac events, including myocardial infarction (MI).
- Durlaza is a nonsteroid anti-inflammatory drug indicated to reduce the risk of death and MI in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

4.3. Vraylar Gets FDA Approval

September 17, 2015

- Allergan and Gedeon Richter announced that the Food and Drug Administration (FDA) has approved Vraylar (cariprazine) capsules for the treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia in adults.
- The FDA's approval was based on data from three 3-week controlled trials in adults with manic or mixed episodes of bipolar I disorder and three 6-week placebo-controlled trials in adults with schizophrenia, which included over 2,700 adults total.
- Treatment with Vraylar showed improvement vs. placebo as measured by Young Mania Rating Scale (YMRS) total scores in patients with bipolar mania and by Positive and Negative Syndrome Scale (PANSS) total scores in patients with schizophrenia. Vraylar also showed efficacy as measured by the Clinical Global Impressions-Severity (CGI-S) rating scale, meeting the study's secondary efficacy endpoints for both condition.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. U.S. FDA Accepts for Priority Review the Biologics License Application for Empliciti (elotuzumab) for the Treatment of Multiple Myeloma in Patients Who Have Received One or More Prior Therapies

September 01, 2015

- Bristol-Myers Squibb Company and AbbVie today announced the U.S. Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application (BLA) for Empliciti (elotuzumab), an investigational Signaling Lymphocyte Activation Molecule (SLAMF7)-directed immunostimulatory antibody, for the treatment of multiple myeloma as combination therapy in patients who have received one or more prior therapies.
- Empliciti was previously granted Breakthrough Therapy Designation, which according to the FDA, is intended to expedite the development and review of drugs for serious or life-threatening conditions. The European Medicines Agency (EMA) also recently validated for review the Marketing Authorization Application for Empliciti, granting it accelerated assessment.

5.2. Amgen And UCB Announce Positive Top-Line Results From Open-Label Phase 3 Study Of Romosozumab Compared With Teriparatide

September 01, 2015

- Amgen AMGN and UCB (euronext brussels:UCB) today announced top-line results from the STRUCTURE trial (STudy evaluating effect of Romosozumab Compared with Teriparatide in postmenopausal women with osteoporosis at high risk for fracture previously treated with bisphosphonate therapy).
- The study (NCT01796301) met the primary endpoint, demonstrating a statistically significant difference in favor of romosozumab in the percent change of total hip bone mineral density (measured by DXA) through month 12.

5.3. Pfizer Announces Positive Top-Line Results from Two Phase 3 Trials of Oral Tofacitinib in Adults with Moderate-to-Severe Ulcerative Colitis

September 21, 2015

- Pfizer Inc. announced today top-line results from two Phase 3 induction trials of tofacitinib 10 mg twice daily (BID) tablets in the Oral Clinical Trials for Tofacitinib in ulceratiVE colitis (OCTAVE) global clinical development program for the treatment of adults with moderate to severe ulcerative colitis (UC): OCTAVE Induction 1 (A3921094) and OCTAVE Induction 2 (A3921095).
- Both studies met their primary endpoints as measured by the proportion of patients receiving tofacitinib in remission at Week 8 compared to patients receiving placebo.

MERGER/ACQUISITIONS/COLLABORATION

6.1. AstraZeneca to invest £11.5 million in new clinical oncology bioinformatics collaboration with The University of Manchester

September 8, 2015

- AstraZeneca and The University of Manchester today announced a collaboration harnessing clinical bioinformatics to deliver personalised healthcare for cancer patients. The five-year agreement will see the organisations apply clinical trial bioinformatics to better identify the right cancer treatment for the right patient at the right time.
- As part of the collaboration, AstraZeneca will provide a total of £11.5 million to support clinical bioinformatics research led by a dedicated team of investigators within the recently established Centre for Cancer Biomarker Sciences at the Manchester Cancer Research Centre.
- The research will be carried out in partnership with the state-of-the-art clinical trials unit of The Christie NHS Foundation Trust, which is at the forefront of experimental cancer medicine in the UK.

6.2. Sun Pharma to acquire ophthalmic drug maker InSite Vision

September 16, 2015

- India's Sun Pharmaceutical Industries Ltd on Wednesday said one of its subsidiaries has entered into an agreement to acquire and merge with it the US- based ophthalmic drug maker InSite Vision Inc.
- The transaction has a total equity value of approximately $48 million on fully diluted basis plus related debt and other transaction costs assuming all shares of InSite Vision are tendered in the offer. The Indian company is in the process of establishing a branded ophthalmic business in the US.

6.3. Amgen to Acquire Dezima Pharma

September 17, 2015

- Amgen and Dezima Pharma B.V. announced that the companies have entered into a definitive acquisition agreement under which Amgen will acquire Dezima, a privately-held, Netherlands-based biotechnology company focused on developing innovative treatments for dyslipidemia.
- With the recent launches of RepathaT and Corlanor® and today's acquisition of Dezima, Amgen is proud to be on the leading edge of an exciting new wave of treatments for cardiovascular disease" said Robert A. Bradway, chairman and chief executive officer at Amgen.

6.4. Daiichi Sankyo signs agreement with Translational Sciences, Inc. to develop and commercialize the first-in-class thrombus dissolving agent, Ts23

September 22, 2015

- Daiichi Sankyo Company, Ltd. (hereafter, Daiichi Sankyo) has signed an exclusive licensing agreement with Translational Sciences, Inc. to develop and commercialize its novel thrombus (blood clot) dissolving agent, TS23, which is currently undergoing Phase I clinical trials.
- Based on this agreement, Daiichi Sankyo will pay Translational Sciences unspecified fees, milestones and royalties for exclusive rights to globally develop and commercialize TS23. This agreement with Translational Sciences, Inc. for Daiichi Sankyo to develop and commercialize this unique thrombus dissolving agent, TS23, is in line with the Daiichi Sankyo R&D strategy to expand its portfolio in the prevention and treatment of thrombosis.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Second drugmaker sues FDA over drug marketing, cites Amarin's 'free speech' win

September 9, 2015

- It looks like the federal court ruling last month that Amarin ($AMRN) had the "free speech" right to promote its fish oil product Vascepa for off-label use will become nettlesome to the FDA. A second drugmaker, Pacira, has now filed suit looking for a court to grant it similar permission on the way it markets its pain drug Exparel.
- The FDA last year sent the New Jersey company a warning letter for promoting Exparel for pain relief in surgeries not listed on its label, Reuters reports. Its 2011 approval was based on studies in bunionectomies and hemorrhoidectomies.
- In an emailed statement, the company explained that its pivotal trials were conducted in soft-tissue (hemorroidectomy) and hard-tissue (bunionectomy) models, which was consistent with the FDA's guidance for analgesics seeking a broad indication. The company said, Exparel is indicated for "administration into the surgical site to produce postsurgical analgesia" and the label does not specify any limitations to use based on surgery type.

7.2. Reanalysis of antidepressant trial finds popular drug ineffective & unsafe for adolescents

September 18, 2015

- The widely used antidepressant paroxetine is neither safe nor effective for adolescents with depression, concludes a reanalysis of an influential study originally published in 2001. The new results, published by The BMJ today, contradict the original research findings that portrayed paroxetine as an effective and safe treatment for children and adolescents with major depression.
- It is the first trial to be reanalysed and published by The BMJ under an initiative called RIAT (Restoring Invisible and Abandoned Trials), which encourages abandoned or misreported studies to be published or formally corrected to ensure doctors and patients have complete and accurate information to make treatment decisions.

TECHNOLOGY/NDDS NEWS

8.1. FDA Accepts First Sensor/Pharmaceutical Hybrid Tablet for Review

September 11, 2015

- Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Proteus Digital Health (Proteus) announced that the US FDA has determined that the New Drug Application (NDA) for the combination product of ABILIFY (aripiprazole) embedded with a Proteus ingestible sensor in a single tablet is sufficiently complete to allow for a substantive review and is considered filed as of September 8, 2015.
- This is the first time an FDA-approved medication (ABILIFY) has been combined and submitted for approval with a sensor within the medication tablet (the Proteus ingestible sensor) to measure actual medication-taking patterns and physiologic response.
- Digital Medicines may enable improved patient medication adherence and better informed physician decision-making to tailor treatment to the patient's needs.

8.2. Glide Technologies, Cilian AG ink pact to develop novel solid dose recombinant flu vaccine

September 22, 2015

- Glide Technologies, the development company focused on solid dose formulations of therapeutics and vaccines, has entered a collaboration with German biotechnology company Cilian AG to develop a solid dose formulation of Cilian's experimental recombinant influenza vaccine, CiFlu, for delivery using Glide's patient-friendly SDI delivery device.
- Initial results from the collaboration demonstrate extremely robust room-temperature stability for the solid dose CiFlu formulation, and preclinical potency testing is planned to confirm the potential for an enhanced immune response to the vaccine, before the year end.
- CiFlu is produced in the unicellular organism Tetrahymena thermophila using recombinant DNA technology, which has the potential to increase the speed, reliability and quality of manufacture. Currently, influenza vaccines are reformulated each year due to changes in circulating viruses, and this process can take up to 28 weeks, leading to delays in the vaccination of vulnerable groups.

LAMBDA implements LIMS (a BioLyte software) in its BA lab located at Ahmedabad with Sciex & Waters followed by Thermo instruments. This will have the advantage of automatic preparing of samples in sequence, processing of the same by freezer custodian for their quick and easy retrieval and in-turn transferring of the samples to the instrument for analysis. This will lead to the import of data from instrument to BioLyte software for the review, approval and subsequent transfer to Biostatistics department, eventually achieving better compliance with increased efficiency.