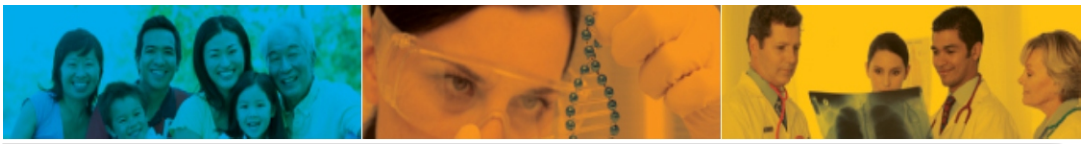

Clinical Research Newsletter Volume - 11, November 2014

LAMBDA

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GLOBAL NEWS

1.1. Novartis and Janssen scoop UK Prix Galien awards Oct 03, 2014

- Novartis' meningococcal vaccine Bexsero and Janssen's tuberculosis drug Sirturo have taken the top prizes at this year's UK Prix Galien Awards. At a ceremony in the House of Commons, the Innovative Product Award was won by Bexsero, which was approved in the European Union and is indicated to help protect all age groups against meningococcal serogroup B disease, including infants who are the most vulnerable.

1.2. National Institutes of Health awards $46 million for BRAIN Initiative research Oct 06, 2014

- The NIH announced its first wave of investments totalling $46 million in fiscal year 14 funds to support the goals of the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. More than 100 investigators in 15 states and several countries will work to develop new tools and technologies to understand neural circuit function and capture a dynamic view of the brain in action. These new tools and this deeper understanding will ultimately catalyze new treatments and cures for devastating brain disorders that are estimated by the WHO to affect more than one billion people worldwide.

1.3. Three scientists shares the 2014 Nobel Prize in Medicine Oct 06, 2014

- Three scientists have shared the 2014 Nobel Prize in Physiology or Medicine, with one half to John O´Keefe and the other half jointly to May-Britt Moser and Edvard I. Moser for their discoveries of cells that constitute a positioning system in the brain.

1.4. UPDATED: Chimerix drug given to USA's first Ebola patient Oct 06, 2014

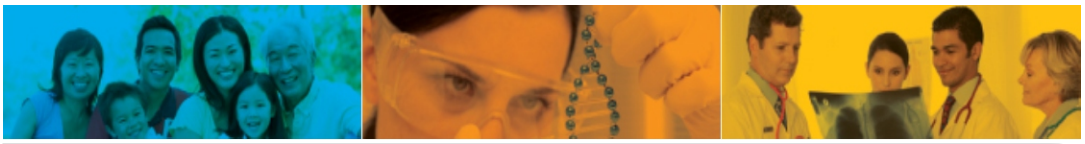
- The US Food and Drug Administration has authorised Chimerix' brincidofovir as an emergency treatment for Ebola and it has been taken by the first person diagnosed with the virus in the USA.

1.5. Teva stops R&D on oncology and women's health, focusing on CNS and respiratory Oct 07, 2014

- Teva Pharmaceutical Industries Ltd has decided to stop R&D activities related to oncology and women's health, and focusing more on core therapeutic areas like Central Nervous System and Respiratory System. These projects amount to more than $150 million in R&D costs in 2015 and in excess of $200 million for each of 2016 and 2017.

1.6. Future looks very clear for Novartis psoriasis drug Oct 11, 2014

- A week or so ahead of a US advisory committee, Novartis has presented more impressive data for its closely-watched psoriasis drug secukinumab. New analyses of Phase III studies have been presented at the European Association of Dermatology and Venereology congress in Amsterdam which show that treatment with secukinumab 300mg resulted in higher rates of clear to almost clear skin at week 12 versus placebo, regardless of patients' psoriasis disease severity.



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DOMESTIC NEWS

2.1. OMICS to organise pharmacovigilance & clinical trials conference in Hyderabad Oct 06, 2014

- OMICS Groups is organising the 3rd international conference and exhibition on pharmacovigilance and clinical trials from October 27-29, 2014 at Hyderabad International Convention Centre (HICC). Keeping the national as well as global pharmaceutical industry growth, OMICS is planning to host this event around the theme safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management.

2.2. SRL Diagnostics develops new techniques to diagnose breast cancer at early stages

Oct 17, 2014

- SRL Diagnostics has developed measures and innovative techniques to diagnose breast cancer at early stages. Accurate detection and diagnosis is confirmed by taking a radiological imaging or biopsy of the concerning lump followed by their most innovative BRCA1 & 2 gene tests. Among all most inherited cases of breast cancer are associated with two abnormal genes viz., BRCA1 (breast cancer gene 1) or BRCA2 (breast cancer gene 2). About 510% of cases are due to genes inherited from one's parents. Women with an abnormal BRCA1 or BRCA2 gene have about a 60% risk of being diagnosed with breast cancer during their lifetimes (compared to 12-13% for women overall).

REGULATORY NEWS

3.1. DCGI to approve clinical trial proposals for new drugs approved abroad Oct 30, 2014

- The clinical trial proposals of new drugs already approved in other countries, fixed dose combinations (FDCs), subsequent new drugs, vaccines, etc. will henceforth be disposed of by the Drugs Controller General of India (DCGI). This practically means that the pharmaceutical companies seeking permission from the Union health ministry to conduct clinical trial of new drugs already approved in other countries, fixed dose combinations (FDCs), subsequent new drugs, vaccines, etc. do not have to go through the present time-consuming process of three-tier screening system under which each and every proposal is examined first by the NDAC (presently renamed as SECs), then by the Technical Committee headed by DGHS and finally by the Apex Committee headed by union health secretary.
- In view of these facts and circumstances, evaluation of the proposals of clinical trial proposals of drugs related to other than Global Clinical Trials and New Chemical Entities may be disposed of at CDSCO level only.

3.2. EMA's new policy on clinical reports to take effect on January 1, 2015 Sep 02, 2014

- The European Medicines Agency (EMA) has decided to publish the clinical reports that underpin the decision-making on medicines. Following extensive consultations held by the Agency with patients, healthcare professionals, academia, industry and other European entities over the past 18 months, the EMA Management Board unanimously adopted the new policy at its meeting on October 2, 2014.

The policy will enter into force on January 1, 2015. It will apply to clinical reports contained in all applications for centralised marketing authorisations submitted after that date. The reports will be released as soon as a decision on the application has been taken.

3.3. Speedy US review for Pfizer's breast cancer drug — Oct 13, 2014

- US regulators have agreed to undertake a speedy review of Pfizer's breast cancer drug palbociclib, signalling their belief that it could offer a major treatment advance for patients. The US FDA has assigned a Priority Review status to the application to market the drug, which means its evaluation process should take just six months rather than the standard 10 months.

DRUG APPROVALS AND LAUNCHES

4.1. UK licenses BI's Spiriva Respimat for asthma — Oct 01, 2014

- As expected, Boehringer Ingelheim's chronic obstructive pulmonary disease blockbuster Spiriva has bagged a UK license and is being launched for the treatment of asthma, becoming the first long-acting muscarinic-antagonist (LABA) approved for the condition

4.2. US approval for Helsinn and Eisai chemo nausea drug — Oct 12, 2014

- The US Food and Drug Administration has approved Helsinn and Eisai's Akynzeo to treat chemotherapy-induced nausea and vomiting. Akynzeo is a combination of oral palonosetron (0.5 mg) and netupitant (300 mg), a new drug for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

4.3. AstraZeneca Pharma bags US nod for Xigduo XR — Oct 30, 2014

- US regulators have approved AstraZeneca's Xigduo XR, giving patients with diabetes type II access to the first once-daily pill combining the SGLT2 inhibitor dapagliflozin and metformin HCl extended-release.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Regeneron, Sanofi report phase 2a study of dupilumab meets endpoints — Oct 01, 2014

- Regeneron Pharmaceuticals and Sanofi announced that a phase 2a proof-of-concept study of dupilumab, an investigational therapy that blocks IL-4 and IL-13 signaling, met all primary and secondary endpoints in patients with moderate-to-severe chronic sinusitis with nasal polyps (CSwNP) who did not respond to intranasal corticosteroids.

5.2. Ardelyx announces positive results from phase 2b trial — Oct 04, 2014

- Ardelyx, Inc., a clinical-stage biopharmaceutical company, announced positive results from its 371 patient phase 2b clinical trial evaluating tenapanor in patients with constipation-predominant irritable bowel syndrome (IBS-C). Results from this study demonstrated statistically significant and clinically meaningful improvement in IBS-C symptoms for tenapanor-treated patients compared to patients receiving placebo.

5.3. Shantha Biotechnics commences phase III trial of investigational rotavirus vaccine Oct 14, 2014

- Shantha Biotechnics, which was acquired by Sanofi Pasteur in 2009, has commenced a phase III clinical trial in India for its investigational rotavirus vaccine, developed and manufactured in Hyderabad. The trial is designed to show non-inferiority against a currently licensed vaccine with the use of three, ready-to-use liquid doses administered orally, starting from six-to-eight weeks of age, with the subsequent doses administered at 4 weeks intervals.

5.4. Novartis announces CTL019 data published in NEJM Oct 17, 2014

- Novartis and the University of Pennsylvania's Perelman School of Medicine (Penn) announced preliminary results from two pilot clinical trials published in The New England Journal of Medicine (NEJM) evaluating the efficacy and safety of CTL019 in patients with relapsed/refractory acute lymphoblastic leukaemia (r/r ALL). The studies, conducted by Penn, demonstrated that 27 of 30 paediatric and adult patients, or 90 per cent, experienced complete remissions with the investigational chimeric antigen receptor (CAR) therapy CTL019.

5.5. Google developing pill to sniff out cancer, heart disease Oct 30, 2014

- Search giant Google is developing a pill that aims to detect life-threatening illnesses such as cancer and heart disease in the earliest stages. Still in the very experimental phase at research unit Google X, the idea behind the pill is that it releases a bunch of nano particles peppered with antibodies or other proteins attuned to certain biomarkers of disease around the body.

MERGER, ACQUISITIONS AND COLLABORATIONS

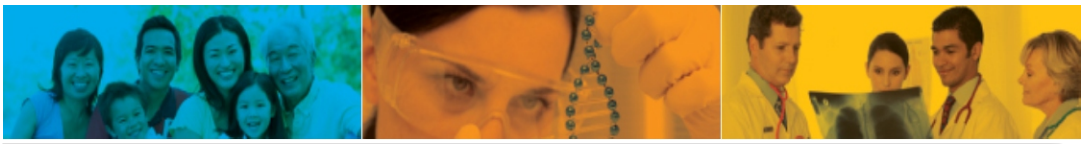
6.1. Merck Serono, ICR & Wellcome Trust collaborate to develop anti-cancer drugs Oct 08, 2014

- Merck Serono, the bio-pharmaceutical, division of Merck, The Institute of Cancer Research (ICR), and the Wellcome Trust, London, announced a co-development and licence agreement building on two independent research programmes at both the ICR and Merck Serono to identify inhibitors of tankyrase, an enzyme of the poly (ADP-ribose) polymerase family. The collaboration will be jointly funded by Merck Serono and the Wellcome Trust.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Tris Pharma files patent law suit against Actavis on generic Quillivant XR Oct 18, 2014

- Tris Pharma, Inc. filed suit against Actavis in the US District Court for the District of Delaware seeking to prevent Actavis from commercialising its ANDA product prior to the expiration of certain US Patents. The lawsuit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of Actavis' ANDA for up to 30 months from the date the plaintiffs received notice of Actavis' ANDA filing or until final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivities.



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TECHNOLOGY NEWS

8.1. Cambridge Consultants designs new injection pen for diabetes patients Oct 07, 2014

- In order to make daily management of the disease easier and more accurate, product development firm Cambridge Consultants has designed an injection pen (KiCoPen) for diabetes patients to capture the exact dose delivered and send the information to an associated smartphone app. And all without a battery the action of removing the injector cap powers the device. There is currently no injector pen on the market that combines these capabilities.