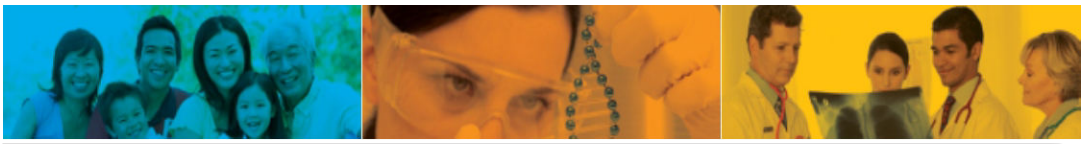

Clinical Research Newsletter Volume - 2, February 2016

LAMBDA

CONTENTS

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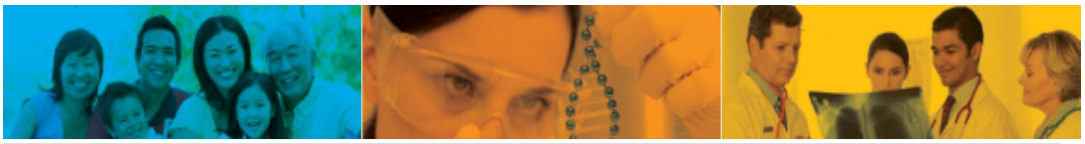

LAMBDA

GLOBAL NEWS

1.1. Painkiller Tapped to Become Future Cancer-Killer January 13, 2015

- Diclofenac is a common painkiller. Aside from easing pain caused by a number of conditions, it has potential as an anti-cancer drug, according to researchers.
- The Repurposing Drugs in Oncology (ReDO) project, an international collaboration between the Anticancer Fund, Belgium, and US based GlobalCures, finds that existing and widely-used non-cancer drugs may represent a relatively untapped source of novel therapies for cancer.

1.2. Simvastatin: cholesterol-lowering drug touted as potential treatment for Parkinson's disease January 11, 2016

- Simvastatin is a drug used to lower cholesterol in patients with very high cholesterol condition, but the drug is now being trialed as a potential cure for Parkinson's patients. The results of a recent trial in multiple sclerosis with simvastatin, and the pre-clinical work investigating its effect on alpha-synuclein clumping (which is a common feature of Parkinson's) indicate that it could be an effective treatment to slow down the progression of Parkinson's
- Researchers for the trial intend to recruit only Parkinson's patients who do not take any statins at the moment, and tests will be conducted across 21 centers across the UK and in Plymouth Hospitals NHS Trust.

1.3. Prescription Drug Prices Climb Over 10 Percent in 2015 January 13, 2015

- In 2015, prescription drug prices were reported to have risen 10.43 percent, according to an analysis released by healthcare data company Truveris.
- But prescription drug prices were not the only drugs to experience an increase. In the same analysis, the cost of -branded medicines jumped 14.77 percent, specialty drugs rose 9.21 percent, generic medicines increased 2.93 percent

1.4. New Data Shows SGLT2 Inhibitors May Be Effective in Preventing Kidney Failure January 22, 2016

- New data presented at the American Society of Nephrology meeting in San Diego last November offers new hope to people with diabetes at risk of kidney disease and kidney failure.
- They suggest a new class of glucose-lowering agents, sodium glucose co-transporter type 2 (SGLT2) inhibitors, may be effective in preventing kidney failure.This data has potential to be critically important due to reduced life expectancy and quality of life among millions of people globally with kidney failure.

DOMESTIC NEWS

2.1. India to join UK for Add-Aspirin global drug trials January 07, 2015

- India will collaborate with UK to conduct 'Add-Aspirin' global drug clinical trials to investigate whether the use of widely-used medicine, aspirin prevents recurrence of the most common cancers, like breast and gastric or oesophagus.
- Aspirin is widely-used as an analgesic to relieve pain, as well as to manage heart disease and stroke in certain patients.

2.2. Lupin gets USFDA nod for contraceptive pills

January 09, 2016

- Lupin has secured US Food and Drug Administration's (FDA) approval to sell the generic version of oral contraceptive Generess (Norethindrone and Ethinyl Estradiol Chewable Tablets, 0.8 mg/0.025 mg and Ferrous Fumarate Chewable Tablets, 75 mg) tablets in the American market.
- The tablets have an annual sale of around $90 million and Lupin will benefit as there is only one more company distributing generic version of the drug in the US.

2.3. Rational compensation guidelines, predictable approval timelines to lead clinical trials in India

January 12, 2016

- A series of developments in the recent past relating to clinical research in the country has to a great extent helped bring balance in the regulatory environment.
- The compensation guidelines are rational and more predictable approval timelines are likely to take shape with the expansion of the Subject Expert Committees (SECs). These were some of the relevant points expressed at the 9th Annual Conference of the Indian Society for Clinical Research (ISCR) in Mumbai from 7 to 9 January, 2016.

REGULATORY NEWS

3.1. Clinical trial rules to be relaxed for academic institutions

January 15, 2016

- The central government plans to tweak the current clinical trial norms to exempt academic institutions from some these stringent conditions, including paying compensation in most of the cases, so that research activities are not stymied.
- ICMR along with the Drugs Controller General of India and the Health Ministry is reworking on the guidelines to clarify some of the issues related to conduct of trials that would not lead to the registration of a new medicine.

3.2. India favours international pharma major pharma by rejecting license for generic diabetes drug

January 21, 2015

- The Indian Patent Office rejected an application from a domestic company that sought a compulsory license to make a generic version of a brand-name medicine. Lee Pharma hoped to sell a lower-cost version of Onglyza, a diabetes pill sold by AstraZeneca.
- The decision was being closely watched as global drug makers look for signs that the Indian government will alter its approach toward protecting patent rights.
- Countries can issue compulsory licenses to a generic drug maker allowing it to copy a patented medicine without the consent of the pharmaceutical company that owns the patent. This right was spelled out in a World Trade Organization agreement.

3.3. Mandate on clinical data sharing proposed January 26, 2015

- The International Committee of Medical Journal Editors (ICMJE) proposes new rules that will require authors to share clinical trial data as a prerequisite for their manuscripts to be considered for publication.
- The goal is to improve the benefit to society from the efforts of patients who volunteer to participate in clinical trials. The ICMJE proposal is outlined in an editorial published simultaneously in Annals of Internal Medicine and 13 other ICMJE member journals.

DRUG APPROVALS AND LAUNCHES

4.1. Torrent launches world's second biosimilar of generic auto-immune drug January 11, 2016

- Ahmedabad-based drug major Torrent Pharmaceuticals launched its biosimilar for Adalimumab, a therapy for the treatment of auto immune disorders like rheumatoid arthritis etc, across India . Torrent's Adfrar would be the second biosimilar of Adalimumab in the world.
- Adalimumab has wide applications for treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis and plaque psoriasis. It is the largest selling drug globally.

4.2. The FDA approves Eagle Pharma's non-alcohol formulation of docetaxel January 11, 2015

- The FDA approves Eagle Pharmaceuticals' non-alcohol formulation of the taxane chemo drug docetaxel for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, adenocarcinoma and head and neck cancer. A chemotherapy drug marketed by Eagle Pharmaceuticals has become the first product approved for commercial manufacture from AMRI's once troubled Burlington facility.

4.3. Novartis receives two new FDA approvals for Cosentyx® (secukinumab) January 15, 2016

- Cosentyx is the first and only interleukin-17A (IL-17A) antagonist approved for adult patients with active ankylosing spondylitis (AS) and psoriatic arthritis (PsA)
- Approvals for both indications based on efficacy and safety outcomes shown across four Phase III studies, including over 1,500 patients with either AS or PsA1
- In studies, Cosentyx met the primary endpoints showing statistically significant improvements versus placebo in the signs and symptoms of AS and PsA.

4.4. FDA Approves NextSource's Brain Tumor Treatment December 23, 2015

- NextSource Biotechnology, LLC announced that Gleostine® (lomustine) 5 mg capsules has been approved by the FDA and is now commercially available in the United States.
- Gleostine® is approved for use as a single agent treatment or in combination with other approved chemotherapeutic agents. Gleostine® is indicated to treat brain tumorsboth primary and metastatic, as well as Hodgkin's disease

4.5. U.S. Food and Drug Administration Approves Humulin® R U-500 KwikPen® January 21, 2016

- The U.S. Food and Drug Administration (FDA) has approved Eli Lilly and Company's Humulin® R U-500 KwikPen®(insulin human injection) 500 units/mL, a pre-filled device containing Humulin R U-500, a highly concentrated formulation of insulin.
- Humulin R U-500 is the only FDA-approved insulin that is five-times more concentrated than standard U-100 insulin. This insulin is used to treat high blood sugar in people with type 1 and type 2 diabetes who need more than 200 units of insulin per day.

4.6. Alectinib highly active in advanced ALK-positive NSCLC January 22, 2016

- In December, the FDA granted accelerated approval to alectinib (Alecensa, Genentech) an oral, small molecule, ATP-competitive tyrosine kinase inhibitor of ALK for treatment of patients with metastatic ALK-positive NSCLC who progressed on or are intolerant to crizotinib (Xalkori, Pfizer).
- This approval was based on results of study by Sai-Hong Ignatius Ou, MD, PhD, clinical professor of health science in the school of medicine at University of California Irvine, and colleagues.
- "The development of resistance to crizotinib is a major barrier to the successful long-term treatment of patients with ALK-rearranged NSCLC," Ou and colleagues wrote. "Progression with crizotinib can be due to acquired resistance mutations in ALK, activation of other signaling bypass pathways, and, in approximately half the patients treated with crizotinib, development and/or progression of brain metastases.
- Therefore, novel ALK inhibitors should not only be more potent than crizotinib and able to inhibit the clinically relevant acquired resistance mutations in ALK but also confer sustained clinical activity in the central nervous system."

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. BioInvent wins FDA approval to study TB-403 for treatment of pediatric brain tumors

January 08, 2016

- BioInvent International has secured approval from the US Food and Drug Administration (FDA) to start the proposed pediatric clinical investigation of TB-403 for the treatment of relapsed or refractory medulloblastoma.
- The FDA has accepted the company's investigational new drug (IND) application for the phase I/IIa study of TB-403, which is expected to start in the first quarter of this year.

5.2. Ebola Vaccine Phase 2 Clinical Trial Begins January 08, 2016

- The Walter Reed Army Institute of Research (WRAIR) announced the initiation of a Phase 2 clinical trial to evaluate the safety and immunogenicity of a prime-boost Ebola vaccine regimen in both healthy and HIV-infected study volunteers.
- This study includes two vaccine candidates, Ad26.ZEBOV from Crucell Holland B.V., one of the Janssen Pharmaceutical Companies of Johnson & Johnson and MVA-BN-Filo from Bavarian Nordic, which will be given sequentially as a "prime boost" regimen.

5.3. FDA grants breakthrough therapy designation for investigational medicine venetoclax in combination with MabThera/Rituxan January 20, 2016

- The FDA granted AbbVie's venetoclax breakthrough therapy status in combination with Roche's Rituxan (rituximab) for the treatment of patients with relapsed/refractory chronic lymphocytic leukaemia (R/R CLL).
- Roche noted that the breakthrough therapy designation for venetoclax was supported by data from the M13-365 study, which were unveiled at the American Society of Hematology annual meeting last month.

5.4. Ophthotech Announces First Patient Dosed in Zimura® Phase 2/3 Study January 27, 2016

- Ophthotech Corporation announced that the first patient has been dosed in a Phase 2/3 clinical study of Zimura® (avacincaptad pegol sodium), an inhibitor of complement factor C5, in patients with geographic atrophy, an advanced form of dry age-related macular degeneration (AMD).
- The Phase 2/3 randomized, double-masked, controlled trial is designed to evaluate the safety and efficacy of Zimura® monotherapy in patients with geographic atrophy.

5.5. BIND Therapeutics Provides Enrollment Update for Phase 2 iNSITE 1 and iNSITE 2

January 27, 2016

- Ophthotech Corporation announced that the first patient has been dosed in a Phase 2/3 clinical study of Zimura® (avacincaptad pegol sodium), an inhibitor of complement factor C5, in patients with geographic atrophy, an advanced form of dry age-related macular degeneration (AMD).
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MERGER/ACQUISITIONS/COLLABORATION

6.1. Allergan Acquires Medical Dermatology and Aesthetic Medicine Company Anterios to Expand Neurotoxin Pipeline January 07 , 2016

- Allergan plc, a leading global pharmaceutical company, announced that it has acquired Anterios, Inc., a clinical stage biopharmaceutical company developing a next generation delivery system and botulinum toxin-based prescription products.
- Under the terms of the agreement, Allergan acquired Anterios for an upfront payment of $90 million and potential development and commercialization milestone payments related to NDS™, Anterios' proprietary platform delivery technology that enables local, targeted delivery of neurotoxins through the skin without the need for injections.

6.2. Biotech Moderna partners with CRO to advance promising RNA therapies into trials

January 11, 2016

- Moderna is a high-profile, privately held biotech company specializing in leverage messenger RNA (mRNA), with the goal of inducing the body to produce its own therapeutic proteins.
- After a long run-up period in which it has built a large pipeline, Moderna has partnered with PPD, a CRO, to help advance its candidates into clinical trials.
- Moderna has many high-profile investors, including large pharma companies like Merck and AstraZeneca.

6.3. Mylan's Biosimilar Collaboration with Momenta

January 11, 2016

- Mylan N.V. announced that it has entered into an exclusive global collaboration agreement with Momenta Pharmaceuticals, Inc., to develop, manufacture and commercialize six of Momenta's current biosimilar candidates, including Momenta's biosimilar candidate, ORENCIA® (abatacept).
- Mylan CEO, Heather Bresch, commented, "Mylan's long-stated strategy has been to strategically invest in the long-term drivers of our future growth, both through our strong internal focus on R&D and through external collaboration with industry-leading partners.

6.4. Tensha Therapeutics To Be Acquired By Roche.

December 22, 2015

- Tensha Therapeutics, a privately-held company based in Cambridge, MA, announced it will be acquired by Roche.
- Founded by James E. Bradner, MD, of the Dana-Farber Cancer Institute, and managed and funded by HealthCare Ventures, Tensha has developed a pioneering epigenetic technology that disrupts bromodomain and extra terminal domain (BET) proteins in order to develop potential treatments for cancer.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Summit Therapeutics gets European patent for antibiotic ridinilazole

January 22, 2016

- Summit Therapeutics plc, a drug discovery and development company advancing therapies for Duchenne muscular dystrophy and Clostridium difficile infection (CDI), announced that the European Patent Office (EPO) has granted a key patent covering the novel antibiotic, ridinilazole, and that the opposition period has expired with the patent having faced no challenge.
- The patent covers the use of ridinilazole for the treatment of infections caused by the bacterium Clostridium difficile.

7.2. NCRM, Chennai gets Japanese patent for nanotechnology based corneal stem cell transplantation methodology January 23, 2016

- Chennai-based Nichi-in Centre for Regenerative Medicine (NCRM) and their Japanese collaborators have received Japanese patent for nanotechnology based corneal endothelial precursor cell transplantation (CEPCT) methodology.
- This patent, when licensed to interested institutes, will help large number of patients suffering from standalone corneal endothelial diseases, said Yoshio Morozumi, chairman of Nichi-In from Tokyo, Japan.

7.3. USPTO grants patent for Kadimastem's innovative technology in diabetes treatment January 23, 2016

- Israeli biotechnology company Kadimastem announced it has received patent allowance from the United States Patent and Trademark Office (USPTO), for its innovative technology in the field of diabetes treatment.
- The patent is for a method of producing insulin-secreting cells from stem cells, and it is likely to constitute the foundation for the company's products in the field of stem-cell based treatment of diabetes. Additionally, the company is in the process of receiving approval for the patent in Europe, Japan, Canada, Australia and Israel.

TECHNOLOGY/NDDS NEWS

8.1. Glide Technologies Announces Successful Proof-of-Concept With Novel Exenatide Solid Dose Formulation January 23, 2016

- Glide Technologies, the development company focused on solid dose formulations of therapeutics and vaccines, announced that the Company has successfully completed a pre-clinical proof-of-concept study with its novel solid dose formulation of exenatide, a GLP-1 agonist for the treatment of type 2 diabetes.
- Results from the pharmacokinetic study show that there was no statistical difference between Glide's solid dose formulation and the clinical dose of Byetta® (exenatide 10 mcg), the currently marketed liquid product.
- Glide's solid dose formulations are designed to be delivered using the Company's self-administered, user-friendly, needle-free SDI® injector. The technology has the potential to significantly improve patient compliance, which is important where self-administered injections are required, such as in diabetes.

8.2. Takeda's Dexilant SoluTab (dexlansoprazole) - a PPI with DDR technology January 23, 2016

- Dexilant SoluTab is a PPI with dual delayed release (DDR) technology that is designed to provide two separate releases of medication.
- Takeda Pharmaceuticals U.S.A., Inc., announced that the United States (U.S.) Food and Drug Administration (FDA) approved Dexilant SoluTab delayed-release orally disintegrating tablets, a new formulation of dexlansoprazole that can be taken by allowing the tablet to melt in the patient's mouth.
- Dexilant SoluTab is a proton pump inhibitor (PPI) indicated for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) and the maintenance of healed erosive esophagitis (EE) and relief of heartburn in adults 18 years and older.