Lambda Research Newsletter

November 2019

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Contact Us

Dr. Tausif Monif
President-Global operations
tausifmonif@lambda-cro.com

Dr. Mrinal Kammili
Executive Director-Global Head, BD
mrinal@lambda-cro.com

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Volume 11 / November 2019

Clinical Research NEWSletter

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Contents

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Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 11 / November 2019

GLOBAL NEWS

1. Gene contributing to autism and schizophrenia identified

A gene that plays a critical role in brain development and contributes to the development of autism spectrum disorders (ASD) and schizophrenia has been identified by the Researchers at the Case Western Reserve University School of Medicine.

Cullin 3 (CUL3) is a core component of an E3 ubiquitin ligase responsible for the cell's clearance of proteins. The mutations of gene CUL3 have been associated with autism and schizophrenia. This discovery was published in the journal *Neuron*, and provides an important insight into the mechanism of ASD and schizophrenia.

Alteration in the gene in mouse models resulted in similar social problems that appear in people with ASD and schizophrenia. Normal mice would spend more time with a mouse over an inanimate object, but CUL3-mutant mice couldn't differentiate between a mouse and an inanimate object, showing a problem with social preference.

Source: news-medical.net

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

2. Public private partnership for advances in the treatment of lung cancer

UNIVERSITAT DE BARCELONA
Facultat de Medicina i Ciències de la Salut

A public-private partnership among the Hospital Clínic de Barcelona, The University of Barcelona (UB) and Boehringer Ingelheim is established in order to improve the efficiency of nintedanib. It is an antiangiogenic and antifibrotic drug indicated for the treatment of lung cancer.

The researchers have identified molecular mechanisms underlying the lack of efficiency of nintedanib in squamous cell carcinoma, a sub-type of non-small cell lung cancer.

Nintedanib was developed by Boehringer Ingelheim and has demonstrated effectiveness in patients with advanced lung adenocarcinoma. It inhibits the receptors involved in the formation of new vessels (angiogenesis) and fibrosis, which drive tumor progression.

The current study analyzed tumor fibrosis (chronic tissue scarring) and the response to the antifibrotic treatment with nintedanib, in cells and tissue samples from lung cancer patients to identify the causes of the differences between the two main sub-types of non-small cell lung cancer. The samples were provided by Hospital Clinic, the Respiratory Diseases Networking Biomedical Research Centre (CIBERES) and the Spanish Society of Pneumology and Thoracic Surgery (SEPAR).

The findings of their research were published in the journal *Cancer Research*. This study could have implications in the design of new therapeutic strategies to expand the clinical benefits of the drug to a larger spectrum of patients with lung cancer.

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

3. Novel protein tag approach to study the immune system

GHENT UNIVERSITY

Researchers from VIB-Ghent Center for Medical Biotechnology, University of Iowa (USA) and other collaborators, developed a novel approach to better understand a basic defense mechanism of our immune system.

Central is ISG15, a small protein with a role in the immune system. The scientists can now identify and study proteins tagged with ISG15 with the newly developed method. This will allow them to study its many functions in fighting diseases. This is potentially expected to unveil novel antimicrobial drugs.

Proteins carry out all types of biological functions in our body. Cells can attach a chemical 'tag' onto a protein to keep control of the expressed proteins. One of the most well-known proteins ‘tag’ is a small protein, called ubiquitin. ISG15 is an ubiquitin-like ‘tag’. The molecular function of ISG15 is elusive. ISG15 and ubiquitin share the same amino acid sequence at their end, exactly where these modifiers are attached to target proteins.

ISG15 is absent under normal conditions unlike ubiquitin. ISG15 is only expressed upon stresses such as a viral or bacterial infection. Thus, they had to complement their approach with an infection model.

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

GLOBAL NEWS

4. Patient's access to information - an industry 'opportunity'

CSL Behring
Biotherapies for Life™

The patients' access to the information in current days is an opportunity for companies to integrate their direct feedback.

Patient centricity remains one of the main topics of discussion during events that bring together experts in the industry.

In his keynote interview during the Financial Times Pharmaceutical & Biotechnology Conference, Lutz Bonacker, CSL Behring's SVP and GM for Europe, stated that "neither I nor any of my 25,000 colleagues have the word 'patient' in their job title, because this should be everybody's job."

Especially the rare and chronic diseases, where the patient's journey through life is accompanied by their disease. The pharmaceutical companies have to understand the whole journey at different stages for more patient centric approaches.

Patients' access to information through the internet should be seen as an 'empowerment component' and an 'opportunity' for the industry to establish a closer communication with patients.

Source: outsourcing-pharma.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 11 / November 2019

PHARMA INDIA

1. National guidelines for gene therapy product development and clinical trials

The Indian Council of Medical Research (ICMR), and the Department of Biotechnology (DBT) has released the National Guidelines for Gene Therapy Product Development and Clinical Trials 2019. These guidelines will cater to the requirements for gene therapy trials.

These guidelines outline the ethical and scientific requirements for gene therapy trials focusing on patient safety and efficacy. The agencies plan to update the guidelines periodically on the basis of scientific development in the field.

The Department of Health Research (DHR) under Union Health Ministry has already constituted 'Gene Therapy Advisory and Evaluation Committee (GTAEC)' as an independent body of experts representing diverse areas of biomedical research, concerned government agencies and other stakeholders.

The gene therapy products come under the category of 'new drug' and shall always be deemed to be 'new drug' as per the New Drugs and Clinical trial Rules (2019). Thus, as per these rules 'academic trials' are not applicable to clinical trials using GTPs.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 11 / November 2019

PHARMA INDIA

2. New protein that plays a significant role in reducing obesity identified

A team of scientists from Hyderabad's Centre for Cellular and Molecular Biology (CCMB) has discovered a new protein called 'secretagogi'. This protein plays a significant role in increasing insulin action in obesity-induced diabetic patients.

Secretagogi protein binds to insulin and protects it from various stresses and increases its stability and adds to its action. The researchers are still working towards understanding the processes regulating insulin synthesis, maturation, secretion and signaling in diabetes patients.

"At present there is a lot that is yet to be understood about the process of functioning of insulin. However as part of research by our research team at CCMB, by injecting secretagogi into obese and diabetic mice, it has given promising results of reduction in excess insulin from the blood circulation and it has also reduced fat mass in the mice" – said Dr. Rakesh Mishra, director CCMB.

The researchers also tested the impact of secretagogi on other animals apart from mice which showed lower levels of harmful LDL- cholesterol and lower lipid accumulation in the liver cells. The discovery of this new protein will give a big boost to provide better solution for obesity and diabetic patients.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

PHARMA INDIA

3. SMART immunologics for cancer management

A sustainable, manageable, adaptive, resourceful and translatable (SMART) approach to cancer care through different collaborations is planned to be introduced in India.

The use of SMART immunologics for cancer care is increasing globally. The recent approvals of Chimeric Antigen Receptor (CAR) T-Cell therapy products have set the stage for a new generation of SMART immunologics. Immunologics for cancer combat in recent years led to the approval of CAR-T therapies. There are over 20 companies working on CAR-T globally.

As India starts to get on the CAR-x map, the support from collaborators, regulators, government institutions, hospitals, academic scientists, clinicians and financial institutions is required.

India is working on a bench to bedside translation through collaboration with IIT-Bombay which will be engaged in product and technology development.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

PHARMA INDIA

4. DCGI issues clarification on environmental conditions for regulated equipments

The Drugs Controller General of India (DCGI) has clarified that the environmental conditions as per Medical Devices (MD) Rules, 2017 will be applicable for the equipments which are to be regulated from next year. For the equipments, which are going to be regulated from January 1 and April 1, 2020, various stakeholders had sought clarifications regarding the environmental conditions.

DCGI has issued a notice clarifying that the environmental conditions referred in the fifth schedule, annexure 'A' of Medical Devices Rules, 2017, will be applicable for equipments regulated from next year such as: well-ventilated area with neat and clean environment, free from dust and other particulate matter, air conditioning etc.

The Central Drugs Standard Control Organization (CDSCO) has mandated that medical devices will require registration and import licensing under the MD Rules, 2017. These devices include all implantable medical devices, CT scanning equipment, X-ray equipment, MRI equipment, dialysis machines, bone marrow cell separators, defibrillators and PET equipment. The CDSCO has also identified four other device types including nebulizers and digital thermometers that will come under the MD Regulations, 2017, starting in January 2020.

The pharmaceuticals companies, both the old companies and new market entrant in medical device segment, will have to register with CDSCO by April 2020 in order to continue legally marketing these products.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

1. Requesting a certificate of confidentiality: FDA unveils draft guidance

The US Food and Drug Administration (FDA) has released a draft guidance for certificates of confidentiality (CoCs).

These certificates can prevent researchers from being compelled to disclose identifiable, sensitive information about research participants.

The 7-page draft explains. “Genomic data also are often considered to fall automatically into the category of identifiable, sensitive information.”

The FDA suggests that sponsors should check the below mentioned questions before submitting a request for a CoC:

- Does the human subject research collect identifiable, sensitive information?
- Does the human subject research, for which a discretionary CoC is being requested, involve the use or study of a product subject to FDA’s jurisdiction and subject to FDA’s regulatory authority?
- Are the requestor’s research measures sufficient to protect the confidentiality of the identifiable, sensitive information?

According to the guidance, the agency will send an electronic response letter to the requestor indicating whether or not the CoC has been granted after a thorough review of the request by FDA. If granted, that letter will serve as the CoC. The NIH-funded investigators do not have to apply for a CoC.

Source: raps.org

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

2. IMDRF clinical guidelines for medical devices

The International Medical Device Regulators Forum (IMDRF) has released the final guidelines for medical devices, and has replaced the earlier versions of the documents developed by the Global Harmonization Task Force (GHTF) for:

- Clinical evaluations (30 pages)
- Clinical investigations (11 pages)
- Clinical evidence (8 pages)

Clinical Evaluations: methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the medical device

- Contains lifecycle of a device
- Used to determine what data will be necessary for marketing a device and the requirement of clinical investigations
- Provides an overview of the general principles of clinical evaluation for medical devices, *in vitro* diagnostics (IVDs) and software as a medical device (SaMD) product

Clinical Investigations:

- Insights on requirements of clinical investigation
- General principles for designing a clinical investigation
- Ethical considerations for protecting human subjects involved in clinical investigations
- Should be considered when data is needed to demonstrate the safety, clinical performance or benefit/risk profile of a device that cannot be gathered from other sources, including scientific literature and nonclinical testing

Clinical Evidence: Clinical evidence itself is defined as “clinical data and its evaluation pertaining to a medical device” and is used to support the marketing of a device.

Source: raps.org

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 11 / November 2019

REGULATORY ROUND-UP

3. FDA OPDP criticizes drug company for failing to disclose risk info online

The US Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) has issued a letter to Rockwell Medical regarding a webpage that only presents information about the benefits of its drug Triferic (ferric pyrophosphate citrate), and lack on the information pertaining to the product's risk profile.

The letter details how Rockwell Medical omitted the risks associated with Triferic on its website. The company has failed to provide information related to the side effects of the drug and has created a misleading impression about the product's safety. Furthermore, the company has also claimed that Triferic is safer and more effective than other IV iron replacement products. This was also taken into notice by OPDP.

"This is particularly concerning given claims made on the webpage such as 'Triferic improves the effectiveness of iron delivery for the majority of dialysis patients. This broad claim suggests that Triferic is indicated for patients receiving any type of dialysis, when it is not intended for use in patients receiving peritoneal dialysis and its safety and effectiveness for use in patients receiving home hemodialysis have not been studied," the letter says.

Source: raps.org

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

REGULATORY ROUND-UP

4. CDSCO to review medical devices to improve safety and quality

The Government of India has issued a draft notification to bring all medical devices, including implants and contraceptives, under the purview of the Central Drugs and Standard Control Organization (CDSCO) in order to improve their safety and quality. The Ministry of Health and Family Welfare plans to define all medical devices as drugs under the Drugs and Cosmetics Act effective December 1. The government has sought comments from all stakeholders within 30 days before the draft notification is finalized.

Now, the CDSCO will certify the import, manufacture and sale of all medical devices. Manufacturers will also have to seek licenses from the Drug Controller General of India (DCGI).

The draft notification also plans to recategorize medical devices that are used for life support, diagnosis, treatment or alleviation of any disease or disability, and even devices that are used to disinfect other medical devices.

Source: raps.org

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

1. Pancreas-targeted immunomodulators: Pandion collaborates with Astellas

Pandion Therapeutics has signed a license and collaboration deal with Astellas Pharma to research, develop, and commercialize locally acting immunomodulators for autoimmune diseases of the pancreas. The deal is worth up to $795m.

The modular biologics and functional immunology expertise of US-based Pandion Therapeutics will be combined with the advanced therapeutics development and global commercialization capabilities of Astellas for the treatment of autoimmune diseases under this collaboration.

Pandion Therapeutics could receive up to $45m as upfront and payments pertaining to research and preclinical activities. Furthermore, Astellas will pay >$750m in future development and commercial milestone payments. Under this agreement:

- Design and discovery of bispecific drug candidates will be handled by Pandion Therapeutics based on its modular immune effector and tissue tether platform
- Astellas will carry out preclinical, clinical and commercialization activities for the selected candidates emerging from the collaboration

Source: globalpharmaupdate.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

2. Regeneron and Vyriad collaborate to develop oncolytic virus-based therapy

Regeneron Pharmaceuticals has entered into a research collaboration and option licencing agreement with Vyriad to discover and develop new oncolytic (cancer-killing) virus-based treatments for various forms of cancer. A five-year research agreement will be signed by the companies to use Regeneron's VelociSuite technologies to jointly design and validate Vesicular Stomatitis Virus (VSV)-based oncolytic virus treatments.

A phase 2 clinical study will be conducted under this partnership in 2020 to evaluate Regeneron's PD-1 inhibitor Libtayo (cemiplimab-rwlc) in combination with Vyriad's oncolytic virus Voyager-V1. These will be evaluated in multiple types of cancer, including melanoma, lung, liver and endometrial cancers.

Libtayo, a fully-human monoclonal antibody immune checkpoint receptor PD-1 (programmed cell death protein-1) inhibitor, is being developed and commercialized by Regeneron and Sanofi. Vyriad's Voyager-V1 is an investigational drug candidate, a potent VSV designed to selectively attack cancer cells and activate the immune system to destroy local and distant cancer cells.

Source: globalpharmaupdate.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Novartis bolt-on acquisition of inclisiran

Novartis has announced the bolt-on acquisition of Medicines Co., with a proposed $9.7bn deal which adds company's sole drug candidate, inclisiran, to its cardiovascular disease (CVD) pipeline. Novartis is betting that this one product will become "one of the largest products by sales" in its portfolio.

Inclisiran was shown to be able to reduce LDL-C alongside standard of care in clinical trials. Patients who are at higher risk of cardiovascular events from high LDL-C, inclisiran could contribute significantly to improved patient outcomes and help healthcare systems address the leading global cause of death.

Three phase 3 clinical trials are already completed for its potential use in CVD indications, atherosclerotic CVD and low-density lipoprotein cholesterol (LDL-C) in people with heterozygous familial hypercholesterolemia.

The company plans regulatory filings in the US in the fourth quarter of 2019 and in Europe during the first quarter of 2020.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

4. CAR NK-cell therapy platform: Takeda and MD Anderson collaborate

The University of Texas MD Anderson Cancer Center and Takeda Pharmaceutical Company Limited have entered an exclusive license agreement and research agreement to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR NK)-cell therapies, 'armored' with IL-15, for the treatment of B-cell malignancies and other cancers.

MD Anderson will provide access to Takeda to its CAR NK platform and the exclusive rights to develop and commercialize up to four programs, including a CD19-targeted CAR NK-cell therapy and a B-cell maturation antigen (BCMA)-targeted CAR NK-cell therapy. Armored CAR NKs could be administered off-the-shelf in an outpatient setting. This enables more patients to be treated effectively, quickly and with minimal toxicities.

Under this agreement, Takeda will be responsible for the development, manufacturing and commercialization of CAR NK products and make an upfront payment to MD Anderson, which is also eligible to receive development and commercial milestones for each target as well as tiered royalties on net sales of any such CAR NK product.

Source: businesswire.com

LAMBDA
Research Accelerated

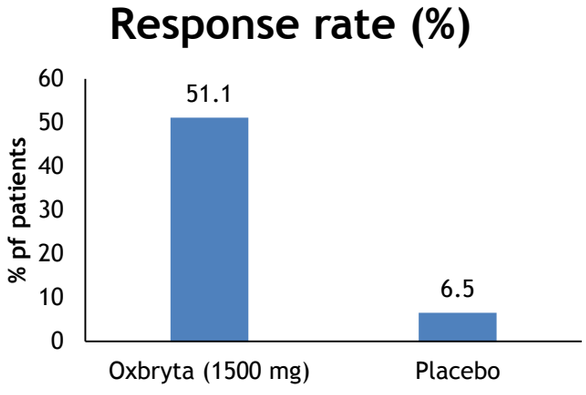
Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

DRUGS: APPROVALS AND LAUNCHES

1. FDA approves voxelotor to target abnormality in sickle cell disease

The U.S. Food and Drug Administration has granted accelerated approval to Oxbryta (voxelotor) for the treatment of sickle cell disease (SCD) in adults and pediatric patients ≥12 years of age.



Voxelotor has demonstrated the inhibition of red blood cell sickling, improved red blood cell deformability (ability of a red blood cell to change shape) and improved the blood's ability to flow in nonclinical studies.

This therapy provides a new treatment option for patients with this serious and life-threatening condition. Oxbryta's approval was based on the results of a clinical trial with 274 patients with sickle cell disease.

Effectiveness was based on an increase in hemoglobin response rate in patients. Common side effects for patients taking Oxbryta were headache, diarrhea, abdominal pain, nausea, fatigue, rash and pyrexia (fever).

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

2. FDA approves givosiren - first treatment for acute hepatic porphyria

The US Food and Drug Administration has approved givosiran (Givlaari — Alnylam Pharmaceuticals) for the treatment of adults with acute hepatic porphyria.

The rare genetic disorder causes the buildup of toxic porphyrin molecules, which are formed during the production of heme.

The FDA has approved givosiran based on the results of a clinical trial involving 94 patients with acute hepatic porphyria. In this study, frequently reported adverse events for patients taking the drug were nausea and injection site pain. The FDA has also issued an advice to health care providers to monitor patients for anaphylactic reaction and renal function.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

3. Xcopri (cenobamate) approved for partial onset seizures

The US Food and Drug administration (FDA) has approved cenobamate (Xcopri) for the treatment of partial-onset (focal) seizures in adults.

Cenobamate is a "new option to treat adults with partial-onset seizures, which is an often difficult-to-control condition that can have a significant impact on patient quality of life," said Billy Dunn, MD, director of the Office of Neuroscience in the FDA's Center for Drug Evaluation and Research.

The FDA has approved the drug based on the results of two phase 2 trials, including 655 adult patients with partial-onset seizures with or without secondary generalization. Cenobamate doses of 100, 200, and 400 mg daily reduced the percent of seizures over 28 days in the trials compared with placebo.

SK Life Science, a subsidiary of SK Biopharmaceuticals, is commercializing cenobamate in the U.S., while the Swiss company Arvelle Therapeutics holds the European rights. The drug is expected to be available in the U.S. in the second quarter of 2020.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

DRUGS: APPROVALS AND LAUNCHES

4. FDA approves Astra Zeneca's Calquence

The U.S. Food and Drug Administration (FDA) had approved Astra Zeneca's Calquence to treat chronic lymphocytic leukemia (CLL), one of the most common types of leukaemia in adults.

The drug was approved under a new speedy review programme in collaboration with drug watchdogs in Canada and Australia, and was also approved to treat small lymphocytic lymphoma, a similar disease.

The shares of AstraZeneca rose 2.7% after the company won earlier-than-expected U.S. regulatory approval for the leukaemia drug.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Phase 3 study of sovateltide to treat acute cerebral ischemic stroke

Pharmazz, a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat patients in critical care, has initiated the dosing in the phase 3 clinical trial assessing sovateltide (PMZ-1620) for the treatment of acute cerebral ischemic stroke.

The results from the previous phase 2 study of sovateltide presented at the 2019 American Heart Association Scientific Sessions, 2019, showed that sovateltide was associated with significant improvement on the NIHSS, mRS, and Barthel Index (BI) compared to standard treatment in patients with acute ischemic stroke.

At day 90 posttreatment:

- In the sovateltide group, 60.87% of the patients saw an improvement of >2 on the mRS compared with 39.13% of patients in the placebo cohort
- Improvements of >40 on the BI (P = .0112) were seen in 36% and 64% of patients in the control and sovateltide group, respectively.
- The sovateltide group saw a larger number of patients achieve a NIHSS score of 0 (P = .04791), mRS of 0 (P = .1193) and BI of 100 (P = .02795) compared with the placebo group.

Source: worldpharmanews.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Positive results from SAkuraSky study of satralizumab

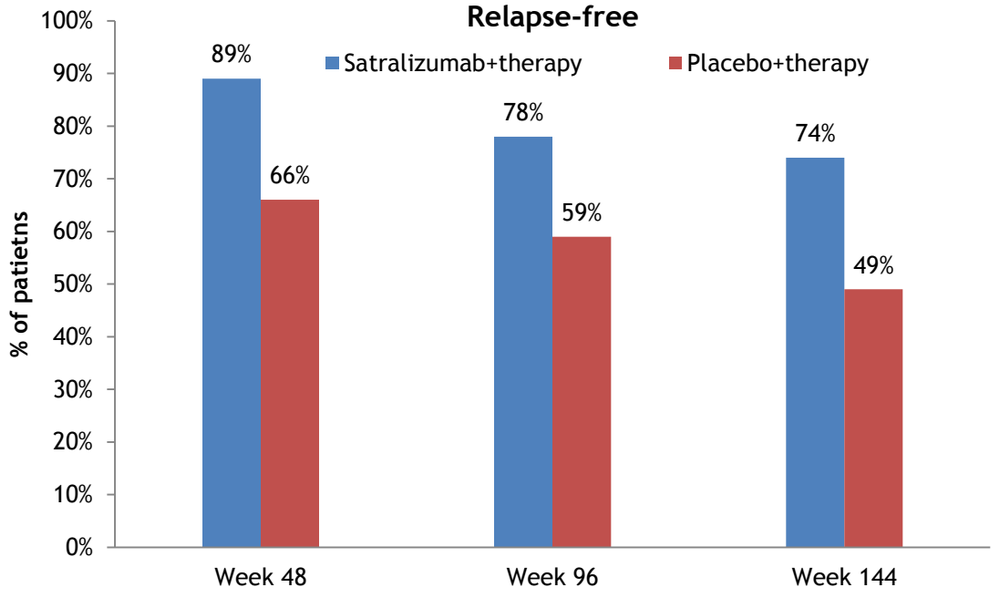
Roche has announced positive results from the SAkuraSky trial, a pivotal phase 3 study of the investigational medicine satralizumab for the treatment of neuromyelitis optica spectrum disorder (NMOSD). These results were published in the *New England Journal of Medicine* (NEJM).

Satralizumab inhibits interleukin-6 (IL-6) signaling, a key player in the inflammation that occurs in people with NMOSD. Satralizumab can be self-administered every four weeks by subcutaneous injection.

In the overall study population, only 20% patients treated with satralizumab in combination with baseline immunosuppressant therapy experienced a protocol-defined relapse (PDR) vs. 43% treated with placebo in combination with baseline therapy (HR=0.38, 95% CI: 0.16-0.88; p=0.02).

Satralizumab has been designated as an orphan drug in the US, Europe and Japan. In addition, it was granted Breakthrough Therapy Designation for the treatment of NMOSD by the FDA in December 2018.

Source: pharmatimes.com



LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. NEURO-TTRansform phase 3 clinical trial for AKCEA-TTR-LRx

AKCEA™ THERAPEUTICS
A subsidiary of Ionis Pharmaceuticals, Inc.

Akcea therapeutics has announced initiation of the NEURO-TTRansform phase 3 clinical trial for AKCEA-TTR-LRx in patients with polyneuropathy caused by hereditary TTR amyloidosis, or hATTR amyloidosis.

AKCEA-TTR-LRx is an antisense drug developed using Ionis' proprietary LIgand Conjugated Antisense (LICA) technology platform and is designed to inhibit production of TTR. It has shown reductions in TTR of up to 94% in a phase 1 clinical study.

NEURO-TTRansform Phase 3 Study Design

- A global, open-label, randomized study to evaluate the efficacy and safety of AKCEA-TTR-LRx in patients (n=140) with polyneuropathy due to hATTR amyloidosis
- Compared to the historical placebo arm from the TEGSEDI® (inotersen)
- Of 140 participants, 20 patients will begin on TEGSEDI and move to AKCEA-TTR-LRx after week 35

The co-primary efficacy endpoints at week 66 are:

- Percent change from baseline in serum TTR concentration;
- Change from baseline in the modified Neuropathy Impairment Score +7 (mNIS+7), a measure of neuropathic disease progression; and
- Change from baseline in Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (Norfolk QoL-DN)

Source: biospace.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

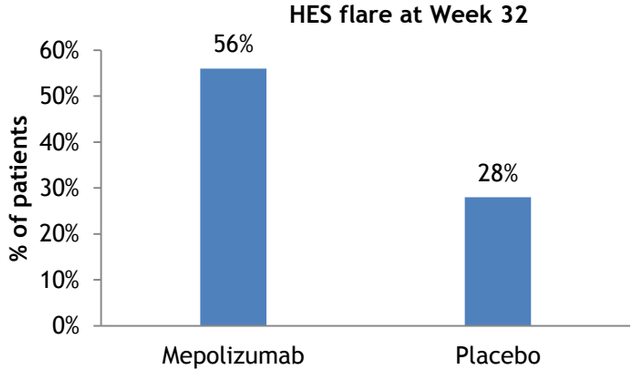
Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Phase 3 study of mepolizumab meets primary endpoint

GlaxoSmithKline plc (GSK) announced positive results from the pivotal study of Nucala (mepolizumab) in the treatment of patients living with Hypereosinophilic Syndrome (HES).

Mepolizumab is the first treatment to demonstrate a reduction in flares for this rare disease.



A statistically significant (p=0.002) result with 50% fewer patients experiencing a HES flare (worsening of symptoms or eosinophil threshold requiring an escalation in therapy) was reported with mepolizumab, compared to placebo, when added to standard of care treatment over the 32-week study period (56% vs. 28%).

Mepolizumab is not approved for use in HES anywhere in the world. GSK is planning to progress for regulatory submissions in 2020 based on these data.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Oramed gets Japanese patent for protease inhibitors

Oramed Pharmaceuticals Inc. has received its Japanese patent for the technology "Protease Inhibitor – Containing Compositions, Compositions Comprising Same, and Methods for Producing and Using Same" by the Japanese Patent Office.

Oramed is a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems.

Oramed has developed a novel Protein Oral Delivery (POD™) and is seeking to revolutionize the treatment of diabetes through its proprietary lead candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of type 1 and type 2 diabetes. Furthermore, Oramed is developing an oral GLP-1 (Glucagon-like peptide-1) analog capsule, ORMD-0901, which has potential to be the first orally-ingestible GLP-1 analog.

Source: prnewswire.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. HHS filed patent infringement lawsuit against Gilead

The U.S. Department of Health and Human Services (HHS) has filed a patent infringement lawsuit against Gilead Sciences, Inc. (Gilead). In the lawsuit, HHS is "seeking damages for Gilead's infringement of HHS patents related to pre-exposure prophylaxis (or PrEP) for HIV prevention."

The U.S. government holds the patents on PrEP. The complaint filed by HHS alleges that Gilead has infringed the patents for PrEP by selling both Truvada and Descovy. The HHS has also alleged that Gilead was aware about the patents for PrEP and has "willfully" infringed them and described Gilead's conduct as "malicious, wanton, deliberate, consciously wrongful, flagrant, and in bad faith."

Source: producer.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWS letter
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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Nativa to receive compulsory license for Pfizer's sunitinib

Russian generic drugmaker Nativa will receive a compulsory license on the production of an antitumor drug Sutent (sunitinib).

Sutent (sunitinib) is originally produced by the USA's Pfizer.

Nativa has received the compulsory license to use Pfizer's patent for sunitinib by the Moscow Arbitration Court on January 25, 2019. This decision was confirmed by the Russian Ninth Arbitration Court of Appeal later in the year, and in the meantime, Pfizer described the decision as "unprecedented, which kills all the basics of patent law in Russia." The company is planning to appeal it in the highest Russian courts.

Nativa to pay royalties to Pfizer to the amount of 10% of the price revenue of sunitinib in the Russian market under the terms of the latest state decision.

Source: pharmabiz.com

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Volume 11 / November 2019

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Purdue Pharma bankruptcy case: lawsuit protection extended

A bankruptcy judge has ruled that lawsuits against Perdue pharma and Sackler family who own it will be frozen for at least 180 days.

A temporary injunction was put in place last month which expired recently. This order has restored the temporary injunction. It came over the objections of some litigants who have argued that the Sackler family does not deserve such legal protection.

The maker of OxyContin 'Purdue Pharma' had filed for bankruptcy earlier in September 2019 as part of a broad opioid settlement proposal with 24 states.

Source: washingtonpost.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

TECHNOLOGY /NDDS

1. Detection of cancer - tiny devices developed

A new cancer-detecting tool, which uses tiny circuits made up of DNA has been developed by the Researchers from Duke University in the US. This device identifies cancer cells by the molecular signatures on their surface.

The research team fashioned the simple circuits from interacting strands of synthetic DNA that are tens of thousands of times finer than a human hair. These circuits attach to the outside of a cell and analyze it for proteins found in greater numbers on some cell types than others. Upon finding the targets, the circuit labels the cell with a tiny light-up tag. "As a result they're much less likely to flag the wrong cells," said study researcher John Reif. This study is published in the *Journal of the American Chemical Society*.

The researchers think that this technology could be used as a screening tool to help rule out cancer, which could mean fewer unnecessary follow-ups, or to develop targeted cancer treatments with fewer side effects.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

TECHNOLOGY /NDDS

2. Drug coated balloon to heal AV fistulas

The US Food and Drug Administration has approved Medtronic's IN.PACT AV drug-coated balloon as a treatment option for failing arteriovenous (AV) fistulae. Medtronic's IN.PACT AV drug-coated balloon (DCB) is designed to treat restenosis within AV fistulae.

The device releases paclitaxel, an anti-proliferative, into the vessel walls around itself during balloon inflation and structural reconstruction of the fistula. This slows the process of restenosis and should reduce the number of such procedures that are required.

The FDA approval is based on data from a prospective, global, multicenter, blinded, randomized (1:1), investigational device exemption (IDE) study, which showed that patients treated with IN.PACT AV DCB maintained patency longer and required 56% fewer reinterventions compared to those treated with standard percutaneous transluminal angioplasty through six months.

Source: medgadget.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

TECHNOLOGY /NDDS

3. Smart microscope to diagnose infectious diseases

Researchers at Duke University have developed a microscope that can intelligently adjust its settings, including the light angles, color, and patterns. This function helps in achieving optimal results when classifying healthy and malaria infected red blood cells.

Rather than to address the capabilities of human eye, the system is designed to address the capabilities of a digital camera, and so can perform incredibly well.

“A standard microscope illuminates a sample with the same amount of light coming from all directions, and that lighting has been optimized for human eyes over hundreds of years,” said Roarke Horstmeyer, the lead researcher. “But computers can see things humans can’t. So not only have we redesigned the hardware to provide a diverse range of lighting options, we’ve allowed the microscope to optimize the illumination for itself.”

According to the researchers, this technology can be used to other diagnostic imaging tasks, potentially automating entire processes that happen in hospital pathology labs.

Source: medgadget.com

LAMBDA
Research Accelerated

Volume 11 / November 2019

Clinical Research NEWSletter
www.lambda-cro.com

TECHNOLOGY /NDDS

4. Protection of pacemakers

A cellulose membrane to cover and protect implantable devices, such as pacemakers developed by the researchers at ETH Zurich has proved successful in animal trials in reducing the undesirable build-up of fibrotic tissue around the implant. In the next step, the protective membrane will be tested in patients. The findings of their research are published in the journal *Biomaterials*.

"Every pacemaker has to be replaced at some point. When this time comes, typically after about five years when the device's battery expires, the patient has to undergo surgery," explains Aldo Ferrari, Senior Scientist in ETH Professor Dimos Poulikakos's group and at Empa. Furthermore, the formation of fibrotic tissues around the pacemaker may complicate the procedure and a surgery is required to cut into and remove excessive tissue.

In the animal testing of the membrane, the researchers implanted membrane-coated pacemakers in pigs and left them in situ. After 1 year, the membranes were well-tolerated and the fibrotic layer that formed on the membrane was only 1/3rd as thick as those on uncovered pacemakers. The researchers are planning to conduct a clinical trial at three large cardiac centers in Germany based on these promising results.

Source: medicalnewstoday.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 11 / November 2019

WHAT'S NEW AT LAMBDA

1. Successful completion of CAP inspection at CL Lab

The College of American Pathologist (CAP) completed its inspection of the Clinical Laboratory of Lambda Therapeutic Research Limited at Ahmedabad, Gujarat. The inspection was carried out on 21 November 2019. Overall, the inspection was successful without any major deficiency.

The successful completion of this inspection yet again proves Lambda's high end quality and impeccable track record.

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