Lambda Research Newsletter

July 2020

LAMBDA

Research Accelerated

Contact Us

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

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

LAMBDA

Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA

Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

1. New peptide derived nanoparticle drug for treating heart attack

The researchers from the Illinois University have developed a new drug that prevents blood clot without increased risk of bleeding. Currently available antiplatelet drugs prevent the blood clotting that causes heart attack and stroke. The study is published in the journal of "*Science Translational Medicine*".

There are two different ways that causes heart attack, one is initial damage caused by the clots and the second way is due to treatment procedure of angioplasty and stent to open the artery combined with antiplatelet drugs, However, fresh blood flowing into the damaged heart tissue following the reopening of the artery can leads to inflammation and causing leaks and clots in small blood vessels and further damage to the heart, this is called reperfusion injury that leads to heart failure and death.

In a previous study, the researchers have identified a signaling mechanism that is important mechanism in blood clots based on this finding the researchers have derived and designed peptide nanoparticle to target signaling mechanism.

This peptide nanoparticle called M3mP6 was tested in preclinical study and observed positive results. After administration of this treatment reduced clots, inflammation and damage to the heart that was improved heart function and increased survival rate.

This new mechanism would help limit reperfusion injury and reduce the chance of heart failure and death.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

2. SMART team found practical way to induce strong immunity against dengue

SMART
Singapore-MIT Alliance for Research and Technology

The researchers from Singapore-MIT Alliance for Research and Technology (SMART) and its enterprise in Singapore have found practical way to induce strong immunity to the dengue virus. Dengue fever is a mosquito-borne tropical disease, an every year approximately 100 million symptomatic infections were noted.

Currently, Dengvaxia® is the only vaccine available to fight against dengue, it consists of four variant dengue antigens, one for each of the four serotypes of dengue and it is expressed from yellow-fever virus. The doses of immunization with the tetravalent vaccine induces only suboptimal protection against DENV1 and DENV2.

People who have not been infected by dengue, the vaccine induces a more severe dengue infection in the future, for that reason the vaccination is only given to those patients who have been previously infected.

To overcome this issues, the SMART researchers tested on mice and found that the sequential immunization induced significantly higher levels of virus-specific T cell responses than tetravalent immunization and also sequential immunization induced higher levels of neutralizing antibodies to all four DENV serotypes. Sequential immunization induced higher levels of neutralizing to all four DENV serotypes than tetravalent vaccination.

Upon this result, the researchers will plan to test the sequential immunization in humans.

Source: news-medical.net

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

3. Anticoagulation agent reduces SARS-CoV-2 replication in vitro

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) gradually spread all over the world and causes acute respiratory distress syndrome, hypercoagulability, hypertension, and multi organ dysfunction. To improve overall prognosis, effective antiviral with safe clinical profile are urgently required.

The researchers have randomly collected cohort of 124 patients with COVID-19, they have found that hypercoagulability as indicated by elevated concentrations of D-dimers was associated with disease severity.

The authors identified an anticoagulation agent dipyridamole (DIP) *in silico*, which suppressed SARS-CoV-2 replication *invitro* using virtual screening of USFDA.

In a proof-of-concept trial involving 31 patients, DIP supplementation was associated with significantly decreased concentrations of D-dimers, increased lymphocyte and platelet recovery in the circulation.

Source: news-medical.net

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

4. Novel method for selecting the best drug therapy for cancer

The researchers at the Weizmann Institute of Science and the Broad Institute of MIT and Harvard have developed novel method for selecting best drug therapy for a tumor based on assigning scores to the cells.

This method helps physicians to choose from an existing treatments and also can helps to identify new molecular targets for the development of future drugs.

The researchers assigned to each pathway an activity score that takes into gene expression levels, knowledge about the structure of each pathway, the interactions of the genes within it, and whether a given gene blocks or stimulates the pathway's message.

After then the team correlated these scores with database containing information based on sensitivity of cancer cell. They were able to make such predictions for more than 30 existing drugs. They could use the pathway knowledge to not only predict, but to alter the cells' response to a drug.

The researchers have obtained lung cancer tissue, their analysis indicated the apoptosis-triggering pathway was not particularly active. In test-tube experiments, this lung cancer tissue was resistant to microtubule-inhibitor drugs but when, in addition to microtubule inhibitors, the researchers simultaneously applied a substance that increased activity in the apoptosis pathway, the combination of drugs effectively killed the cancer cells.

In further analysis of the datasets, the researchers correlated the activity scores of signaling pathways genes play such an essential role in various tumors that silencing, or blocking, these genes can kill the tumor. They found that pathway scores helped to identify such sensitive genes in a variety of tumors.

Source: news-medical.net

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

PHARMA INDIA

1. UK and India extend their collaboration for global fight against AMR

The United Kingdom and India are further extend their existing scientific research collaboration with five new projects for advances in the global fight against antibiotic-resistant bacteria and genes.

India is the global supply chain for the production of antimicrobial drugs and have better understanding how waste from antimicrobial manufacturing could be inadvertently fuelling anti-microbial resistance (AMR).

The UK is contributing four million pounds from the UK Research and Innovation Fund for International Collaboration and India is matching this with its own resources.

The UK has already partnered with India's Serum Institute to manufacture the vaccine for COVID-19, if clinical trials are successful they have planned to distribute vaccines to a billion of people across the developing world.

The UK is India's second-biggest research partner, with joint research expected to be worth 400 million pounds by 2021.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

PHARMA INDIA

2. DBT invites research proposals for COVID-19

The Department of Biotechnology (DBT) has invited call for proposals on BRICS STI Framework Programme in response to COVID-19 pandemic coordinated call for BRICS multilateral Research and Development (R&D) projects 2020. The aim of the BRICS STI Framework Programme is to support excellent research on priority areas.

DEPARTMENT OF BIOTECHNOLOGY
GOVERNMENT OF INDIA

The initiative should cooperate among the researchers and institutions and consist of at least three partners of the Brazil, Russia, India, China and South Africa (BRICS) countries.

The researchers are focused on research and development of new technologies for diagnosing COVID-19, including genomic sequencing of SARS-CoV-2 and studies on the epidemiology and mathematical modelling of the COVID-19 pandemic.

The another area of research includes AI, ICT and HPC oriented research for COVID-19 drugs design, vaccine development, treatment, clinical trials and public health infrastructures and systems and epidemiological studies and clinical trials to evaluate the overlap of SARS-CoV-2 and co-morbidities. The last date for submitting the application is August 24, 2020.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

PHARMA INDIA

3. Covaxin: India's first COVID-19 vaccine under CT at NIMS Hyderabad

Nizam's Institute of Medical Sciences (NIMS) is one of the 12 institutes selected by Indian Council of Medical Research (ICMR) for Phase-I clinical trials of the vaccine.

As part of the clinical trial, Covaxin is India's first Covid-19 vaccine, Covaxin was given in two volunteers at NIMS, who were received the first dose of the vaccine in the morning, both are stable and not observed any side effects and reaction. The volunteers will remain under the observation of a team of doctors remotely monitored for 14 days.

Hyderabad-based Bharat Biotech had announced that the Phase-I clinical trials began across the country on July 15. This is a randomized, double-blind, placebo-controlled clinical trial in 375 volunteers in India.

The SARS-CoV-2 strain was isolated and transferred to Bharat Biotech, This inactivated vaccine was developed and manufactured in Bharat Biotech's high containment facility located in Genome Valley, Hyderabad

Source: indiatvnews.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

PHARMA INDIA

4. NPPA directs orthopedic knee implants price data by 26th July 2020

The National Pharmaceutical Pricing Authority (NPPA) has informed that for price monitoring purpose companies of manufacturing and importing orthopedic knee implants to provide price data by 26th July 2020. As per NPPA notice the requisite data in the prescribed format shall be emailed on medicaldevices-nppa@gov.in.

To prevent unethical profit and ensure affordable and quality for a common man the Government fixed the ceiling prices of orthopedic implants.

NPPA has categorized knee implants in to two category:

1. Primary Knee Replacement Systems
2. Revision Knee Replacement Systems

In each category are includes four sub category Femoral Component, Tibial Component or Tibial Tray, Articulating Surface or Insert and Patella. There are there are super-sub-categories distinguishable based on feature or material such as titanium alloy, oxidized zirconium, Hi-flex, cobalt chromium, polyethene.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUND-UP

1. EMA'S new guideline on water quality

European Medicines Agency release new pharmaceutical water quality guideline that provides suggestions for the minimum acceptable quality of water to be used for the manufacture of sterile and non-sterile medicinal products and active substances.

Depending on the different pharmaceutical uses water quality grades are required. This new guideline applied to the manufacture of active substances for human, veterinary and advanced therapy of medicinal products and also apply to the investigational medicinal product manufacture.

The guideline said that the European pharmacopoeia has classified quality standards in three grades:

- Water for injections
- Purified water
- Water for preparation of extracts

Potable water should be the source feed water for the production of pharmacopeial grade waters.

Source: regulis.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

REGULATORY ROUND-UP

2. USFDA released draft guidance on cannabis clinical research

The US Food and Drug Administration (FDA) has released a draft for clinical research of cannabis-derived compounds.

The main psychoactive ingredient in cannabis are defined as hemp. Cannabis and its derivatives containing less than 0.3% of delta-9 tetrahydrocannabinol (THC).

According to the Drug Enforcement Administration (DEA), the products containing more than 0.3% are classed as Schedule I controlled substances. This guidance provides extensive instructions on how to calculate THC content in solution-based and solid oral dosage forms.

The guideline also provide detailed information about sampling and testing methods for evaluation of THC levels.

Source: regulis.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

3. EU agencies clarify PV expectations during pandemic

The European Medicines Agency (EMA) and European Commission and Heads of Medicines Agencies (HMA) have released guidelines to describe regulatory expectations for medicinal products during COVID-19 in April.

There are joint new three question answer related to pharmacovigilance (PV). New questions addressed corrective and preventive actions management, PV system audits and on-site PV inspections:

- Is there any impact on corrective and preventive actions under the PV provisions?
- Is there any flexibility in the planning and conduct of PV system audits?
- Which measures will be taken in difficulties to conduct on-site PV inspections during the COVID-19 pandemic?

The guideline also updated with the validity of good manufacturing practice (GMP) certificates, which are extended for the clarification, the sites located in the European Economic Area (EEA) and outsides of the area cannot receive extension for changes in the scope of the GMP certificate.

Source: regulis.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

4. FDA e-submissions for medical devices

The US Food and Drug Administration (FDA) has finalized new guideline for the structure of electronic submissions for medical devices.

The guidance has explained electronic submission:

- Premarket notifications (501k)
- De novo submissions
- Premarket approval applications (PMAs)
- Product development protocols
- Investigational device exemption applications
- Humanitarian device exemptions
- Emergency Use Authorisations
- Specified Investigational new drug applications (IND)
- Biological license applications (BLA)

Subsequent submissions of an original submission must also be done electronically.

Source: regulis.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

MERGERS /ACQUISITIONS /COLLABORATIONS

1. Takeda collaborate with Twist Bioscience to expand discovery capabilities

Twist Bioscience Corporation has collaborated with Takeda Pharmaceutical Company Limited to approach for the discovery, validation and optimization of antibodies in Takeda's pipeline of biologics for oncology, rare diseases, neuroscience, and gastroenterology.

Twist Bioscience has ability to generate strong, diverse libraries through its proprietary silicon platform simultaneous with Takeda's drug discovery and development to help in targeted biologic candidates.

According to the agreement, Takeda will receive license of "Library of Libraries" a synthetic antibody display libraries derived only from sequences that exist in the human body. Both the companies are jointly work to discover, validate and optimize new antibody candidates. Twist Bioscience will receive licensing fees as well as milestones and royalties for all compounds discovered from the Twist phage display libraries.

Source: selectscience.net

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

2. Gilead acquire Tizona Therapeutics in $300m

Gilead Sciences is acquire Tizona Therapeutics through an investment of $300m. Tizona has discovered antibody candidate to target HLA-G for different tumor types.

The US Food and Drug Administration has approved Tizona's antibody investigational new drug (IND) application for TTX-080 earlier.

Tizona will launch a Phase I trial of the candidate as monotherapy and combination therapy with advanced cancer patients in the third quarter of this year. Gilead has agreed to provide funding support for Tizona's ongoing research and development.

The completion of acquisition is expected for third quarter of this year. Gilead will have the right to appoint two individuals to Tizona's board of directors after closing of the deal.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Clarity collaborate with ImaginAb for new cancer targets

Clarity Pharmaceuticals has entered into a collaboration agreement with ImaginAb, Inc for the development of new targeted theranostic (diagnostic and therapy) products for cancer types. Clarity Pharmaceuticals is a radiopharmaceutical focused on the treatment of serious disease and ImaginAb, Inc. is a company that harnesses the specificity of monoclonal antibodies.

Both the companies will combine their proprietary technologies for the development of novel minibody and cys-diabody radiopharmaceutical products using Clarity's copper chelators. ImaginAb designs highly targeted proteins known as minibodies and cys-dibodies using standard Positron Emission Tomography (PET).

Clarity and Imaginab are already working together for manufacture, regulatory structures and clinical development of fast-track new theranostic products.

Source: itnonline.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

4. Roche and Jnana agreed with multi-target collaboration

Jnana Therapeutics has signed a multi-target collaboration and license deal with Roche for the discovery of small molecule drugs for the treatment of immune-mediated and neurological diseases.

Roche and the Massachusetts-based biotech company have agreed to work together on drug discovery and preclinical development for treatment of immune and neurological disease. The partnership will be further developed by the Swiss pharma and will get commercial rights.

Under the collaboration, the drug discovery and research work uses US firm's RAPID platform, which will screen small molecule libraries for identifying novel modulators of any SLC transporter. According to the US company, SLC transporters are a protein family which are different in mechanism and structure.

Under the agreement, Jnana Therapeutics will be paid $40m upfront in cash by the Swiss pharma major. The US firm will also receive research funding, preclinical, development, and commercialization milestone payments, and also royalties.

Source: pharmaceutical-business-review.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

1. FDA approves CAR T-Cell therapy for mantle cell lymphoma

The USFDA has approved third chimeric antigen receptor (CAR) T-cell therapy, it is the first cell-based gene therapy for the treatment of relapsed or refractory mantle cell lymphoma (MCL).

MCL is a type of non-Hodgkin lymphoma, It is occurring in cells from the “mantle” zone of the lymph node. MCL is an aggressive cancer and mostly affects men over age 60.

This is the second CAR T-cell therapy for Kite Pharma. This new CAR T-cell therapy will be manufactured by patient’s T cells and genetically modifying them and include a new gene that helps target and kill lymphoma cells. Then engineered T cells are then infused again into the patient. This therapy sold as Tecartus.

The USFDA has approved based on multicenter study of 60 patients with relapsed MCL and followed up at least 6 months. After treatment the complete remission rate was 62% and the objective response rate was 87%.

The availability of Tecartus as the first-ever cell therapy provides an important option with a response rate of nearly 90 percent.

Source: ajmc.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

2. Cipla gets DCGI nod to sell favipiravir under brand 'Ciplenza'

DCGI has approved Cipla to launch favipiravir in the country under the brand name Ciplenza for the treatment of mild to moderate COVID-19. As part of the unmet need Ciplenza will be launch in the first week of the august at price Rs. 68 per tablet.

Ciplenza has been jointly developed by Cipla and CSIR-Indian Institute of Chemical Technology (IICT). According to the partnership, CSIR-IICT has successfully developed a convenient and cost-effective synthetic process for Favipiravir. The whole process and API of the drug has been transferred to Cipla for manufacture and market the drug.

Favipiravir is an off patent oral antiviral drug uses to treat COVID -19 patients with mild to moderate symptoms.

Source: wefornews.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

3. EC approves subcutaneous Remsima for IBD and ankylosing spondylitis

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European commission has approved world's first subcutaneous formulation of infliximab for the treatment of inflammatory bowel disease and ankylosing spondylitis. This SC injection can be easy to administer by patients.

The SC formulation can be administer by patients themselves and reducing treatment time to approximately two-five minutes with a comparable efficacy and safety profile to the IV formulation of the drug.

The approval of the formulation is based on data from a pivotal study and comparing the efficacy and safety of the SC and intravenous (IV) formulations of Remsima in people with active crohn's disease and ulcerative colitis, throughout a one-year treatment period.

Based on the results of the pivotal study, Remsima has been approved 120mg fixed dose of SC for use in the EU.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

4. Teva UK launch Ajovy injector pen

Teva UK has launched a pre-filled pen Ajovy (fremanezumab) injection for migraine patients, it is more convenient and flexible dosing option and can be self-administer in the home.

Ajovy is used for the treatment of migraine in adults who have at least four episodes of migraine per month. It is well tolerated, effective and particularly useful for complex migraine patients.

This is the new Ajovy pre-filled pen has developed in the UK at Teva's research and development site. This pre-filled pen uses the push-down mechanism, button-free, audible sign that signal progress of administration, and a window that displays when the dose has been delivered. It can be apply into areas of the abdomen, thigh, or upper arm.

A pen device can easy for patients to self-administer and reduced appointment and waiting times.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Serum Institute conducts phase-III trial for COVID-19

Serum Institute of India Pvt Ltd (SIIPL) and Department of Biotechnology's National Biopharma Mission conducting phase III clinical trial of a recombinant BCG vaccine VPM1002 candidate.

The phase III, multisite randomized, double-blind placebo-controlled study to evaluate the ability of VPM1002 in reducing infection incidence and severe disease outcomes of COVID-19 among high-risk persons of co-morbidities and high-exposure healthcare workers (HCWs).

BCG vaccine is administered routinely to newborn babies as a part of the National childhood immunization programme to prevent tuberculosis (TB) an infection caused by bacteria and affects the lungs.

In clinical trial about 6000 health workers and high-risk individuals have been enrolled and trial to determine the recombinant Bacillus Calmette-Guerian (rBCG) immunity to fight against virus.

There are an urgent need to ensure the safety and health of HCWs, household contacts of COVID positive patients.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Zydus initiate clinical trials of Desidustat in CIA

The US Food and Drug Administration had approved Zydus to initiate clinical trials of Desidustat in chemotherapy induced anemia (CIA). CIA causes fatigue and impaired quality of life.

Zydus is a global, leading discovery based pharmaceutical company. Desidustat is a novel, oral, prolyl hydroxylase inhibitor.

Desidustat is expected to increase the red blood cell count and restore the erythropoietin levels to the normal levels in the cancer patients with CIA.

Phase III DREAM-ND trial is being conducted in 588 CKD patients (not on dialysis) and phase II DREAM-D trial is being conducted in 392 CKD patients (on dialysis). In phase II trial desidustat met its primary endpoints and showed good safety profile.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. AZ's Farxiga first medicine to cut risk of death in CKD trial

AstraZeneca's Farxiga's (dapagliflozin) has cleared primary and secondary endpoints in a late stage trial in patients with chronic kidney disease (CKD). The trial met all its secondary endpoints in CKD patients with and without type II diabetes. Farxiga is the first medicine to significantly reduce the risk of death from any cause in this patient population. Globally, CKD is a serious, progressive kidney function affecting nearly 700 million people.

Dapagliflozin is a potential as a long-awaited new treatment option for patients with chronic kidney disease and shown overwhelming efficacy and improvement on survival in chronic kidney disease patients both with and without type II diabetes.

AZ would submit results of the trial for presentation at medical meeting.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Janssen and MeiraGTx gets positive results in XLRP patients

Janssen has showed six-month data from Phase I/II trial of its investigational gene therapy for the treatment of inherited retinal disease X-linked retinitis pigmentosa (XLRP).

Currently, there are no any approved treatment are available. The data shown that the investigational adeno-associated virus retinitis pigmentosa GTPase regulator (AAV-RPGR) developed with MeiraGTx were generally well-tolerated and shown significant improvement in vision with low and intermediate doses.

Normally, the photoreceptors is responsible for converting light into signals sent to the brain but in XLRP patients don't function as they should and leads to degeneration of the retina and blindness in adulthood.

The AAV-RPGR gene therapy trial is being ongoing to treat the most common and severe forms of XLRP caused by mutations in the RPGR gene, after treatment at six month the low and intermediate dose shown significant improvement from baseline in retinal sensitivity.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 7 / July 2020

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Novartis claim against Regeneron for infringement of patent

In the U.S. International Trade Commission Novartis has filed complaint against Regeneron. Novartis claimed Regeneron's prefilled syringe tech infringed upon its patent and said that to block imports of the competitor syringes.

ITC has started investigation and Regeneron has to provide answer within 20 days, but Regeneron has filed petitions against Novartis and Vetter Pharma for challenging the validity of its patent and antitrust violations in the U.S. Patent and Trademark Office. Vetter is the exclusive filler for the Lucentis prefilled syringe and Regeneron's collaborator on Eylea.

Regeneron says Novartis secured the patent with frauds. Novartis is allegedly reached a settlement around the then-pending patent to obtain control and influence over Vetter's PFS filling services so as to inhibit anti-VEGF rivals like Regeneron.

Source: fiercepharma.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Indivior agreed to pay $600m to settle opioid drug marketing claim

Indivior has agreed to pay $600m to settle US claims of illegal scheme to increase prescriptions of its Suboxone as opioid addiction treatment. The agreement has been signed with the US Department of Justice, the Federal Trade Commission (FTC) and US state attorneys general.

According to the settlement, Indivior pleaded guilty for false statement related to health care matters in 2012. The payment will be made over a period of seven years and in turns the Department of Justice will release all charges returned by a grand jury.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Korean companies try to add Forxiga as dapagliflozin patent goes off

Korean pharmaceutical companies are try to add a generic version of diabetic medicine Forxiga to their portfolio, because the popular dapagliflozin will go off patent in about three years. Dapagliflozin is used in type II diabetes associated with weight loss benefit.

SGLT-2 inhibitors decreases the blood sugar level by blocking glucose reabsorption in the kidney. As glucose is released out of the body it helps in the loss of body weight and the risk of cardiovascular disease.

The diabetes market where dapagliflozin and other SGLT-2 inhibitors grow fast has prompted. The combination of SGLT-2 inhibitors and metformin amounted to 28.14b won ($23.5 million) in the first quarter in Korea.

SGLT-2 inhibitors consists of AstraZeneca's Forxiga and Xigduo, Boehringer Ingelheim's Jardiance and Jardiance Duo, Astellas' Suglat, and MSD's Steglatro.

Source: pulsenews.co.kr

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Bayer reworks on Roundup settlement after judge cue

Bayer has decided to rework the portion of its proposed Roundup settlement which was focused on future lawsuits after judge's cue.

Bayer said that complainant who claim that the Roundup weedkiller caused cancer had withdrawn a file of $1.25 billion section of the settlement deal.

Under the proposal, Bayer would set up an independent panel of scientists to determine whether Roundup can cause cancer. If the panel don't find a causal relationship, no new cancer claims could be brought against the product.

Source: fiercepharma.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 7 / July 2020

TECHNOLOGY /NDDS

1. Novel drug delivery nanoparticles can cross BBB

Biomedical engineers at the Tufts University School of Engineering have developed novel lipid nanoparticles uses as a neurotransmitters to help carry drugs, large molecules, and even gene editing proteins across the blood-brain barrier and into the brain in preclinical trial.

This innovation study is published in journal of *"Science Advances"*. This remedy can be used to overcome the limitation of delivering of therapeutics in the central nervous system.

A delivery of Cre-recombinase (gene editing protein) is successful into the mouse brain. Transfer of Cre-recombinase packaged in an NT-lipidoid-doped lipid nanoparticle is demonstrated when the Cre-recombinase activates expression of the tdTomato fluorescent protein in the cells of the mutant mice. Transfected neurons located throughout the brain (cerebellum shown here) light up in red (scale bar 100μm).

Biomedical engineers said that they can deliver a wide range of molecules by packaging them into the lipid-based nanoparticles without chemically modifying the drugs themselves. We can also achieve delivery across the blood-brain barrier without disrupting the integrity of the barrier.

Clinical trials and more studies ate require for efficacy and safety of this delivery method.

Source: news.knowledia.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 7 / July 2020

TECHNOLOGY /NDDS

2. Chewing robot as a potential drug delivery system

The Researchers at the University of Bristol (UoB) have developed a robot for the testing of drug release from chewing gum.

The robot has built in humanoid jaws which closely replicate chewing motions and releases artificial saliva xylitol (a type of sweetener common in gum), it allow researchers to estimate the transfer of substances from the gum to a potential user.

The team also took saliva and artificial saliva samples after 5, 10, 15, and 20 minutes of continuous chewing. The robot's gum was then tested similarly and compared to that of the human participants.

Chewing gum can be recognized as drug delivery method, but currently aren't any reliable method for testing how much of a particular compound can release during use. The study has been published in the journal of "IEEE Transactions on Biomedical Engineering".

This is the greater opportunity for pharmaceutical companies to investigate medicated chewing gum.

Source: zmescience.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

TECHNOLOGY /NDDS

3. Nanogenerators can help monitor cardiac activity

A team of engineers at Purdue University has demonstrate that polyvinyl alcohol (PVA) is one of the most common polymers used in biomedicine that is used to produce efficient triboelectric nanogenerators (TENGs) that can act as cardiac activity monitors such as continuous heart rate monitors and insulin pumps.

This wearable device can detect the imperceptible degree of skin distortion induced by human pulse and capture the cardiovascular information encoded in the pulse signals with high fidelity.

TENGs with PVA contact layers produce peaks for blood ejection, blood reflection in the lower body, and blood rejection from the closed aortic valve, which may use for detection of common cardiovascular diseases such as coronary artery disease and ischemic heart disease.

Source: medgadget.com

LAMBDA
Research Accelerated

Volume 7 / July 2020

Clinical Research NEWSletter
www.lambda-cro.com

TECHNOLOGY /NDDS

4. USFDA approved EVA15 for minimally invasive procedures

USFDA has approved EVA15 insufflator and smoke evacuation system device for use in laparoscopic, endoscopic, endolumenal, and robotic procedures.

Insufflation pumps CO2 into the pneumoperitoneum and inflating the abdomen, so there are make to space and evacuation used to move smoke away from the cavity that allowing clinicians a clear view inside.

The EVA15 also has a 0.1 micron two-stage filter that helps to remove some of the dangerous particles within the smoke. This system is operated via pedal, which helps to use CO2 only when necessary and lowering costs, preventing patients from freezing on the inside.

There are three insufflation modes:

- Constant flow
- Standard insufflation
- Continuous pressure insufflation

Continuous pressure insufflation is able to any leaks so that the CO2 entering the surgical scene comes in at the appropriate pressure to keep things clear. The low-pressure insufflation that keeps pressure at no more than 7mmHg.

Source: medgadget.com

Research Accelerated