Lambda Research Newsletter

August 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 8 / August 2020

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA

Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

1. Advanced electron microscopy can help develop drugs that target proteins

The researchers at the Portland State University have used advanced electron microscopy to develop a 3-D recreation of a membrane protein at a unique level of resolution and development of drug that could target effectively the protein for the treatment of different diseases.

In the cell, for the understanding of how individual proteins interact and function at the molecular level, the researchers have uses cryo-electron microscopy (cryo-EM) and computer modeling.

The aim of this research was two proteins of the eye lens connexin-46/50, which develop pathways for cell to cell communication. The team has used lipid nanodisc technology to arrange the proteins back into their native-like membrane environment that can create image the protein at a high resolution of 1.9 Angstrom. This is the first membrane protein below 2.0 Angstrom using cryo-EM.

The high resolution provided new insight and play an important role in protein structure and function. The 3D structure also showed that connexin-46/50 has a long-range effect on the stability and biophysical properties of the eye lens membrane.

Source: news-medical.net

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

2. SMART discover a new way to inverse antibody resistance in bacteria

SMART
Singapore-MIT Alliance for Research and Technology

The researchers at Singapore-MIT Alliance for Research and Technology (SMART) have discovered a new way to inverse antibody resistance in bacteria. The team has conducted study using hydrogen sulfide (H_2S), the SMART group added H_2S releasing compounds to Acinetobacter baumannii. (pathogenic bacteria that do not produce H2s on its own)

Following the study, they was found that instead of causing antibiotic tolerance exogenous H_2S sensitized the A. baumannii to multiple antibiotic classes and also the hydrogen sulfide even reversed acquired resistance in A. baumannii to gentamicin. The researchers said that it might be generalized to all types of bacteria.

H2S can improve sensitivity of antibiotics and also reverse antibiotic resistance in bacteria that do not naturally produce the agent.

Source: republicworld.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

3. New therapeutic targets to treat cardiovascular disease

A team of Baltimore (Maryland) has identified a potential therapeutic target for clogged arteries and other health risks in the bloodstream. The results of this study has published in *PLOS Genetics*.

Cardiovascular diseases occurs when lipid from the blood plasma are deposited in the wall of blood vessels. Researchers have explained how cell processes on lipid. The combination of lipid and protein called ApoB-containing lipoproteins and it is essential for transporting lipid from the intestine and liver, however they causes arterial disease it's called bad cholesterol.

The researchers have focused on protein that is critical for the synthesis of ApoB-containing lipoproteins. This protein known as microsomal triglyceride (MTP), it is the initial step in the synthesis of ApoB-containing lipoproteins. MTP can transfer different types of lipid that is major source of energy and phospholipids that are building blocks of membranes in the cell, however the researchers revealed for the first time a mutation in MTP that blocks the loading of triglycerides but not phospholipids onto ApoB.

The separation of these two transfer functions was unexpected and is important because high triglyceride levels in lipoproteins are correlated with bad clinical outcomes like diabetes and heart disease. The mutation of MTP prevent both transfer functions of the protein and create malabsorption syndrome and also develop more serious problem.

MTP is help in lower triglyceride levels in the blood and prevent cardiovascular disease. However, the existing chemical inhibitors of MTP are too effective and block all MTP function, which can cause intestinal fat malabsorption and a dangerous accumulation of fat in the liver.

Source: businessworld.in

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

GLOBAL NEWS

4. Researchers identify mechanisms for severe viral infections

The researchers at the Melbourne have identified mechanism leading to immune system failure in response to severe viral infection such as COVID-19 and HIV. Severe viral infections and cancer cause impairments to the immune system, including to T cells and its called exhaustion.

Immune exhaustion is a major goal for the development of new therapies for cancer or severe viral infections. Several new mediators of immune exhaustion are targeted in new therapies. The study is published in "*today in Nature Immunology*".

The researchers were able to show that T cells down-regulate their function within days while T cells responding to a weaker infection remained highly functional. T cell function is impaired is central to improving these therapeutic approaches and applying them to other diseases such as viral infections.

The data of the study show that T cells could be manipulated during early stages of severe viral infection to improve their activity.

Source: news-medical.net

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

PHARMA INDIA

1. Online pharmacy services in India

Amazon is making its entry in medicine market in the country, amazon has launched an internet pharmacy in India.

During this coronavirus pandemic the online drugs business has given major boost. In this year the US technology giants have invested billions of dollars in the Indian market.

Amazon provides over the counter, traditional Ayurveda medication and basic health devices. It will help customers meet their essential needs while staying safe at home.

Amazon has started its move into pharmaceutical retailing in 2017. It bought US-based home delivery medications startup PillPack. In January, Amazon has filed to trademark the name Amazon Pharmacy in the UK, Australia and Canada.

Source: bbc.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

PHARMA INDIA

2. India and the US have great potential for collaboration in healthcare

Indian ambassador said that India and the US have great potential for collaboration in healthcare such as in pharma, basic research, vaccines, diagnostics, devices, telemedicine, hospital administration, healthcare supplies, and health-care expertise.

Indian pharma companies are world leaders in affordable low-cost medicines and vaccines and are also collaborating with US companies in vaccine development, therapeutics and diagnostics.

Gilead has entered into licensing agreements with seven Indian companies to manufacture REMDESIVIR and supply it to more than 127 countries.

The scientists and institutions of both countries have been actively engaged in the exchange of information. COVID 19 virtual networks is being developed under India-US Science and Technology Endowment Fund (IUSTEF) that will allow Indian and US scientists and engineers to carry out joint research activities virtually and leverage current infrastructure and funding mechanisms.

Source: businessworld.in

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

PHARMA INDIA

3. In India stempeucel will launch for CLI treatment

In India Cipla and Stempeutics will launch the latter's cell therapy product stempeucel for the treatment of critical limb ischemia (CLI). They have received regulatory approval by the Drug Controller General of India (DCGI).

The product is indicated to treat CLI due to buerger's disease and atherosclerotic peripheral arterial disease.

CLI is a progressive form of peripheral arterial disease that is caused by severe blockage in the arteries thereby reducing blood flow. This may result in the development of sores and wounds in legs and feet with a high risk of limb amputation. According to the agreement, Cipla has received exclusive rights to market and distribute the product in India.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 8 / August 2020

PHARMA INDIA

4. First Indian covid test kit

The Indian Council of Medical Research (ICMR) has approved of Delhi-based Oscar Medicare's indigenous point-of-care (POC) rapid test kits. This is the first Indian covid test kit.

Oscar Medicare one of the largest manufacturers of pregnancy kits and it also makes HIV, HCV, dengue and malaria POC diagnostic kits, they are planning to launch two lakh test kits in September. The test is look like a glucometer and result will provide in 20 minutes.

Dhiti Life Science has manufactured raw material of test kits 'corona fusion antigen, they are expected to be priced at around Rs 200.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

REGULATORY ROUND-UP

1. Final guidances for two device-specific

FDA using the safety and performance based pathways, the device-specific guidances establish performance criteria to support 510(k) clearance.

The guidances have been finalized for cutaneous electrodes and conventional foley catheters.

There are four device-specific guidances which still remain in draft for orthopedic non-spinal metallic bone screws and washers, spinal plating systems, magnetic resonance (MR) coils and soft hydrophilic daily wear contact lenses.

The new optional safety and performance based pathway builds on its abbreviated 510(k) program to give device makers the flexibility to use performance criteria and voluntary consensus standards rather than direct comparison testing against a predicate device to support 510(k) clearance.

If legally marketed device performs at certain levels relevant to its safety and performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device Instead of reviewing data from direct comparison testing between the two devices.

Source: regulis.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

2. EC introduced measures for future COVID-19 outbreaks

The European Commission (EC) has introduced an immediate short term measure to improve health preparedness for future COVID-19 outbreaks.

The EU and state members have introduced measures to reduce social and economic impacts such as:

- Maintaining the functioning of the internal market
- Supporting the transport and tourism sectors
- Protecting employment and supporting medical care services for vulnerable groups.
- Member states are increasingly coordinating their response

The priority actions for national authorities and EU Agencies are included:

- Increased testing coverage, contact tracing and surveillance.
- The smooth supply of personal protective equipment, medicines and medical devices through mechanisms
- Maintaining rapid access to public health surge capacities without neglecting other areas of healthcare.
- Provision of targeted and localized non-pharmaceutical measures, informed by research and evidence.
- Supporting vulnerable groups such as the elderly, those with underlying medical conditions and those on the margins of society.
- Reducing the burden of seasonal flu.

The EC and Member States has encouraged continued vigilance and rapid response to ensure that the future generalized lockdowns can be avoided.

Source: regulis.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUND-UP

3. FDA presented draft on marketing status notifications

The US Food and Drug Administration (FDA) has presented final draft for clarifying. Holders has to submit marketing status notifications when their products are withdrawn from sale or are not available for sale.

When the products (new drug application and abbreviated new drug application) are withdrawn from the market, the company has to notify FDA prior to 180 days.

Withdrawal notifications should only be submitted when the product has been withdrawn under all relevant national drug codes (NDCs). The same expectation applies to NDA holders who have marketed a branded and generic version of the same drug.

In such cases, the company should notify FDA 30-60 days prior launch when holder has notified that a product would not be available for sale but company wants to market the drug.

Source: regulis.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUND-UP

4. Orphan and paediatric regulations evaluation

The European Commission (EC) has reported an evaluation results of the EU orphan and pediatric regulations. This evaluation will be used to guide future legislative changes and pharmaceutical strategy.

The evaluation found that improved the development and availability of medicines for patients with rare diseases and children. The report credits the orphan regulation with increasing the speed at which patients could access these medicines by 9 months on average. Furthermore, the orphan regulation is estimated to have added 210,000-440,000 quality-adjusted life years for patients in the EU.

The pediatric regulation increased the amount of clinical trials involving children by almost 50% and led to more than 1000 pediatric investigation plans (PIPs).

Source: regulis.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

1. Takeda signs agreement license deal with Engitix

Takeda has signed agreement with UK biotech Engitix for the development of new therapies against advanced fibrotic liver diseases.

The companies will work together using extracellular matrix (ECM) discovery platform and by incorporating tissue-and disease-specific human ECM into in vitro models.

The platform preserves the natural cell microenvironment offering the unique capability.

Takeda is the world's leading company having development and commercialization capabilities. Under the agreement, Takeda will receive rights for development and commercialize clinical candidates against validated targets, Engitix will receive an upfront payment, with near-term payments based on the confirmation and functional validation of selected targets and also receive royalty payments of commercialized products.

Source: pharmatimes.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

2. AZ joined with RenalytixAI to develop medicine stratrgy for chronic diseases

AstraZeneca has joined with RenalytixAI for development and launch of medicine strategies for cardiovascular, renal and metabolic diseases.

The companies will use in vitro diagnostic platform KidneyIntelX, for further improving outcomes in patients with chronic kidney disease (CKD) and its complications.

This collaboration will define leverage KidneyIntelX to improve the care and outcomes in patients affected by chronic diseases.

The company's initial goal is to help improved outcomes for more than 240,000 patients with chronic kidney disease within the Mount Sinai Health System.

Source: als.blogspot.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Eli Lilly and Innovent biologics expands its collaboration

Eli Lilly has expanded its strategic collaboration with Innovent Biologics for immuno-oncology drug Tyvyt (sintilimab injection). Tyvyt is an anti-PD-1 monoclonal antibody and it is part of China's National Reimbursement Drug List (NRDL).

Last year, Eli Lilly and Innovent had started commercializing the drug in China following marketing approval for treatment of relapsed or refractory classic Hodgkin's lymphoma. Currently, the companies jointly commercialize the drug in China.

Under the expanded agreement, Eli Lilly will receive an exclusive license to the drug for markets outside of China. The company plan to register Tyvyt in the US and other countries. Innovent will receive a $200m upfront payment and also eligible to receive up to $825m in potential development and commercial milestones as well as sales royalties.

Both the companies will retain to evaluate the drug in combination with other medicines under their own clinical programmes.

Eli Lilly and Innovent are assessing the drug to potentially treat non-squamous non-small cell lung cancer (NSCLC) and multiple other cancer types.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

4. Gilead collaborate with Tango therapeutics for targeted cancer therapies

Gilead Sciences has joined with Tango Therapeutics for discovery, development and commercialize immune evasion therapies for cancer patients.

Under the deal, Tango will use its CRISPR-enabled functional genomics target discovery platform to detect new immune evasion targets. Gilead will have an option for global rights to programmes related to these targets over the coming seven years.

Gilead will have the right to pay option extension fees to Tango for activities through early clinical development. Tango will have an option to participate in the development and promotion of the lead products for up to five programmes in the US.

Tango will receive an upfront payment of $125m along with a $20m equity investment. Gilead can option up to 15 programmes over the next seven years for up to $410m per programme.

Source: pharmaceutical-technology.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

1. Intas gets DCGI approval for hyperimmune globulin clinical trial

Intas Pharma has received Drug Controller General of India (DCGI) approval to conduct clinical trial of its COVID-19 specific hyperimmune globulin for treatment of severe COVID-19 infection. Hyperimmune globulin is potential as prophylaxis for high-risk population in contact with COVID-19 patients.

This could be an important therapeutic option until a vaccine is available. This is the first approach to adopt for treating COVID-19 patients.

In high concentration hyperimmune globulin will provide purified and enriched preparation of COVID-19 specific neutralizing antibodies, free from blood transmitted viruses and other plasma proteins and also enable consistent, precise dosing and predictable response early in the treatment of COVID-19 infections.

Hyperimmune globulin can be administered to the patients anywhere and does not require blood group matching or donor selection while administering to the patient.

Intas is establishing collaboration with medical research institutions and blood donation groups to collect the plasma from recovered COVID-19 patients.

Source: expresspharma.in

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

2. FDC launches two variants of Favipiravir in India

FDC has launched two variants PiFLU and Favenza of the Favipiravir for the COVID-19.

Earlier the Drug Controller General of India (DCGI) had approved the oral antiviral drug Favipiravir as an off patent drug, drug shown quick recovery in mild to moderate COVID-19 patients.

FDC will working with the government and healthcare fraternity to make Favenza and PiFLU available across the country. Currently both the brands are available across the country with the price of Rs 55 per tablet.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 8 / August 2020

DRUGS: APPROVALS AND LAUNCHES

3. FDA approves GlaxoSmithKline's blood cancer drug

The US Food and Drug Administration has approved GlaxoSmithKline's BLENREP (belantamab mafodotin) for treatment of relapsed and refractory multiple myeloma in adults.

In the U.S. multiple myeloma is the second most common form of blood cancer and it is treatable but not curable.

Earlier, the USFDA panel had raised question about the drug causing deposits on the cornea of the eyes, but later they are agreed due to benefits of the treatment of overweigh the risks.

Last month, a panel of the European Medicines Agency (EMA) also recommended approving the drug.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHES

4. USFDA approved key generic asthma drug

The USFDA has approved Lupin to make ProAir 90 mcg Sulfate Inhalation Aerosol at a time for the treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms.

This is the key rescue inhalation product for asthma patients who are at an increased risk of covid-related complications.

The annual sales of this drug is over $1 bilion dollar. The total sales of albuterol sulfate inhalation aerosol included $1.3 billion generated by the innovator.

Source: livemint.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Novartis conducted phase III ASCEMBL study

Novartis has conducted phase III, multicenter, open-label and randomized study comparing the oral investigational treatment asciminib (ABL001) versus bosutinib in patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. Novartis has received primary endpoints.

Asciminib is a STAMP inhibitor and help to address tyrosine-kinase inhibitor (TKI)-resistance and intolerance in later treatment lines of chronic myeloid leukemia (CML).

The study evaluates asciminib is a novel investigational treatment target of ABL myristoyl pocket (STAMP) in adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase which are previously treated with tyrosine-kinase inhibitors.

The data from the ASCEMBL study will be submitted in upcoming medical meeting and result will be shared in regular authorities.

Source: pharmabiz.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

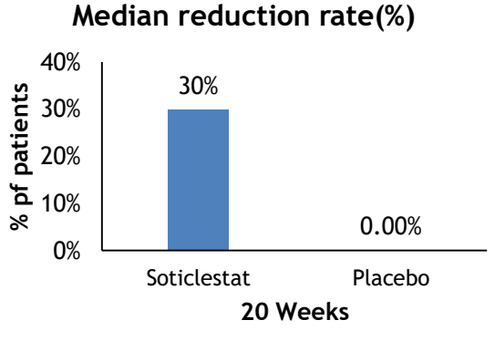
Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Soticlestat reduces seizures in Phase II ELEKTRA clinical trial

Takeda and Ovid Therapeutics have received positive data from the Phase II ELEKTRA clinical trial of soticlestat for the treatment of Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS) in children. Soticlestat is a selective inhibitor of the cholesterol 24-hydroxylase enzyme.

In clinical trial a total of 141 patients aged two to 17 had enrolled and 126 patients have completed the trial.



In Phase II trial soticlestat met its primary endpoint, convulsive seizure (DS) and drop seizure (LGS) frequency were decreases 27.8% median from baseline during the 12-week.

During the 20-week treatment period Soticlestat led to a 29.8% median reduction in convulsive (DS) and drop seizure (LGS) frequency compared with 0% median seizure frequency in the placebo group. Soticlestat demonstrated 33.8% median decrease in convulsive seizure frequency compared to a 7% median increase with placebo during the 20-week treatment period in cohort patients.

The safety data shown the drug was well-tolerated. Based on these results, the companies plans to discuss with regulatory authorities regarding Phase III registrational programme.

Source: clinicaltrialsarena.com

LAMBDA
Research Accelerated

Clinical Research NEWS letter
www.lambda-cro.com

Volume 8 / August 2020

DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. GSK received positive data in Phase IIa trial

GSK has received positive results from Phase IIa study of its candidate GSK'836 (GSK3228836) for the treatment of chronic hepatitis B.

After four week of treatment, GSK'836 led to a decrease in hepatitis B surface antigen (HBsAg) and hepatitis B virus DNA compared with placebo group. GSK'836 uses antisense oligonucleotide technology to suppress the virus and the viral proteins, the virus is not completely destroyed but is at low levels that can be addressed by the immune system.

Globally, chronic hepatitis B affects around 260 million people and lead to 900,000 deaths per year due to liver failure and liver cancer.

The study was enrolled 31 chronic hepatitis B patients. The patients were received 150mg and 300mg doses of GSK'836 subcutaneously, following the last treatment dose all patients were administered tenofovir or entecavir as a first line monotherapy.

The main efficacy analysis assessed the change in serum HBsAg and plasma hepatitis B virus DNA from baseline to the end of four weeks treatment. The primary endpoints were safety and tolerability. Additional endpoints of other antiviral parameters and pharmacokinetics were included.

Based on the positive data the company will go ahead in a Phase IIb clinical programme.

Source: clinicaltrialsarena.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Bicycle therapeutics conduct Phase II trial using novel Bicycle® technology

Bicycle Therapeutics and Oxurion have conducted Phase II study of THR-149 in patients with diabetic macular edema (DME). THR-149 is an inhibitor of novel Bicycle-based plasma kallikrein (PKal). Bicycle Therapeutics uses proprietary bicyclic peptide (Bicycle®) technology. They have dosed one first patients.

During the Phase I trial of THR-149, investigators had observed that patients experienced a sustained improvement in best corrected visual acuity for 90 days following a single administration of THR-149.

The Phase II trial KALAHARI is expected to include approximately 122 patients with central involved DME who do not respond adequately to anti-VEGF.

In part A will enroll 18 patients, it is a dose-ranging study in which including multiple administrations of THR-149 will be evaluated. The primary objective of Part A is to identify the optimal dose. In part B will enroll 104 patients, it is a double-blind active control study that will evaluate the efficacy of THR-149 at the dose level selected in Part A versus the comparator aflibercept.

Source: businesswire.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. US patent has approved Bio-Helix's patent for ECL

US Patent and Trademark Office has approved Bio-Helix's patent application for its proprietary enhanced chemiluminescent substrates (ECL). Originally the US patent application was submitted and filed on 13th July 2018 with the title "*Reagent and Kit for Performing Chemiluminescent Reaction*".

In the summer of 2019, the announcement of three different sensitivity levels of chemiluminescent substrates, which are part of the UltraScence series. Globally, they have shipping the liquid and powder form ECLs over 35 countries for advancing research in Western Blot and ELISA applications.

The long chemiluminescent signal duration makes both digital and film-based imaging possible without any loss of the signal. Appropriate primary and secondary antibody dilutions has suggested for attaining optimal signal intensity and duration.

Source: news-medical.net

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWSletter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Merck filed petition against Aurobindo Pharma

In the United States District Court Merck & Co has filed patent infringement against Aurobindo Pharma Ltd. Merck alleging that the Indian drug maker was planning to come out with the generic versions of its blockbuster drug Janumet before expiration of patent.

Janumet (metformin hydrochloride and sitagliptin Phosphate) is used for the indication of type 2 diabetes. According to Merck's 2019 annual report patents of Janumet will expire in July 2022 for the USA with six-month paediatric exclusivity.

Merck said that the Aurobindo Pharma had submitted abbreviated new drug application to the USFDA for the approval of commercial manufacturer, sale and importation of generic drug prior expiration of the 708 patent.

Merck has demanded, the Indian drug maker's ANDA Products or any other drug product covered by the 708 patent, prior to the expiration.

In June, Merck was filed same patent issues with Dr Reddy's Laboratories. Under Paragraph IV Patent Certifications a company can seek FDA approval to market a generic drug before the expiration of patents related to the branded medicine that the pharma company seeks to copy.

Source: news18.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. AZ claim patent court to cancel IPTAB decision about Forxiga

AstraZeneca has filed a claim in the patent court to cancel the decision of Intellectual Property Trial and Appeal Board (IPTAB) that favoured Dong-A ST regarding its SGLT-2 inhibitor Forxiga.

AstraZeneca said that, Forxiga has two substance patents over the active ingredient dapagliflozin that expire on 7th April 2023 and 8th Jan 2024. Dong-A ST was avoided both the patents.

AstraZeneca was filed a patent litigation against Dong-A ST and after on 23rd June IPTAB ruled in favour of Dong-A ST that the local drug company's investigational generic drug of Forxiga did not infringe the original drug.

AstraZeneca claimed that the ingredient of the Dong-A ST's experimental drug demonstrated same pharmacokinetics in the body as dapagliflozin. As the ingredient is converted like dapagliflozin to exert its effect, it infringes on Forxiga's substance patent.

Source: koreabiomed.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Isofol Medical gets two new patent grants for arfolitixorin

Isofol Medical AB has received two new patent grants for arfolitixorin in Japan and its make more strengthen its position in the second largest market for treatment of mCRC. Arfolitixorin is Isofol's proprietary drug candidate. It is developed to increase the efficacy of standard of care chemotherapy for advanced colorectal cancer.

One patent is related to preparation process of the drug for injection, this patent is valid until 2034. Another patent is related to dosage regimens, including those applied in the ongoing global Phase III study AGENT, this patent is valid until 2034.

Both the patents will ensure a strong and extended patent protection for the important future Japanese market until 2038.

Source: prnewswire.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

1. Researchers developed natural wearable sweat sensor

The researchers from Brazil have developed a wearable sweat sensor using microbial nanocellulose. This system can uses different metabolites and biomarkers present in sweat, and could be useful for monitoring conditions such as diabetes.

Microbial nanocellulose is a natural polymer that provides breathable space underlying the skin and provide space to travel through for electrochemical analysis using printed electrodes.

Natural polymer is produced by bacteria from sugar. It is advantageous over plastic is its far better interface with human skin. The sensors are very small and only 1.5 cm length, Electrodes are printed onto the nanocellulose membrane and contain a high proportion of carbon.

Chemical redox reactions produce an electrical signal that measures the concentration of the metabolite. The sensor is connected to a potentiostat that makes electrochemical measurements and the results transmitted to a computer and converted into standard curves.

Source: medgadget.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

2. Surgical robotic assistant to perform microsurgeries

The researchers from Harvard's Wyss Institute and Sony Corporation have developed a tiny robotic surgical assistant that can be used to perform precise surgical tasks.

The researchers using Pop-Up MEMS technique that contains bonding layers so that they can open up from flat starting shape. The remote centre of motion manipulator can move with impressive precision. The mini-RCM can produced much cheaper than conventional micromechanical devices. It is very small and this new device is also easy to install and remove.

The researchers tested this new robotic surgical manipulator by connecting to a haptic controller (Phantom Omni) and perform a tracing task with and without its help. The researchers also used their device to perform mock retinal vein cannulations on synthetic vessels. They were able to accurately puncture these vessels consistently without causing damage outside the target area.

Optical sensors that constantly monitor the motion of the robot and adjust it to maintain consistency.

Source: medgadget.com

LAMBDA
Research Accelerated

Volume 8 / August 2020

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

3. High-flow nasal oxygen remedy for severe patients

Doctors of Pune using high-flow nasal oxygen (HFNO) to treat respiratory distress in COVID-19 patients instead of mechanical ventilation. Due to COVID-19 nearly 20% in patients have damaged lung, which decrease the O2 supply in the body this condition is called hypoxia.

Doctors are treating this problem via facemasks or ventimask system, but oxygenation using cannula is not enough to maintain optimum blood oxygenation levels in some patients.

In such cases an HFNC is beneficial remedy for this problem, The HFNC delivers warmed (37°C) and humidified oxygen at very high flow rates through plugs that are fitted to patient's nostrils and maintains body temperature, reduces airway inflammation and maintains mucociliary function. The HFNO is used only very severe case.

Source: economictimes.indiatimes.com

LAMBDA
Research Accelerated

Clinical Research NEWSletter
www.lambda-cro.com

Volume 8 / August 2020

TECHNOLOGY /NDDS

4. LG developed electronic air purifier face mask

The South Korean electronics manufacturer LG has developed a PuriCare Wearable Air Purifier face mask that cleans the air and makes it easy to breathe.

Face mask contains two replaceable H13 HEPA filters with battery-powered fans to help breathe, the device has sensors to detect breathing in or out and adjust the fan accordingly and it makes feel like not wearing a mask.

The fan, sensors and electronics are powered by 820 mAh battery, inside the mask having UV-C LEDs charging case, that kill outer germs.

According to the company, at the end of this year the Air Purifier face mask is scheduled for sale in certain countries.

Source: medgadget.com

Research Accelerated