Lambda Research Newsletter

October 2018

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Research Accelerated

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Clinical Research NEWSletter

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GLOBAL NEWS

1. US Department of Defense offers grant for UIC study on prostate cancer

The US Department of Defense has offered a grant to the University of Illinois at Chicago for SELENOF gene development for its role in the treatment of prostate cancer among black men. There were 179 cases of prostate cancer reported in black men, and 106 cases in white men per 100,000 men in 2011- 2015.

There are genetic and environmental factors responsible for the high incidence of prostate cancer among black men. Human clinical sample that revealed SELENOF levels were lower in cancer tissues compared to benign tissue, of black men.

The researchers will also study the mechanism by which reduced SELENOF levels are associated with higher prostate cancer risk. The experiment will be conducted in animal (mice) models.

According to the data from the National Cancer Institute, approximately 3.1 million men had prostate cancer in 2015. About 165,000 new cancer cases are anticipated in 2018 with nearly 30,000 deaths projected.

Source: news-medical.net

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GLOBAL NEWS

2. Expert guideline for the treatment of bone loss in HSCT patients

Hematopoietic stem cell transplantation (HSCT) is the advance transplantation and supportive treatment option for patients having leukemia and multiple myeloma. However, HSCT is associated with major challenges of bone loss and osteoporosis leading to an increased risk of bone fractures, severe pain, difficulty in movement and loss of quality of life. The various forms of cancer treatments, HSCT transplantation, hypogonadism, HSCT preparative regimens, nutritional factors, and glucocorticoid use are among the leading causes of bone loss.

The International Osteoporosis Foundation (IOF) Expert Working group of Cancer and Bone Diseases has published an expert guideline to address this issue. The expert guidance provides methods for monitoring, evaluation and treatment of bone loss in HSCT patients.

The review published by the expert group 'Bone management in hematologic stem cell transplant recipients' outlines clinical management strategies based on the latest evidence and best practice.

Source: news-medical.net

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GLOBAL NEWS

3. New research on HPSC to highlight the etiology of diabetes

The major cause of diabetes is pancreatic beta-cell dysfunction. Beta cells are released from the islets of Langerhans and beta cells exocytosis of insulin. Researches on diabetes have been based on animal and cellular model, but have some limitations in applying these findings for humans as the pancreatic islet development and physiology for these models differ from the humans. Now researchers offer a more precise model based on human pluripotent stem cells (HPSC).

Pluripotent stem cell is a renewable source of beta cells. In the current experiment, stem cells derived beta cells were directly differentiated and used in the development of beta cells, based on a monogenic diabetic mechanism using 3D suspension culture.

The experiment was done on immune compromised mice, where beta cell function can be evaluated closely in systemic context.

Researchers also showed that an activating mutation in STATE3 gene was found to cause neonatal diabetes by inducing pancreatic endocrinogenesis. They also demonstrated that INS gene mutations causing proinsulin misfolding were found to impair developing beta-cell proliferation due to increased endoplasmic reticulum stress.

Source: news-medical.net

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GLOBAL NEWS

4. DNA islands to fight *S. aureus*

A new study has demonstrated that genomic islands developed from viruses can be converted to drones, which can in turn target and disable *S. aureus* bacteria, often resistant to antibiotics.

The research was conducted by the NYU School of Medicine and the study was published in the "*Nature Biotechnology*". DNA from viruses stayed permanently in the bacteria that are infected to become a part of the bacteria's genome.

The result is a hybrid entity that contains useful genes passed on by the bacteria when they reproduce, but that is also in some cases cut out of the bacterial superstructure, and packaged like a virus in a protein shell (capsid) that can inject its DNA into other bacterial cells.

The researchers suggested that this mix of evolutionary leaps has fashioned genomic islands as perfect drone-like vehicles to deliver genetic payloads throughout bacterial populations. When injected into mice with an otherwise lethal staph infection, the research team's engineered *S. aureus* pathogenicity islands (SaPIs) killed the bacteria and rescued the treated animals.

Source: prnewswire.com

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PHARMA INDIA

1. Traditional Indian medicine systems included in WHO module

The Indian traditional medicine systems Ayurveda, Siddha and Unani have been included in the International Classification of Diseases (ICD). ICD is the World Health Organization's second traditional medicine module.

Traditional medicines are important for several healthcare programs, especially under the Sustainable Developmental Goal-3 (SDG-3) of the WHO. This news is a very important boost for the Indian healthcare system in research and development as it is internationally accepted and will lead to increased research.

According to the WHO, ICD has included a new chapter ICD-11 for traditional medicine, although millions of patients use traditional medicines already. Traditional medicine within the ICD allows measuring, comparing and monitoring over time, although many countries follow a national classification system. Such medicine system has not been standardized globally.

Officially, ICD-11 will be presented in May 2019 for adaptation and it will come into force in January 2022.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

2. NCMR develops India's first bio-repository for microbe resistant drugs

The National Centre for Microbial Resource (NCMR), Pune has developed a bio-repository to collect, preserve and characterize the drug resistant microbes. Bio-repository is the storage place of biological material like urine, blood, tissue, cells, DNA, RNA and proteins from animals, plants and humans for further investigation.

NCMR
राष्ट्रीय सूक्ष्मजीव संपदा केंद्र

Researchers have said that this is a great innovation field for anti-microbial resistance research; they can obtain sample from clinicians, can collect and deposit the biological material from patients diagnosed with specific diseases for investigation. The bio-bank is going to be very useful for research and development in future.

Antimicrobial resistance is a major problem in India. So much research is required in this field and this bank may help such research. An estimated 7% ill patients are resistant to antibiotics, and 58,000 neonatal deaths occur each year in Indian hospitals.

Source: pharmabiz.com

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PHARMA INDIA

3. NACO releases HIV estimations reports

The National AIDS Control Organization (NACO) has released its estimation report of 2017; the main objective of this report is to get updated information of HIV population at national and state levels in India.

For HIV estimation, NACO had collaborated with the Indian Council of Medical Research (ICMR) and National Institute of Medical Statistics (NIMS). The first estimation was done in 1998 and this is the 14th round in this series.

According to the report, there has been a significant achievement of national AIDS prevention response. The 2017 report states its ambitious goal as 'End of AIDS' by 2030.

India had about 21.40 lakh people living with HIV infection with a adult prevalence of 0.22%, ~87.58 thousand new HIV cases and 69.11 thousand deaths due to HIV, in 2017. The current report has noted a decrease in the annual new HIV cases in recent years. There is an 80% decline in the HIV infection rate from 1995 to 2017, and estimated HIV related deaths have been decreased to 71%.

Source: pharmabiz.com

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PHARMA INDIA

4. Growth in Indian Pharma market

The Indian Pharmaceutical Market (IPM) has seen a growth of 8.7% during August 2018 and reached Rs.11,343 crore when compared to July 2018. According to the All Indian Origin Chemists & Distributors (AIOCD) report, the volumes have slowed down, and fixed dose combination (FDC) market has declined by 2.2% compared to non-FDC market which is at 8.9%. The growth of single molecule industry is 8.7%.

Multinational Pharma companies (MNCs) achieved a growth of 6.6% in August 2018, while Indian companies grew faster at 9.2%. In non-National List of Essential Medicines (NLEM) Indian companies, a growth of 7.5% was seen whereas MNCs grew at 9.8%. Intas has the highest growth at 13.6%, Lupin at 13.4% and Torrent at 10.8%. There are 46 corporates showing a positive growth in IPM. From the top 50 companies, Sun Pharma has shown a 5% growth, while Ranbaxy stood at 6.2%, Emcure at 9.9% and Zuventus at 10.4% in August 2018. Among the Top 60 MNCs, Boehringer Ingelheim is the fastest growing at 33.5% followed by Bayer at 33.3% and AstraZeneca at 22.9%.

There were a total of 14 companies launched in the last 36 months with 2 companies gross over 10 crores. Positive growth was seen in 17 therapeutic areas in August 2018 with the highest growth seen in gastrointestinal diseases. In the chornic disease therapy segment, anti-diabetics have increased by 14%. In the combination market Amoxycillin + clavulanic acid is the top most achieving a 10.4% growth, followed by glimepride + metformin with 8.1%.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. Most ANDA complete responses in one year

The US Food and Drug Administration (FDA) have issued more complete responses for Abbreviated New Drug Applications (ANDAs) in 2018. But in complete response, there is a very drastic gap at 2515 in the year 2018 vs.1603 in the year 2017 vs.1725 in the year 2016.

The Generic Drug User Fee Amendments (GDUFA II) and the volume of complete responses are consistent with the expectations.

Approximately 800 applications did not have the official goal date in GDUFA I over the time period.

The FDA has a total of 57 approvals in 2018 till date compared with 80 approvals in 2017 and 73 approvals in 2016. The authorization creates a new user fee structure, aims and review of generic drugs to increase the interaction between the agency and the companies.

Source: raps.org

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REGULATORY ROUND-UP

2. Device makers disagree with FDA's biliary stent guidance

The US FDA had released a 27 pages draft guideline in July 2018 for the metal expandable biliary stents, and generated new recommendations for shelf-life and packaging, MRI compatibility and preclinical bench testing. Now, the Boston Scientific and Cook, who are the makers of medical devices, have expressed disagreement over the new guidance document and have requested modifications in the graft guidance 510(k) in product testing, device description, appropriate pathway for submitting the changes for metal expandable biliary stents to the USFDA.

According to them, the described guidance is narrower than that of the regulatory definition, which does not restrict the use of stents to palliation of malignant structure. The companies suggested that FDA should change its recommendation for corrosion testing. The test methods listed in guidance is focused on electrochemical principles.

The USFDA draft guidance notes that clinical evidence is not required for biliary stents, and the FDA expands the guidance to include recommendation on testing model making biliary stents not eligible for submission under the special 510 (K) paradigm.

Source: raps.org

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REGULATORY ROUND-UP

3. Indian national drug authority to get a new name

The India's national drug regulatory agency, the Central Drugs Standard Control Organization (CDSCO) is set to be renamed, as they have added one more role and responsibility as a regulatory authority. CDSCO has expanded several areas of new drugs including vaccines and clinical trials, medical devices and cosmetics, central licensing authority for blood banks under the drugs and cosmetic act.

The government said that present nomenclature does not reflect the role and responsibility of the CDSCO. The government has requested suggestions and comments from the stockholders for regulations and design of a new logo for the authority.

The expert committee on drug regulatory system recommends the creation of a National Drug Authority (NDA) or Central Drug Authority (CDA); The Drug Technical Advisory Board (DTAB) recommend renaming the CDSCO and Indian Drug Administration (IDA).

Source: business-standard.com

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REGULATORY ROUND-UP

4. Health Ministry bans OTC sale of topical steroids

The Indian Health Ministry has banned over-the counter sale of steroidal topical preparations like alclometasone, beclomethasone, desonide, desoximetasone and flucinonide.

Ministry of Health
Government of India

As per the Drugs and Cosmetics act 1945, a notification has been issued in March that there are 14 steroidal creams and ointments that fall under the Schedule H category.

The decision was taken by the Drug Technical Advisory Board (DTAB), which recommended a ban on the sale of steroidal creams without prescription, and they have submitted the recommendation letter to the Central Drugs Standard Control Organization (CDSCO).

The dermatologists across the country complained that pharmaceutical companies were selling steroid based creams to the patients without medical guidance. This rule is applied only for skin steroid cream without prescription, not for face-cleansing and moisturizers.

Source: business-standard.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Strides Pharma merges with Arrow Pharma and Apotex

Strides Pharma science Ltd. and Apotex have announced to merge with Arrow Pharma and Apotex Australia to form a new company. The Australian Competition and Consumer Commission (ACCC) has given the clearance to the merger.

Arrow and Apotex both distribute generic prescriptions and over-the-counter medicinal products.

ACCC said that the combinations of two or more largest competitors will require checking. However, there is a high competition between companies i.e., for Arrow-Apotex face strong competition from Mylan and Sandoz. The latter suppliers are backed by their strong international parent companies.

Source: pharmabiz.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novo Holdings acquires Envirotainer partnering with Cinven

Novo Holdings announced that they acquired 24.9% in Envirotainer in partnership with the private equity firm Cinven. Envirotainer is the leader in the global market with an innovative product, consistent service delivery, and global delivery capability. Envirotainer is a great leader of airfreight controlled solutions and they are transporting 2 million doses of medicine per day serving 600 customers worldwide.

Novo Holdings healthcare is an expert in knowledge and development in the pharmaceutical market and is in an excellent position. Envirotainer has an attractive opportunity with this collaboration. Both Novo and Cinven will support Envirotainer's global growth for development and technology and expanding its global service network.

Source: biospace.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. LEO Pharma collaborate with MorphoSys to develop peptide-derived drugs

Leo Pharma and MorphoSys AG both are jointly developing antibody based therapies in the field of dermatology. Leo Pharma, a global leader in the dermatology and MorphoSys AG, a late-stage, biopharmaceutical company, announced an expansion of their strategies including peptide-derivative therapeutics for the unmet medical needs that is valuable for both the companies.

According the agreement, Leo Pharma selects the target and MorphoSys would identify lead molecules using peptide based technology. Leo Pharma would develop this lead molecule and design to make drug candidates. Leo Pharma has rights for the development and commercialization.

MorphoSys said that peptide based therapeutics boost their pipeline for the high unmet medical needs in dermatology. They will receive R&D funding, development, regulatory and milestone payments with royalties on net sales.

Source: pharmabiz.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Indian and US scientists collaborate to research on eye diseases

Indian scientist from a non-profit institution who have conducted a research on eye disease like diabetic retinopathy, glaucoma and age related macular degeneration (AMD), will collaborate with the US scientists to boost their scientific efforts.

The Department of Biotechnology (DBT) and the National Institutes of Health (NIH) under the US Department of Health and Human Services will focus on genetic susceptibility and biomarkers. The proposal also initiates congenital cataracts, retinitis, pigmentosa, refractive error, and corneal injury, and basic translational, epidemiological research will also be encouraged.

All Government of India recognized academia, trust and research foundations are eligible to take part in this programme. The Indian and US governments have been successfully collaborating for several years now.

The DBT will provide funds for the Indian component and NIH research will directly support salaries of US personnel and research activities within the US. The initiative would help the study on environment pollutants in ocular disease and corneal transplantation.

Source: pharmabiz.com

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DRUGS: APPROVALS AND LAUNCHES

1. USFDA approves Glenmark's generic drug

Glenmark pharmaceutical has got a final approval from the US health regulator for Estradiol Vaginal Insert 10 mcg, a generic version of the novardisk's VAGIFEM for reliving menopausal symptoms.

Glenmark's current portfolio includes authorization for production of 139 products in the US while 61 drugs are pending approval from Abbreviated New Drug Applications (ANDAs).

The company's stock was trading atRs 695.40 up 0.65% on the BSE.

Source: health.economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

2. FDA approves Lumoxiti for hairy cell leukemia

The U.S. Food and Drug Administration has approved a new treatment Lumoxiti (moxetumomab pasudotox-tdfk) for hairy cell leukemia (HCL). HCL is a rare slow growing blood cancer in which the bone marrow develops a large amount of beta cells.

LUMOXITI™
moxetumomab pasudotox-tdfk
for injection

Lumoxiti (moxetumomab pasudotox-tdfk) is an intravenous injection with purine nucleoside analog for the treatment of relapsed and refractory HCL. Lumoxiti is a CD22 directed cytoxin.

The approval was based on a single arm, open-label clinical trial in 80 patients, where the complete response (CR) was achieved in 30% patients and 75% patients showed the overall response rate (partial + complete response). There was no serious adverse event reported but common side effects like infusion related reaction, swelling, nausea, headache, fever and constipation were observed.

The prescribing information states about the risk of developing capillary leak syndrome. Symptoms of capillary leak syndrome involves difficulty in breathing, increased weight, decreased blood pressure, swelling of arms, legs and face and hemolytic uremic syndrome. Women should avoid breastfeeding during Lumoxiti.

Source: worldpharmanews.com

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DRUGS: APPROVALS AND LAUNCHES

3. Teva gets US nod for fremanezumab for prevention of migraine

The U.S. Food and Drug Administration (FDA) has approved Teva's new drug Ajovy (fremanezumab) for the prevention of migraine. Migraine is a neurological condition affecting more than 36 million people in the US. Approximately 40% of people are living with migraine, but majority of patients are untreated.

Fremanezumab is a monoclonal antibody, which binds and inhibits the calcitonine gene- related peptide (CGRP) and exerts a preventive effect for both migraine and cluster headache. This is the first anti-CGRP treatment for the prevention of migraine using quarterly and monthly dose.

The clinical trial was conducted in chronic migraine patients and showed a 50% reduction in the number of average headache days per month using a quarterly dose of fremanezumab and 41% reduction using the monthly dose compared to 18% in the placebo group.

Using fremanezumab, the reduction in the average number of headache days per month was about 4.4% and 4.6% at quarterly and monthly doses compared to 2.5% in placebo group.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

4. BTG launches ICEfx cryoablation system

BTG, a global healthcare company, has launched ICEfx cyroablation system. ICEfx is an evolution of the existing visual ICE system which is predictable, reliable with seamless therapy, easy to operate and delivery. It is designed for the interventional radiologist for minimally invasive treatment options.

Cryoablation procedures are safe, efficient, precise and effective treatment therapy without the need of surgery and repeated radiation therapy. Cryoablation products address patient conditions across multiple physician specialties. The system has a new and compact design that simplifies using the set of on-screen prompts. This updated version works on the current lines of BTG Cryoablation probes.

Cryoablation technology will support in research in clinical studies for therapeutic areas like bone, kidney, lung and prostate. The new technology was launched at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) in September 2018.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Researchers develop new drug for pancreatic cancer

The University of Houston researchers have developed a new medicine MA242 for fatal pancreatic cancer. The drug works on two major pathways: it inhibits the nuclear factor of activated T cells1 (NFAT1) and murine double minute 2 (MDM2) genes.

The discovery represents significant advances in cancer treatment. The drug would be a first-in-class, new therapy for pancreatic cancer and a new conceptual framework for developing other drugs.

Pancreatic cancer often leads to metastasis and shows a poor response rate of chemotherapy. Gemcitabine is the only modest clinical beneficial treatment for advanced pancreatic cancers. Stromal depletion and immunotherapy have also have been proposed to offer substantial promises for treating advanced pancreatic cancers.

NFAT1 and MDM2 are cancer-causing genes that are linked to the pancreatic cancer and regulate the p53 tumor suppressor gene. In the absence of tumor suppressor gene p53, MDM2 will cause cancer on its own. NFAT1 up regulates MDM2 expression and encourages tumor growth.

MA242, inhibits both the proteins at the same time and increases specificity and efficiency of tumor killing. MA242 is a potent dual inhibitor which can deplete both proteins at the same time increasing specificity and efficiency of tumor killing.

Source: worldpharmanews.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Lilly gets rights to develop oral non-peptide GLP-1 receptor agonist

Chugai Pharma and Eli Lilly have entered into a license agreement for OWL833 oral non-peptide GLP-1 receptor agonist. OWL833 is phase 1 ready asset being studied for the treatment of type-2 diabetes.

Lilly will receive license for the development and commercialization, and Chugai will receive an upfront payment of $50 million based on predetermined milestones. Lilly is committed to developing the next generation of diabetes therapies.

OWL833 is best in class oral non peptide GLP-1 receptor agonist with enhanced clinical development to help people live with diabetes.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Camurus gets positive results in Phase III study

Camurus gets positive results in a Phase III efficacy study for patients with opioid dependent chronic low back pain.

The Phase III study demonstrated effective results of CAM2038 as it provides a long acting relief from chronic pain in patients previously treated with opioids. The study met successful primary and secondary endpoints, significantly improving relief of worst pain compared to placebo.

The primary and secondary efficacy endpoints of the study were the change in means of the average and worst pain intensity from baseline to week 12. The treatment difference for CAM2038 versus placebo was 1.03 ($p<0.001$) for the average pain intensity and 1.11 ($p<0.001$) for the worst pain intensity.

The overall safety profile of CAM2038 in chronic pain patients was beneficial. The patients with opioid dependence were evaluated in a 52-week, open-label extension study, in which patients either continued from the randomized efficacy part of the study or are included directly in the open-label extension phase.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Novartis shows positive results in Phase III study in ROP

Novartis has announced positive results from a Phase III study of Lucentis (ranibizumab) vs. laser surgery in premature infants with retinopathy of prematurity (ROP), a rare and leading cause of childhood blindness.

ROP is developed by an abnormal development of extra blood vessel and high level of vascular endothelial growth factor (VEGF). The estimated 23,800 to 45,600 infants were diagnosed with irreversible ROP last year.

Laser treatment is the current standard of care, but it can damages eye tissues and is associated with complication like myopia. Lucentis is focused on reducing the elevated intraocular pressure and VEGF, which is the major cause of the disease.

Lucentis (ranibizumab injection) is the first anti-vascular endothelial cell growth factor (anti-VEGF) therapy licensed for ophthalmic use. It has revolutionized the treatment of nAMD and has helped to reduce the blindness due to nAMD by 50% in several parts of the world.

The RAINBOW was a randomized, open-label, multicenter study in 26 countries for evaluation of the efficacy and safety of intravitreal Lucentis (ranibizumab) compared with laser surgery in 225 patients having ROP. The trial was conducted with two different 0.1mg and 0.2mg dose. The outcomes were measured after 24 weeks from the treatment.

In the Phase III RAINBOW study, despite marginally missing statistical significance for the primary endpoint of demonstrating superiority of Lucentis to laser surgery, Lucentis was shown to be an efficacious, safe and well-tolerated treatment for infants with ROP. Novartis plans to file ex-US for a new indication in ROP to bring transformative treatment to premature infants facing severe vision loss - the first anti-VEGF product to seek an ROP indication.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Sandoz announces global resolution of biosimilar adalimumab patent disputes

Sandoz, a Novartis division and the global leader in biosimilars, announced a global resolution of all intellectual property (IP) related litigation with AbbVie concerning the proposed Sandoz biosimilar Hyrimoz® (adalimumab) for reference medicine Humira® (adalimumab).

Under the terms of the agreement, AbbVie grants Sandoz a non-exclusive license to AbbVie's intellectual property relating to Humira®, beginning on certain dates in certain countries in which AbbVie has IP.

The license period will begin on October 16, 2018 in most countries in the European Union, and on other dates in various other countries outside the US where AbbVie has IP. In the US, the license period will begin on September 30, 2023.

Sandoz biosimilar adalimumab was recently approved by the European Commission (EC) for 31 countries of the European Economic area, which comprises the 28 member countries of the European Union plus Norway, Iceland and Liechtenstein. It is the seventh approved Sandoz biosimilar medicine.

Source: health.economictimes.indiatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. CAN04 antibody gets Japanese patent

Cantargia, a biotechnological company, has announced that its CNNO (nidanilimab) antibody has received Japanese patent. Nidanilimab binds with interleukin 1 receptor accessory protein (1IL1RAP) that blocks and inhibits its activity and the antibody and is being developed for cancer therapy. CNNO is active against IL1RAP. The Japanese patent number is JP6396488.

According to the research, CNNO4 is currently under Phase I/IIa clinical trial focused only on non-small lung cancer and pancreatic cancers. Currently, it has been granted the patent in Japan and used in cancer treatment. The patent in Japan confers protection until 2035. Cantargia also has patents granted around IL1RAP as a target molecule for antibody-based cancer therapy.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Texas has patented a smart seat cushion for prosthetics

Researchers of the Texas University at Arlington have patented a smart seat cushion used with air pressure to redistribute and maintain body weight. This will prevent ulcers caused by sitting for long periods on wheelchairs. The same technology can be used to create prosthetic liners that adapt their shape to accommodate changes in body volume.

This seat cushion worked on sensors that generates a pressure map and identifies vulnerable areas where pressure relief is needed. Automated pressure modulation uses this data to reconfigure the seat cushion surface to offload and redistribute pressure from sensitive areas. Additionally, the seat cushion periodically changes the pressure profile to eliminate pressure buildup over time.

The researchers recently presented the results of their studies on a full-sized seat cushion prototype at the ASME 2018 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference held in Quebec City, Canada.

Source: sciencedaily.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Perrigo settles patent issue for picato gel

Perrigo, a leading health care company, announced that it has settled with Hatch-Waxman litigation regarding the topical drug treatment picato gel (ingenol mebutate), which has been brought by LEO Pharma. The terms and conditions of the settlement are confidential.

Picato (0.015%, 0.05%) is used for the treatment of actinic keratosis; the annual market sales of drug were $80.5 million according to IQVIA.

The company has said that this settlement is the long-term investment for the extended topical drug treatment.

Source: prnewswire.com

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TECHNOLOGY /NDDS

1. Researchers developed a new brain imaging method

Researchers have developed a new method for diagnosing Alzheimer's disease that shows exact presence, distribution and accumulation of tau protein in the brain. Tau protein is a main indicator of Alzheimer's disease.

In Alzheimer's disease, there is a deposition of two types of protein, one is tau protein and the second is beta amyloid proteins. Tau proteins develop tangle and block nerve synapses. Beta amyloid protein causes formation of plaques across the brain. In the disease, tau protein starts to spread to neuronal cells which begin to die resulting in memory loss and other difficulties.

Researchers performed positron emission tomography (PET) scans and detected presence of tau proteins in the brain. The PET scans used radioactive markers administered intravenously that light up tau protein clearly detect the presence or absence of tau protein.

This new tau - PET imaging test is able to detect 90-95% positive results compared to MRI test. This method would be useful in the clinical trials used in Alzheimer's to check their effectiveness. This study is published in the scientific journal "*JAMA* (*Journal of the American Medical Association*)."

Source: news-medical.net

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2. Potential and advanced digital technologies in healthcare transformation

Many advanced technologies are being incorporated into the primary health care systems like Artificial intelligence (AI), Machine learning (ML), Natural language processing (NLP) and Blockchain.

AI and ML have potential in certain disease conditions like breast cancer. A Bangalore-based start-up is using relatively low-cost thermal cameras to capture body heat-emission patterns, which is then read by computerized AI-ML quickly into a first-pass breast-cancer diagnosis. It has potential to transform survival of cancer.

Approximately 10% population is affected with mental disorders, for which the most effective treatment is still cognitive behavior therapy (CBT) which is very costly and not affordable for middle class patients. The Bangalore based start-up has combined with NLP and AI to develop Wysa using a fully validated counseling approach. When deployed at scale, in combination with a good primary care structure, and the support of well-trained human staff, it has the potential to transform the lives of millions of young people and adults at little or no additional cost.

Blockchain is an Electronic Health Records (EHR) system that is able to securely store and maintain health records in a single version to securely share patient's data with a range of healthcare providers, and integration with AI-ML systems. AI can be used as a biomedical device to play key roles as sensors to help measureor monitor breathing rates, blood oxygen level, B.P. and diabetes.

The US Food and Drug Administration has recently approved an AI program. In the program, IDx-DR, for detecting diabetic retinopathy, the physician uploads the digital images of the patient's retinas to a cloud server on which IDx-DR software is installed, and the software provides the doctor with the diagnosis. As in the case of medicines and vaccines, regulators need to measure and evaluate medium and long-terms impact of such new technologies as they approve these interventions based on the short-term data.

Source: health.economictimes.indiatimes.com

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3. TINY device effective in Kaposi sarcoma-associated herpes virus

Tiny Isothermal Nucleic Acid Quantification (TINY) is a cancer detector device powered by sunlight and has successfully detected Kaposi sarcoma-associated herpes virus (KSHV). TINY has got funding from the National Institute of Health. The team is planning for testing over the next several years. The study has been published in "*Nature Biomedical Engineering.*"

Kaposi Sarcoma is a cancer, developed in lymph or blood vessels, which sometimes appear on the skin, mouth or internally. KSHV is most common in sub-Saharan Africa. TINY performs loop-mediated isothermal application for nucleic acid quantification (LAMP) required power source for 154 degree heating. The team had collected biopsy sample from 71 patients' in Uganda with KS, the samples were tested with TINY and via quantitative polymerase chain reaction (qPCR). Agreement between TINY and qPCR was 94% (67 of 71), and the team showed that all disagreement stemmed from assay limitations and not TINY capability.

TINY can be used in clinic and hospital. TINY will be expanding the testing to other countries and also has applied for patent in Cornell's Center for Technology Licensing.

Source: sciencedaily.com

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4. New sugar-powered sensor to detect, diagnose and prevent diseases

A team led by Indian origin scientist has developed an implantable sugar power sensor for monitoring body's biological signals to detect, prevent and diagnose diseases. This detector uses a biofuel cell and sugars from body fluids to run.

The sensor, described in IEEE Transactions of Circuits and Systems journal, has a unique integration of biofuel cell with electronics to process physiological and biochemical signals with high sensitivity.

Many popular sensors for disease detection are either watches, which need to be recharged, or patches that are worn on the skin, which are superficial and can't be embedded. The sensor developed by the team could also remove the need to prick a finger for testing of certain diseases, such as diabetes.

Source: health.economictimes.indiatimes.com

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WHAT'S NEW AT LAMBDA

1. New method development for PK and immunogenicity for large molecule

Lambda has successfully developed and validated bioanalytical methods to support pharmacokinetics measurement and immunogenicity assessment of Romiplostim. Romiplostim is a fusion protein analog of Thrombopoietin and is indicated for treatment of chronic idiopathic (immune) thrombocytopenic purpura (ITP).

The pharmacokinetic measurement assay is a sandwich ELISA based ligand binding assay, which employs anti-romiplostim antibody as capture and biotin conjugated anti-romiplostim antibody as detection reagent. The endpoint is colorimetric and is measured in terms of Optical Density. The assay is extremely sensitive with the lowest limit of quantification at 40 pg/mL and is selective and specific to detect and quantify low serum levels of romiplostim.

An electro-chemiluminescence immunoassay (ECLIA) has been developed for immunogenicity assessment of romiplostim. The assay is based on bridging format and employs biotin conjugated romiplostim and sulfotag conjugated romiplostim for capture and detection of anti-romiplostim antibodies, respectively.

The bioanalytical romiplostim methods were used to support a Phase III trial of the biosimilar of N-Plate (Amgen Inc.) and the results obtained were corroborating with the reported data of N-Plate by Amgen Inc.

2. Successful site inspection by the USFDA

Proud to announce that we have successfully completed an Inspection/Audit of 5 parallel multi-centric site inspections by the US Food and Drug Administration (USFDA) with zero 483s. This achievement reiterates our constant endeavor and commitment towards Quality in Patient based Clinical Trials in India.

The inspection was conducted for Clinical trials carried out between 15th and 26th Oct for two Atopic Dermatitis studies and one Chronic Myeloid Leukemia study. With this successful closure, we have now cleared 38 multi-centric Inspections/Audits by the USFDA for patient based trials carried out for US submission across various sites & geographies we have developed in India.

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