Lambda Research Newsletter

May 2019

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Research Accelerated

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WHAT'S NEW AT LAMBDA

1. Successful completion of NPRA inspection at Ahmedabad facility

The National Pharmaceutical Regulatory Agency (NPRA) of Malaysia completed its inspection of the bio-availability/bio-equivalence (BA/BE) clinical facility of Lambda Therapeutic Research Limited at Ahmedabad in Gujarat, India, from 15-19 April 2019. The clinical and bioanalytical phases for three bioanalytical/bioequivalence (BA/BE) studies were inspected during this audit. The audit was successful without any critical observations.

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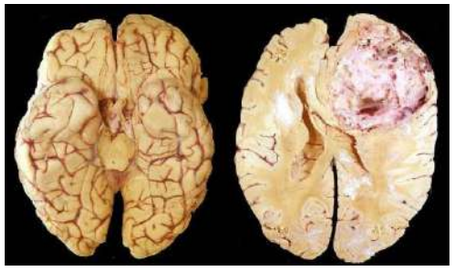
GLOBAL NEWS

1. Study reveals Achilles' heel of aggressive brain cancer



In a study, researchers from the University of Helsinki in Finland has demonstrated that inhibiting the functions of a gene may lead to the death of the most prevalent and lethal type of brain tumours in adults.

Glioblastomas are the brain tumors that adept at invading tissue and metastasizes in the brain. There is currently no curative treatment available for the disease and it cannot be surgically completely excised due to metastasis. Furthermore, glioblastoma cells are extremely resistant to existing drug therapies.

In earlier studies, it has been reported that the ability of glioblasatoma cells to invade tissues is increased by the expression of a small fatty acid-binding protein (MDGI, or FABP3). This invasion of glioblastoma to other tissues is linked with a poorer prognosis. The current study revealed that inhibiting the function of this gene results in the death of the tumour cells.

The inhibition of the MDGI fatty acid affects the transport of linoleic acid from outside to inside cells resulting in a significant change to the fatty acid composition of the lysosomal membrane leading to leakage of acidic and proteolytic enzymes present in the lysosomes into the cytoplasm eventually initiating cell death. Furthermore, phospholipid composition of the lysosomes in glioblastoma cells was found altered due to the inhibition of MDGI, which also increased the membrane permeability.

Overall, researchers concluded that MGDI is the first gene found to regulate and maintain the structure of lysosomal membrane.

Source: economictimes.indiatimes.com

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GLOBAL NEWS

2. Severe dry eye disease treatment by a new enzyme

Dry eye disease is manifested by the production of abnormal tears and inflammation of the cornea. In severe dry eye disease, corneal tissues are extremely inflamed causing disabling eye pain and sensitivity to light. It is often accompanied with Sjogren's syndrome and ocular graft-versus-host disease (GVHD).

There are currently only two approved drugs available for the treatment of dry eye disease, which have shown poor results for few patients, especially in cases of severe disease. Normally, enzymes present in tears chop up and clear DNA and other debris on the cornea, but in patients with dry eye disease, there is not enough deoxyribonuclease (DNase) to clear the material.

According to the study published in the *Journal of Translational Vision Science and Technology*, a new enzyme-based treatment drastically reduced the signs of severe dry eye disease and discomfort. The study compared eye drops containing a biosynthetic form of an enzyme called DNase with eye drops without the enzyme. The study resulted in less eye discomfort with healthier cornea in patients who received drops with DNase. In the DNase group, a statistically significant and clinically meaningful reduction in corneal damage was observed compared with the placebo group at eight weeks.

"The data from this early clinical trial suggests that DNase eye drops may be safe and effective for treating severe dry eye, and we look forward to conducting larger randomized trials to definitively prove its efficacy," said principal investigator of the study, Dr Sandeep Jain.

Source: economictimes.indiatimes.com

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GLOBAL NEWS

3. Four hallmarks of cancer metastasis identified

Motility and invasion, modulation of the microenvironment, plasticity and ability to colonize have been identified as the four hallmarks of cancer metastasis by researchers at the University of Alabama at Birmingham and the University of Kansas Cancer Center. A literature review of >10,000 publications on cancer metastasis was conducted and the findings are published in the journal *Cancer Research*, from the American Association for Cancer Research.

The cancer metastasis – spreading of cancer to different parts of the body from where it has started – leads to ~90% cancer deaths. The treatment outcomes of cancer metastasis are very poor. Brain, bones, lungs and liver are the most common cancer metastasis sites; other sites include adrenal gland, lymph nodes, skin and other organs.

The literature review has identified four hallmarks of metastasis:

1. Motility and invasion
2. Modulation of the microenvironment
3. Plasticity
4. Ability to colonize

The researchers hope to provide a conceptual framework to accelerate the discovery of treatment strategies for metastatic cancer by defining the hallmarks of metastatic cancer cells.

Source: economictimes.indiatimes.com

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GLOBAL NEWS

4. Heart cells regeneration by gene therapy

Scientists from King's College London, UK, have developed a gene therapy that can induce regeneration and repairing of the damaged heart cells after heart attack. Heart attack causes permanent structural damage to heart cells through the formation of a scar.

Several attempts have been made to regenerate the heart cells using stem cells but have failed. "It is a very exciting moment for the field that for the first time real cardiac repair was observed," said Mauro Giacca, from King's College London.

In a study, researchers delivered 'microRNA-199', a small piece of genetic material, to the heart of pigs with myocardial infarction. This genetic material resulted in a nearly complete recovery of cardiac functions one month later. The study results are published in the journal *Nature*.

This is the first demonstration that cardiac regeneration can be achieved by administering an effective genetic drug that stimulates cardiac regeneration in a large animal, with heart anatomy and physiology similar to that of humans.

Source: economictimes.indiatimes.com

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PHARMA INDIA

1. Growing burden of lung cancer: Two million yearly cases in India

In India, lung cancer is the most common cancer and has the highest mortality rate when compared to other cancers.

The early detection of the disease can improve patient survival according to doctors at the first international conference and live workshop on endobronchial ultrasound (EBUS) and advanced lung cancer treatments at Yashoda Hospital, Hyderabad.

The Indian Council of Medical Research estimates that over two million lung cancer cases occur in India every year.

“Lung cancer constitutes 7.5% of all new cancer cases and 10% of all cancer related deaths in India,” said Dr Pavan Gorukanti, Director of Yashoda Hospitals.

Source: economictimes.indiatimes.com

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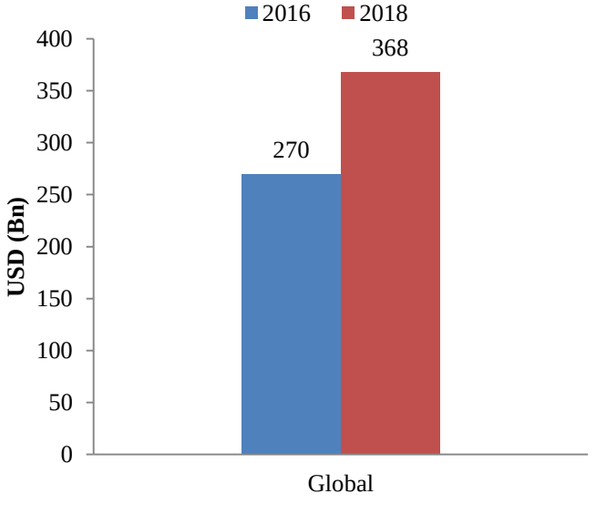
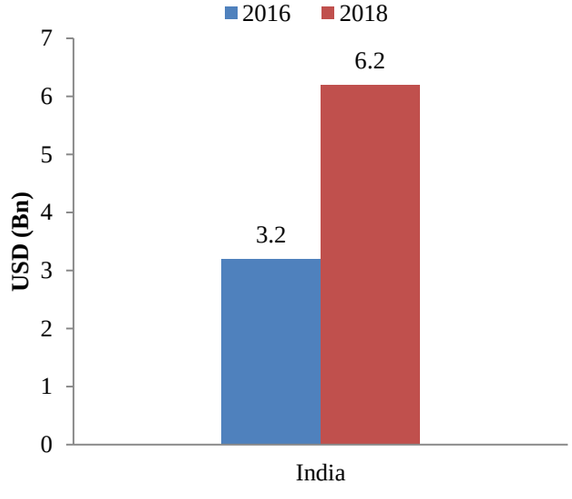
PHARMA INDIA

2. Home healthcare market to grow to US $6.2 billion by 2020

The home healthcare market in India is projected to grow from US $3.2 Billion in 2016 to reach US $6.2 Billion by 2020 at a compound annual growth rate of (CAGR) of 18%. The Indian healthcare landscape is currently led by some promising startups, even as healthcare providers begin to eye the growing market. The global home healthcare market is anticipated to reach US $368 Billion by 2020 from US $270 Billion in 2016 at a CAGR of 8%.





With a growing pharma, medical devices and hospital industry, India's healthcare industry is fast changing and adopting new trends to meet the growing healthcare demands of its customers. In view of this, the home healthcare sector is expected to change the complete landscape of Indian healthcare.

Source: pharmabiz.com

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PHARMA INDIA

3. Netmeds.com to set up 26 'Fulfillment Centers' across the country by 2020

Netmeds.com, India's leading online pharmacy, is expected to set up 26 Fulfillment Centers (FCs) across metros and Tier II cities by 2020. This exercise is an effort from Netmeds.com to reach rural as well as urban areas for quick and efficient delivery of medicines.

Netmeds has currently 14 Fulfillment Centers in India: three centers in Chennai, and one each in Bangalore, Hyderabad, Delhi, Mumbai, Kolkata, Ahmedabad, Pune, Noida, Lucknow, Raipur and Guwahati.

Currently serving >3.7 million customers in >610 cities and 19,000 pin codes across the country, Netmeds.com provides access for >50,000 prescription drugs.

Source: pharmabiz.com

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PHARMA INDIA

4. China to offer great opportunity for Indian drug makers

China is considered the second largest healthcare market globally. It has huge potential for the Indian pharmaceutical industry to explore. Traditionally, China has not been easily accessible for the Indian generic pharmaceutical manufacturers due to their stringent regulatory system and complex trade barriers.

The demand for healthcare needs is rising in China due to an ageing population and currently, the Chinese government is looking towards reducing their healthcare costs. This may be the right time for Indian generic makers to explore the opportunity in China to get a bigger market share.

The Union Ministry of Commerce and Department of Pharmaceuticals are in regular discussion with the Chinese regulators and their market leaders to ease the regulatory system and trade barriers so that Indian companies can explore Chinese healthcare and pharmaceutical markets.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. FDA: 34 New and Revised Product-Specific Draft Guidance Documents

The US Food and Drug Administration (FDA) has released the latest batch of 25 new and nine revised (n=34) product-specific guidance documents. These documents will support in the development of generic drugs. The product-specific guidance is aimed to spur generic competition.

The list of new draft guidances was topped by human immunodeficiency virus (HIV) antiretrovirals and antibiotics with a total of five documents; ophthalmic ailments and cancers products followed the list. The revised product-specific draft is for azelaic acid and ivermectin; both the drafts were revised for the second time.

Each guidance document provides product-specific recommendations to help pharmaceutical manufacturers for designing the bioequivalence (BE) studies to support abbreviated new drug applications (ANDA). The total number of product-specific guidances has reached to 1,744 since 2007.

In February 2019, the last set of product-specific guidances was issued by the USFDA including 22 new and 52 revised draft guidances.

Source: raps.org

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REGULATORY ROUND-UP

2. FDA preparations for new guidance on benefit-risk assessment

As a part of the US Food and Drug Administration (FDA) preparations in drafting new guidance on the benefit-risk assessment of new drugs and biologics for FY 2020, the agency officials and pharmaceutical industry experts had a meeting to discuss how FDA should assess the benefits and risks of new drugs from the preclinical to postmarket phases.

The FDA's Center for Drug Evaluation and Research (CDER) explained that the guidance document will reflect the agency's decision-making context for benefit-risk assessments for pharmaceutical products throughout their lifecycle.

The guidance document will assist the pharmaceutical manufacturers to communicate and submit data to FDA. The guidance will also explain the way to incorporate patient experience data that will be used for benefit-risk assessments.

Furthermore, new ideas related to an updated integrated review template, that FDA will use internally, were also discussed in the meeting.

Source: raps.org

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REGULATORY ROUND-UP

3. DBT, CDSCO organizing workshops on regulations for innovators

Department of Biotechnology (DBT) jointly with Central Drugs Standard Control Organisation (CDSCO) is organizing a national series of six regulatory workshops across the nation on facilitating resolution of regulatory concerns faced by innovators in India.

This workshop series is being conducted by the Biotechnology Industry Research Assistance Council (BIRAC) and Clinical Development Services Agency (CDSA).

Three workshops in the series have been conducted in New Delhi, Pune and Bengaluru. The fourth in this series is being organized on 29th May 2019 at the National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad.

This workshop series aims to facilitate Make in India drive by helping the innovators. It will offer an opportunity to the innovators to interact with the regulators to resolve their regulatory issues thereby facilitating them to seek market authorization.

Deliberations will be done on various regulatory pathways applicable for the development of new drugs, biopharmaceuticals, vaccines, medical devices & IVD kits, phytopharmaceuticals from discovery to commercialization.

It is intended to prove beneficial for innovators, personnel working in the government national laboratories, academics and research institutions, participants from non-governmental institutions, startups, SMEs, MSMEs, industry, researchers etc.

Source: biospectrumindia.com

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REGULATORY ROUND-UP

4. GMP in combatting antimicrobial resistance: WHO document

The World Health Organization (WHO) issued a 24-page draft document on environmental aspects of good manufacturing practices (GMP) intended to raise awareness among the inspectors and manufacturers of antimicrobials. The document is WHO's response to the threat of antimicrobial resistance (AMR).

The WHO document will provide the best ways to interpret relevant GMP guidance sections applicable to managing waste and wastewater from antimicrobials' production. This WHO document also proposes guidance on controlling and minimizing the environment contamination from production processes of antimicrobials and chemicals. WHO has asked inputs on the draft, including the proposals for ways to combat AMR when manufacturing drugs.

AMR is considered a broader term than antibiotic resistance, which includes resistance to drug treatments of bacterial infections caused by more microbes such as parasites. The antibiotic resistance is limited to only bacteria. In recent years, both AMR and antibiotic resistance have been spreading, posing a global threat.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Pfizer to buy biotech firm Therachon Holding for $810m

Pfizer will acquire Swiss biotechnology firm Therachon holding up for $810m to support its rare disease portfolio. Pfizer will make an upfront payment of $340m and a further $470m upon achieving certain milestones in the development and commercialization of TA-46.

TA-46 is an investigational, soluble recombinant human fibroblast growth factor receptor 3 (FGFR3) decoy being developed as a weekly subcutaneous injection to address the overactive FGFR3 signaling pathways related to bone development abnormalities in achondroplasia in children and adolescents. Achondroplasia is a genetic dwarfism responsible for serious cardiovascular, neurological and metabolic complications. There are currently no approved treatments for this condition.

Phase I study for TA-46 has been completed and the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) has been granted orphan drug designation.

Therachon's pipeline also features apraglutide for rare gastrointestinal (GI) diseases, TA-46 LCM for skeletal dysplasias, and TA-100 FGFR3 decoy for achondroplasia and other rare skeletal dysplasias.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novartis to buy blockbuster-in-waiting 'Xiidra' of Takeda in $5.3bn deal

Novartis is set to buy Takeda Pharmaceutical's Xiidra 5% drug for a total consideration of up to $5.3bn. Xiidra (lifitegrast ophthalmic solution) is an anti-inflammatory medicine indicated to treat dry eye disease.

Novartis will make an upfront payment of $3.4b, potential milestone payments of up to $1.9b under this deal. The net sale of Xiidra for the fiscal year ending on 31 December 2018 was $388m.

Previously, Takeda had acquired Xiidra from Irish biopharmaceutical company Shire for $62b acquisition deal. Xiidra was first launched in the US in 2016, and generated sales of around $400m last year.

This deal fits with Novartis' strategy focusing on first-in-class medicines or breakthrough therapies to help offset generic competition to its intraocular hypertension drug Travatan and antihistamine Pataday.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. AstraZeneca collaborates with Transgene to develop cancer drug candidates

AstraZeneca has signed an agreement with French biotech company Transgene to develop cancer drug candidates using genetically engineered vaccinia viruses.

AstraZeneca will leverage Transgene's Invir.IO platform to design oncolytic immunotherapies. The company will provide expertise in areas such as viral design and engineering.

Transgene will be paid with an upfront payment of $10m by AstraZaneca, along with up to $3m when the drug candidates meet pre-clinical milestones.

Furthermore, Transgene will also be eligible to receive an option exercise payment for each product, if AstraZeneca decides to exercise its license option. Transgene will receive development and commercial milestones, as well as royalties.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. AstraZeneca partnered with BenevolentAI

AstraZeneca has partnered with artificial intelligence (AI) company BenevolentAI to develop treatments for chronic kidney disease and idiopathic pulmonary fibrosis.

The companies will leverage machine learning and AI-based reasoning to examine the data and underlying mechanisms of diseases under this long-term alliance.

The companies will combine AstraZeneca's genomics, chemistry and clinical data with BenevolentAI's target identification platform and biomedical knowledge.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. FDA approves Roche's drug combo Venclexta plus Gazyva

Roche has received U.S. Food and Drug Administration's (FDA) approval for Venclexta (venetoclax) plus Gazyva (obinutuzumab) for people with previously untreated chronic lymphocytic leukaemia.

Compared to a standard-of-care, Venclexta plus Gazyva is the only chemotherapy-free option of fixed duration that provides durable responses to help people live longer without progression of their disease.

The approval is based on randomised Phase 3 CLL14 study, which showed that fixed 12-month treatment with Venclexta plus Gazyva significantly reduced the risk of disease progression or death by 67% compared to the current standard-of-care Gazyva plus chlorambucil. The overall response rate was 85% for Venclexta plus Gazyva compared with 71% for Gazyva plus chlorambucil ($P<0.001$).

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

2. Novartis' cancer treatment Kymriah gets Japanese approval

Novartis' cancer treatment Kymriah (Tisagenlecleucel) has been approved by a Japanese government panel at a price of 33.5 million yen ($305,800).

Kymriah works by removing disease fighting T-cells from individual patients, modifying them to attack cancer, and then re-infusing them back into the patients.

The Swiss drug-maker aims to use the one-time personalized therapy in Japan for children and young people with acute lymphoblastic leukemia (ALL) and adult patients with diffuse large B-cell lymphoma (DLBCL).

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. Pfizer gets U.S. FDA approval for tafamidis

The U.S. Food and Drug Administration (FDA) has approved Pfizer's 'tafamidis' for the treatment of a rare and fatal heart disease 'transthyretin amyloid cardiomyopathy'.

Tafamidis has already received breakthrough designation from the FDA based on the clinical data that it reduces the risk of death by 30% in patients with transthyretin amyloid cardiomyopathy when compared with placebo.

The annual sales forecast for tafamidis is >$1 billion in 2024, according to Refinitiv data. The FDA has also approved another oral formulation of tafamidis under the brand name Vyndamax.

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

4. Glenmark Pharma launches Remogliflozin in India

Glenmark Pharma has launched the anti-diabetic drug remogliflozin in India. "Glenmark is the first company in the world to launch the novel SGLT2 inhibitor remogliflozin and India is the first country to get access to this innovative drug...the drug is indicated in the treatment of type-2 diabetes mellitus in adults," the company said in a regulatory filing.

Glenmark will commercialize remogliflozin in India under the brand names 'Remo' and 'Remozen'. Glenmark has received regulatory approval for remogliflozin etabonate 100 mg tablets based on the successful results from phase 3 clinical trials.

India's diabetes market is estimated at Rs 11,413 crore as (MAT March 2019) as per IQVIA data. The market size of SGLT2 inhibitors is estimated at Rs 574 crore (MAT March 2019).

Source: economictimes.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Phase 3 study of Ryaltris to treat seasonal allergic rhinitis

Ryaltris, an investigational fixed-dose combination nasal spray for the treatment of seasonal allergic rhinitis (SAR), has met its primary endpoint of achieving clinically meaningful and statistically significant change from baseline in average morning and evening Reflective Total Nasal Symptom Score (rTNSS) compared to placebo in a Phase 3 trial.

The study of Ryaltris (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg] nasal spray) met its primary endpoint in pediatric patients aged 6 to under 12 years of age. The results were consistent with clinical trial experience in patients aged ≥12 years.

Ryaltris, also known as GSP 301 Nasal Spray, has been conditionally accepted by the FDA.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. ReGenTree begins ARISE-3 Phase 3 trial for dry eye syndrome

ReGenTree, LLC, a joint venture company between GtreeBNT and RegeneRx Biopharmaceuticals, has initiated ARISE-3 trial - a randomized, double masked, placebo-controlled phase 3 study for dry eye syndrome.

The ARISE-3 study will compare the safety and efficacy of 0.1% RGN-259 eye drops to placebo for the treatment of signs and symptoms of dry eye syndrome in ~700 patients at 15 nationwide clinical sites. The trial is expected to be completed in the middle of next year.

RGN-259 eye drops contain the active small protein, thymosin beta 4. It is a naturally-occurring protein in tears, other body fluids, and cells. ARISE-1 and ARISE-2 clinical studies have already established the safety and tolerability of RGN-259 eye drops; minimal ocular discomfort on instillation similar to placebo were reported.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Biocon and Mylan to present final survival data for Ogivri

Mylan and Biocon will present the final data from the HERITAGE study at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago in June, 2019.

The HERITAGE study compared Ogivri, a biosimilar to the reference product - Herceptin, in patients with HER2+ metastatic breast cancer (MBC). The study evaluated the combination of Ogivri and taxane agent for the first 24 weeks and then as Ogivri as monotherapy until disease progression.

Ogivri is the first biosimilar for Herceptin approved by the US Food and Drug Administration (FDA) for all indications including HER2 positive breast and gastric cancers. Ogivri has received regulatory approval in >65 countries globally.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Abrocitinib meets goals in Phase 3 study for atopic dermatitis

Abrocitinib has met the primary endpoints of a Phase 3 study in patients aged ≥12 with moderate to severe atopic dermatitis. Abrocitinib is a JAK inhibitor that blocks the inflammation-causing enzymes 'Janus kinases'.

The study tested two doses of the drug in 387 patients and demonstrated that abrocitinib was consistently well-tolerated and achieved statistically significant improvements in clearing the skin when compared with placebo. Abrocitinib also met the secondary goals of reducing itch severity.

The Pfizer drug has received breakthrough therapy designation from the U.S. Food and Drug Administration (FDA) last year.

Source: economictimes.indiatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Vectura wins patent litigation battle against GSK for Ellipta products

Vectura has won the patent litigation trial against US GlaxoSmithKline (GSK). Vectura had filed a patent infringement lawsuit against GSK in July 2016 claiming that sales of certain GSK Ellipta products infringed Vectura patents.

The US District Court for the District of Delaware ruled that Vectura's US patent 8303991 was found valid and the US sales of three of GSK's Ellipta products had infringed Vectura's patents.

Vectura has been awarded $89.7million for the damages in period from August 2016 through December 2018 at a rate of 3% of US sales of these products.

Source: pharmatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Centrient initiates patent litigation against Dalas Biotech

Centrient Pharma has filed a patent litigation suit against Dalas Biotech claiming that the later has infringed upon its patent for enzymatic process for preparing amoxicillin trihydrate. The company has filed a lawsuit at the Delhi High Court in India.

Centrient holds a patent that describes an enzymatic process for preparing amoxicillin trihydrate with low free water content.

Centrient is also seeking compensation for damages and a permanent restriction to prevent the patent infringement regarding amoxicillin trihydrate produced by a process that amounts to patent infringement.

Karl Rotthier, CEO at Centrient said: “After having previously filed a patent litigation against Sinopharm Weiqida Pharmaceuticals for patent infringement in India, and the Court granting an injunction since April 2017, Centrient shows that it will continue to rigorously enforce its IP assets worldwide against any additional potential infringers in India or abroad.”

Source: expressbpd.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Gilead patent cliff looms as Teva plans generic Truvada launch

Gilead's HIV blockbuster Truvada (emtricitabine/tenofovir disoproxil fumarate or TDF) was expecting the onset of generic competition in 2021, but a recent SEC filing form Gilead suggests Teva – in pole position to bring a generic version to market – is now able to launch in 2020. Thus, Gilead is set to face generic competition with $3 billion annual sales at stake, a year earlier than expected.

The early arrival of Teva's generic to Truvada makes Gilead to accelerate the take-up of its emtricitabine/tenofovir alafenamide or TAF based regimens.

In Europe, Gliead has filed a patent protection extension by a supplementary protection certificate (SPC), but it was overturned last year and Gilead is already facing competition to Truvada with the generic launch.

Source: pharmaphorum.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Second US lawsuit filed against Aurobindo Pharma

Aurobindo Pharma and few other firms in the US generic drug industry are facing a second lawsuit for violation of antitrust laws, which was filed by US states on May 10, 2019, the second after the one filed in December 2016.

The US states filed a second lawsuit in Federal Court alleging these companies had violated antitrust laws by fixing prices and allocating customers. The "Second State AG Action" includes additional parties and additional products, not referenced in the "First State AG Action".

The first anti-trust lawsuit was filed in December 2016 against Aurobindo pharma and other companies in US generic drug business for fixing prices.

Aurobindo had denied all the accusations in the First State AG Action and is defending against the matter. Now, the company is reviewing the Second State AG Action and is expected to file papers denying the accusations.

Source: economictimes.indiatimes.com

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TECHNOLOGY /NDDS

1. Device to detect bacteria in minutes, not days

Scientists have developed a device that uses microtechnology to trap single bacteria cells that can then be viewed under an electron microscope. This will allow clinicians to determine the presence of bacteria in as little as 30 minutes instead of three-to-five days such lab work currently takes. This will also avoid prescription of antibiotics in cases where bacteria are not present.

The device was invented by a team at Penn State University and the details are described in a paper published in the Proceedings of the National Academy of Sciences.

The researchers have applied for a provisional patent for their device.

Source: economictimes.indiatimes.com

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Clinical Research NEWSletter
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2. DNA test: effective cervical cancer detecting tool

Researchers have established that DNA test is an effective method of cervical cancer screening for women in low-and-middle-income countries. There is a lack of adequate screening such as routine Pap smear testing for cervical cancer in low- and middle-income countries.

Researchers found that 28% of 1,732 women screened were positive for a high-risk HPV type; of these, 26% had >1 HPV infection. The study was published in ASCO's Journal of Global Oncology. The study also revealed that the most common HPV genotypes detected were different than those commonly found in the United States.

Researchers hope that these findings will guide studies of actual cervical cancer tissue and will help in designing therapeutic vaccine trials.

Source: economictimes.indiatimes.com

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3. mySugr App and Accu-Chek launched in India

Roche Diabetes Care (RDC) has launched its latest Integrated Diabetes Management Solution (IDMS) with “mySugr” app and “Accu-Chek Instant” blood glucose monitoring system; both of these form the next generation blood glucose monitoring system.

The mySugr app provides bluetooth connectivity with Accu-Chek Instant, which enables automatic uploading of patients’ glucose level data.

With this, the patient’s caregivers and doctors can easily access blood glucose monitoring data of the patient, which will enable modifications in the treatment dynamically.

The accuracy of Accu-Chek Instant is 10/10 in blood sugar monitoring, which exceeds the current accuracy criteria of ISO 15197:2013/EN ISO 15197:2015 system accuracy requirements.

Source: economictimes.indiatimes.com

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4. Radiation-free device to detect cancerous lymph nodes

Involvement of lymph node is very common in many breast cancer patients, and lymph nodes in majority of these patients are surgically removed to ensure that cancer does not metastasize. However, patients have difficulty in raising their arms due to removal of lymph nodes in their armpits. In lieu of the absence of an affordable technique to detect \ lymph node metastasis, doctors have been removing them.

Irillic, a start-up company in India, has invented a hand-held device — Irillic.nm Fluorescence Imaging System — to detect cancerous growth in lymph nodes. This system is an infra-red device that can scan body parts when given an injection of benign contrast dye called Indo-Cyanine Green (ICG), within seconds. This scanning allows detection of any abnormal growth in a lymph node.

Such devices are already available in the US and Japan, but the Indian device has several advantages such as affordability, better image quality and ease of use. Leading surgeons at Bengaluru have used this device, which costs INR <10,000 per test.

Source: pharmatimes.com

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