Lambda Research Newsletter

January 2023

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GLOBAL NEWS

1. Gilead's CAR T-cell therapy recommended for use across the NHS

Treatment involves adult patients with relapsed or refractory diffuse large B-cell lymphoma.

Gilead Sciences has announced that the National Institute for Health and Care Excellence (NICE) has recommended Yescarta (axicabtagene ciloleucel) for routine commissioning on the NHS across England.

It concerns the treatment of particular adults with certain forms of lymphoma – specifically patients with diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) who have already been treated with two or more systemic therapies.

CAR T-cell therapy is a treatment for patients currently licenced for those living with some types of advanced blood cancer. Meanwhile, CAR T-cell therapy engineers the individual patient's own immune cells to detect, target and destroy cancer cells.

The Cancer Drugs Fund, in 2018, England was the first country in Europe to provide access to a CAR T-cell therapy to treat these blood cancers. Since then, over 500 patients in England have received axicabtagene ciloleucel.

Source: pharmatimes.com

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GLOBAL NEWS

2. Moderna becomes latest company to join the ABPI

Company becomes the latest member of the ABPI and galvanises the company's UK connections.

Moderna is the latest member of the UK's leading pharmaceutical industry body, the Association of the British Pharmaceutical Industry (ABPI). It demonstrates a wider long-term commitment by the American-based company to expand its footprint and investment across the UK.

The company, which pioneers messenger RNA (mRNA) therapeutics and vaccines, is currently targeting rapid global growth. Essential to these ambitions will be a new vaccine research, development and manufacturing facility in the UK. This is due to create many jobs, while also building on the strength of the UK's life sciences ecosystem.

The ABPI represents companies of all sizes who invest in discovering the medicines of the future, including some of the world's largest, most innovative, and most successful pharmaceutical firms. All members sign up to adhere to the high standard of conduct captured by the ABPI Code of Practice.

Source: pharmatimes.com

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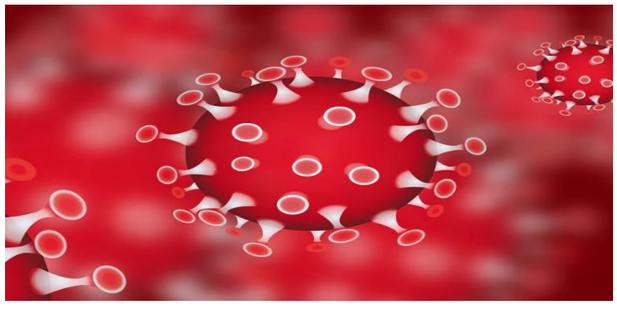
GLOBAL NEWS

3. Valneva delivers additional data for COVID-19 booster vaccine

Company has reported booster details from a study of its inactivated COVID-19 candidate.

Following a clinical study, Valneva's COVID-19 booster vaccine candidate, VLA2001, has yielded more data. A subset of participants received VLA2001 following two or three doses of the mRNA COVID-19 vaccine, with or without break-through infection among 25 to 50 participants per group.



VLA2001-307 is a multi-location, open-label clinical study investigating the safety, tolerability and immunogenicity of the VLA2001 booster vaccination in participants aged 18 years and older. Approximately 275 participants – either healthy or with a stable medical condition – were enrolled in the trial.

Valneva is now seeking regulatory approval for VLA2001 as a homologous booster as well as heterologous booster in AstraZeneca-primed individuals.

Source- pharmatimes.com

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GLOBAL NEWS

4. Mission Therapeutics concludes clinical assessment for lead DUB inhibitor

Safety, tolerability and pharmacokinetic endpoints for MTX652 have been successfully met.

Mission Therapeutics – a company which concentrates on selecting inhibiting deubiquitylating enzymes (DUBs) – has announced the successful completion of its first phase 1 clinical assessment for its lead USP30 DUB inhibitor, MTX652.

The phase 1 first time in human study began in May last year, following clinical trial approval in March. It involved over 80 healthy volunteers and research was led by Principal Investigator Dr Annelize Koch, senior medical director at Simbec-Orion.

The study achieved its key goals of demonstrating the safety, tolerability and pharmacokinetics of MTX652, with the treatment provided as a single and multiple-ascending doses of oral solution or suspension to healthy participants.

Source: pharmatimes.com

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PHARMA INDIA

1. Lupin gets tentative USFDA nod for Dolutegravir, Emtricitabine and Tenofovir tablets

Pharmaceutical firm Lupin Ltd on Tuesday said it has received tentative approval from the US health regulator for its new drug application Dolutegravir, Emtricitabine and Tenofovir Alafenamide (DETAF) tablets.

The tentative approval by the United States Food and Drug Administration (USFDA) has been granted under the President's emergency plan for AIDS relief (PEPFAR), Lupin said in a regulatory filing.

DETAF would be a welcome new addition in the management of HIV infections and will be available for supplies to low and middle-income countries, it added.

The new drug is well researched and affordable fixed-dose combination, which will significantly improve glycemic control in adult patients. This product would be manufactured at Lupin's Nagpur facility in India, the company said.

Source: economictimes.indiatimes.com

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PHARMA INDIA

2. Maharashtra FDA books 12 people in a counterfeit drug death case in Mumbai based Saifee Hospital due to ADR

Maharashtra Food and Drug Administration (FDA) has booked 12 people in a counterfeit drug death case that was reported in Mumbai based Saifee Hospital in November last year. A 55-year-old patient died at Saifee Hospital after adverse drug reaction (ADR) suspected to be linked to a fake injection – Inj. Orofer FCM, following which the Maharashtra FDA initiated a thorough investigation into the matter.

An adverse drug reaction can be defined as a harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product.

Tracking down the whole chain from the suppliers to the medical store owner, the Maharashtra FDA filed a complaint with the Mumbai police, leading to an FIR being registered against 12 people.

The offenders in the case included the medical store owner and a few drug suppliers who had allegedly sold the drug to the patient, as per the probe initiated by the Maharashtra FDA. The drug in question was found to be counterfeit and the police also filed a case against the offenders.

Source: pharmabiz.com

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PHARMA INDIA

3. DCGI approves MSD's Keytruda for additional indications of cervical and esophageal cancers

US-based pharma major MSD (tradename of Merck & Co., Inc) announced that the Drugs Controller General of India (DCGI) has approved its anti cancer drug Keytruda (pembrolizumab), for additional indications of cervical cancer and esophageal cancer.

The company said that the anti-programmed death receptor-1 (PD-1), has received approval for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS =1, and for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma, in adults whose tumours express PD-L1 with a CPS=10.

The approval was based on the phase III Keynote 590 and 826 studies for esophageal and cervical cancer respectively.

As reported earlier, the Subject Expert Committee for Oncology and Haematology which advises the drug regulator, has considered the proposal by the company and recommended grant of approval for additional indications in the second half of 2022.

The Committee noted that the post marketing data from India are consistent with the global established safety profile. It also observed that cervical cancer and esophageal cancer are serious or life-threatening diseases and the indications are already approved in countries such as the USA, European Union, Canada and Japan.

Source: pharmabiz.com

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PHARMA INDIA

4. WHO calls for action to protect children in the wake of detecting contaminated drugs

In the wake of the adverse events reported related to the over-the-counter cough syrups with confirmed or suspected contamination with high levels of diethylene glycol (DEG) and ethylene glycol (EG) the World Health Organisation (WHO) has released an urgent call to action to countries and the stakeholders to prevent, detect and respond to incidents of substandard and falsified medical products.

"Over the past four months, countries have reported on several incidents of over-the-counter cough syrups for children with confirmed or suspected contamination with high levels of diethylene glycol (DEG) and ethylene glycol (EG). The cases are from at least seven countries, associated with more than 300 fatalities in three of these countries. Most are young children under the age of five. These contaminants are toxic chemicals used as industrial solvents and antifreeze agents that can be fatal even in small amounts, and should never be found in medicines," said the WHO.

Based on country reports, WHO has issued three global medical alerts addressing these incidents including one in October 5, 2022 focused on outbreak in Gambia and another in January 11, 2023 focused on Uzbekistan, wherein products allegedly manufactured in India caused the adverse events. Another incident was reported on November 6, 2022 in Indonesia, where multiple drugs including paracetamol reportedly had adverse events, on which the WHO issued a global medical alert.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. Global Pharma under CDSCO watch after USFDA curbs eyedrops imports

The Central Drugs Standards Control Organisation (CDSCO), the country's drug regulator, has sent a team of experts to inspect Chennai-based manufacturer Global Pharma Healthcare after the US Food and Drug Administration (FDA) restricted the import of eye drops manufactured by the company. The FDA said the company's Artificial Tears brand of eyedrops were linked to multiple adverse events. "To date, there are 55 reports of adverse events, including eye infections, permanent loss of vision and a death with a bloodstream infection", the FDA said in a statement. The company has voluntarily recalled all the lots of the eyedrop due to possible contamination, the FDA said.

Experts from DGCI are inspecting Global Pharma Healthcare's production facilities, and samples will be taken for further investigation, ET has been told by people aware of the developments.

Global Pharma Healthcare said it is notifying distributors Aru Pharma Inc and Delsam Pharma, and requesting wholesalers and retailers to recall the product. Customers who have the purchased the product should stop using it, the company said in a statement. This recall is being conducted with the knowledge of the US Food and Drug Administration, it further said.

Source: economictimes.indiatimes.com

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REGULATORY ROUND-UP

2. Stelis Biopharma receives establishment inspection report from USFDA

Strides Pharma Science on Wednesday said its arm Stelis Biopharma has received an establishment inspection report (EIR) from the US health regulator specific to drug-device combination products to be commercialised at its flagship facility in Bengaluru. This follows the abbreviated quality system inspection technique drug pre-approval on-site inspection specifically conducted by the US Food and Drug Administration (USFDA) for the drug-device combination products that are to be manufactured and commercialised at the site for the partner products by Stelis, it said in a regulatory filing.

Stelis is an emerging biopharmaceutical contract development and manufacturing organisation (CDMO) and the biologics arm of Strides Pharma Science.

It had previously received an EIR from the USFDA in September 2022 based on on-site pre-approval Inspection (PAI) and, consequently, the first product approval for one of its key customers in December 2022, the filing added.

Source: economictimes.indiatimes.com

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REGULATORY ROUND-UP

3. Study shows FDA-approved TB regimen may not work against the deadliest form of TB due to multidrug-resistant strains

Findings from a Johns Hopkins Children's Center study in animal models show that a U.S. Food and Drug Administration (FDA)-approved antibiotic regimen for multidrug-resistant (MDR) tuberculosis (TB) may not work for TB meningitis. Studies in a small number of people also provide evidence that a new combination of drugs is needed to develop effective treatments for TB meningitis due to MDR strains.

Tuberculosis, caused by the bacteria Mycobacterium tuberculosis, is a global public health threat. According to the World Health Organization, it is one of the leading killers by a single infectious agent.

About 1%-2% of TB cases progress into TB meningitis, the worst form of TB, which leads to an infection in the brain that causes increased fluid and inflammation.

Source: sciencedaily.com

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REGULATORY ROUND-UP

4. Use of Clinical Trials Information System becomes mandatory for new clinical trial applications in the EU

From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022.

In the past, sponsors had to submit clinical trial applications separately to national competent authorities (NCAs) and ethics committees in each country to gain regulatory approval to run a clinical trial. Registration and the posting of results were also separate processes. With CTIS, sponsors can now apply for authorisations in up to 30 EU/EEA countries at the same time and with the same documentation. The system includes a public, searchable database for healthcare professionals, patients, and other interested parties.

The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while the European Medicines Agency (EMA) is responsible for maintaining CTIS. The European Commission (EC) oversees the implementation of the Clinical Trials Regulation.

Source: Ema.europa.eu

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Orion and Alligator reveal second stage of immuno-oncology research collaboration

Second study will develop a bispecific antibody with potential applications in solid tumours.

Alligator Bioscience (Alligator) has announced an expansion to its licence agreement and research collaboration with Orion Corporation (Orion). The link-up is focused on the discovery and development of new bispecific antibody cancer therapeutics.

The partnership has been extended to include the development of a second bispecific antibody using Alligator's RUBY platform. Meanwhile, Alligator will also provide validated monospecific binders for one target, while Orion will do the same for another target.

Under the initial agreement, which was signed in 2021, Alligator employed its proprietary phage display libraries and RUB bispecific platform to develop immuno-oncology product candidates based on design criteria outlined by Orion.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. SanegeneBio and Orbit join forces to establish targeting peptides

Agreement covers cell-based studies, with an additional option to further develop screening activities.

Orbit Discovery (Orbit) – a company which focuses on the discovery of therapeutic peptides – has announced it has entered into a partnership with SanegeneBio (Sanegene), a start-up aiming to develop novel RNAi-based medicines.

The main ambition of the link-up is to identify tissue-specific delivery of a RNA (ribonucleic acid) therapeutics to efficiently knock down disease-causing genes.

Furthermore, the agreement covers cell-based internalisation studies, with an additional option for Sanegene to further develop hits resulting from screening activities. Through the collaboration with Orbit, Sanegene is looking to develop a portfolio of advanced RNAi therapeutics.

ORBIT DISCOVERY

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. AstraZeneca makes CinCor Pharma acquisition

Agreement involves access to global rights of blood pressure lowering therapy baxdrostat.

AstraZeneca (AZ) has agreed to acquire CinCor Pharma (CinCor) – a company which concentrates on developing novel treatments for hypertension and chronic kidney disease.

The addition of the company will increase AZ's cardiorenal pipeline as it will include CinCor's candidate drug, baxdrostat.

Baxdrostat is a selective, oral small molecule inhibitor of aldosterone synthase – the enzyme responsible for the synthesis of aldosterone in the adrenal gland – and can be used for blood pressure lowering in treatment-resistant hypertension.

The drug represents a potentially leading next-generation aldosterone synthase inhibitor as it is selective for aldosterone synthase and, critically, spares the cortisol pathway among humans.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Prochem joins hands with Tapasya to offer customised solutions ranging from APIs to formulations in various geographies

Prochem's pharma division, a globally recognised leader in API powder handling solutions for various domains has merged with Tapasya, a proven expert in granulation and a single-stop solution provider of solid formulations to pharmaceutical, nutraceutical, and food industries. This will help the companies leverage their combined expertise, manufacturing strengths, and market knowledge and further strengthen Prochem's efforts in its quest to offer innovative and customised solutions to enterprises across verticals from active Pharma ingredients to formulations in various geographies and many industries like speciality chemicals, agro chemicals, nutraceuticals etc.

The new business entity Prochem Tapasya Pvt Ltd will add value to create a one-stop solution for pharma and allied industries. The value proposition for customers will be in terms of project execution at a faster pace and hence better return on investment. The alliance will also add value in terms of quality and cost optimisation.

"I am truly excited about the possibilities this merger of Tapasya with Prochem's Pharma Division offers. As a leader in Granulation, Tapasya has its own distinct strengths in the pharma and FMCG industries, and its RMG specially the Sizoner is the highest sold machine in the global market and widely used across industries. Together we will be able to offer our clients across verticals, innovative solutions that deliver better performance and reliability going forward. We can grow to become stronger and have a better impact, a reflection of the 'Make in India' vision we have been pursuing," said Shashi Rai, director of Prochem.

Source: pharmabiz.com

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DRUGS: APPROVALS AND LAUNCHES

1. AstraZeneca's Tezspire receives approval for asthma treatment

Green light for new asthma pen which offers self-administration option across the EU.

AstraZeneca's (AZ) Tezspire has received a positive opinion from the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP).

It concerns a self-administration treatment in the form of a pre-filled, single-use pen for patients aged 12 years and older with severe asthma. Meanwhile, the CHMP opinion can be implemented without the need for a European Commission decision due to the nature of the type-2 label variation.

The approval for self-administration followed results from the PATHFINDER clinical trial programme, which included results from the PATH-BRIDGE phase 1 trial as well as the PATH-HOME phase 3 trial.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

2. Granules gets USFDA's nod for Amphetamine capsules

Granules India announced on Tuesday that the US Food and Drug Administration (US FDA) has approved the abbreviated new drug application (ANDA) filed by its US subsidiary -- Granules Pharmaceuticals, Inc (GPI) -- for Amphetamine mixed salts used for treating attention disorder.

Amphetamine is bioequivalent to the reference listed drug product (RLD), Adderall XR extended-release capsules of Takeda Pharmaceuticals. This product will be manufactured at Granules manufacturing facility in hantilly, Virginia, and is expected to be launched shortly, according to a company statement shared with stock exchanges.

An abbreviated new drug application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug.

Mixed salts of single-entity Amphetamine ER Capsules are indicated for the treatment of attention deficit hyperactivity disorder (ADHD). The company added Granules now have a total of 53 ANDA approvals from US FDA with 51 final approvals and two tentative approvals.

Source- economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. Sun Pharmaceutical launches phenobarbital sodium injection in US

Sun Pharmaceutical Industries Ltd on Wednesday launched its phenobarbital sodium injection, SEZABY for treatment of neonatal seizures in the US. SEZABY is the first and only product approved by the US Food and Drug Administration (USFDA) for the treatment of neonatal seizures in term and preterm infants, Sun Pharma said in a regulatory filing.

It is a benzyl alcohol-free and propylene glycol-free formulation of phenobarbital sodium powder for injection.

"The launch of SEZABY is an exciting addition to our growing portfolio of specialty branded products in the US," Sun Pharma CEO North America Abhay Gandhi said.

He further said, "As the first and only FDA-approved product for the treatment of seizures in term and preterm infants, SEZABY has the potential to make a meaningful difference in the lives of patients and their families, and we are proud to be able to provide physicians with this new treatment option."

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

4. Stada and Xbrane receive approval for Ximluci

Biosimilar gains MHRA marketing authorisation for use throughout Britain. Stada and Xbrane have announced that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has provided a marketing authorisation for Ximluci. Also known as ranibizumab, the therapy is a biosimilar which references Lucentis.

Ximluci is an anti-vascular endothelial growth factor for the treatment of retinal vascular disorders, which are a major cause of blindness globally.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Parexel notes rise in healthcare funds to aid upgrade infrastructure & increase pace of clinical trials

Increased allocation in healthcare from Union government budget to widen clinical trials activity with improved infrastructure, said Sanjay Vyas, EVP, global SBU head-clinical logistics & global safety services and managing director India at Parexel.

With India focused more on innovation over the last two years and the government taking a keener look at healthcare aligned with the SDG-3 goals of 2030, we would expect a substantial increase in the FY 22 allocation to the overall research budget. To aid in the growth of research in the pharmaceutical industry, the budget should include supporting policies, streamlined regulations, and straightforward GST requirements. Making business more convenient will boost investment and support the sector's sustained growth, he added.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. NRx Pharma to begin phase 3 trial of NRX-101 to treat bipolar depression with acute suicidality

NRx Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company, announced that its first clinical trial site has been contracted (with others expected in near future) and that first dosing of patients is expected in early 2023.
This phase 3 clinical trial of NRX-101 is for the treatment of severe bipolar depression with acute suicidal ideation and behaviour (SBD-ASIB), a lethal condition that currently takes the lives of thousands of Americans each year. NRX-101 is the first investigational medicine to target this condition, for which the only currently approved treatment is electroconvulsive therapy.

Based on preliminary efficacy demonstrated in the company's phase 2 STABIL-B trial, the FDA awarded Breakthrough Therapy Designation to NRX-101 in 2018. The company subsequently received an FDA agreement for the phase 3 trial under a Special Protocol Assessment which indicated that "based on the information submitted [FDA] agrees that the design and planned analysis of your study adequately address the objectives necessary to support a regulatory submission."

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. AstraZeneca to buy US-based clinical-stage biopharma company, CinCor Pharma

AstraZeneca has entered into a definitive agreement to acquire CinCor Pharma, Inc. (CinCor), a US-based clinical-stage biopharmaceutical company, focused on developing novel treatments for resistant and uncontrolled hypertension as well as chronic kidney disease.

The acquisition will bolster AstraZeneca's cardiorenal pipeline by adding CinCor's candidate drug, baxdrostat (CIN-107), an aldosterone synthase inhibitor (ASI) for blood pressure lowering in treatment-resistant hypertension.

Baxdrostat represents a potentially leading next-generation ASI as it is highly selective for aldosterone synthase and spares the cortisol pathway in humans. The opportunity also brings the potential for combination with Farxiga and complements AstraZeneca's strategy to provide added benefit across cardiorenal diseases, where there is a high unmet medical need.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Onivyde® improves survival in Phase III pancreatic cancer trial

Onivyde® (irinotecan liposome injection) treatment regimen significantly improved survival in a Phase III trial compared to nab-paclitaxel plus gemcitabine.

Data from a Phase III trial evaluating a regimen of Onivyde® (irinotecan liposome injection), in previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC) demostrated significant improvements in patient survival.

Dr Zev Wainberg, Professor of Medicine at UCLA and co-director of the UCLA GI Oncology Program discussed the results of the NALIRIFOX regimen (liposomal irinotecan 50mg/m2 + 5-FU 2400mg/m2 + leucovorin 400mg/m2 + oxaliplatin 60mg/m2).

“For the first time, a clinical study in the first-line setting for mPDAC demonstrated superior overall survival (OS) and progression-free survival (PFS) for an investigational regimen when compared to standard of care treatment with nab-paclitaxel and gemcitabine.”

Source: europeanpharmaceuticalreview.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Evoke announces Teva ends pursuit of Paragraph IV ANDA against Gimoti

Evoke Pharma, Inc., a specialty pharmaceutical company, announced that a joint stipulation of dismissal has been filed in the Gimoti patent infringement case (Civil Action No. 1:22-cv-02019) in the United States District Court for the District of New Jersey.

The filing of the stipulation arises from Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.'s (Teva) conversion from a Paragraph IV certification to a Paragraph III certification. A paragraph III Abbreviated New Drug Application (ANDA) is not eligible for approval until the last expiration date of current and potential future orange book listed patents for the reference listed drug in conjunction with appropriate FDA review.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. MSF urges patent office to reject J&J's patent application for TB drug bedaquiline

Médecins Sans Frontières/Doctors Without Borders (MSF) along with the petitioners who challenged a patent application by Johnson and Johnson for its TB drug bedaquiline, urged the Indian Patent Office to reject the secondary patent application filed by the company.

The organisation said that the Indian Patent Office, on January 17, is set to hold the final hearing on a patent challenge filed by two tuberculosis (TB) survivors, against a patent which could extend the company's patent rights on the drug beyond the primary patent's expiry this July.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. AXIM Biotechnologies files patent application on Fentanyl neutralizing antibody test with US Patent & Trademark Office

AXIM Biotechnologies, Inc., an international healthcare diagnostic solutions development company, announced that it has filed a provisional patent application with the US Patent and Trademark Office on an innovative new test designed to measure the neutralizing antibodies against fentanyl, a synthetic opioid responsible for the world's leading cause of overdose. Additionally, the Company has filed for a license to handle the controlled substance with the Drug Enforcement Administration (DEA) as required for research.

Fentanyl is a powerful synthetic opioid that is 50 to 100 times stronger than morphine and has a strong addiction profile and associated overdose risk. Prevention of fentanyl addiction and overdose within the current healthcare landscape is difficult. However, new research is being conducted on potential immunotherapies (source) and vaccines (source) that prevent fentanyl from breaching blood-brain barrier to preemptively circumvent its overdose effects.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Scohia Pharma, Kuria Therapeutics receive US patent covering novel Nrf2 activator

Scohia Pharma, Inc, a Japanese biotech company dedicated to developing medicines for lifestyle-related diseases with high unmet needs, and Kuria Therapeutics, Inc., a US pharmaceutical company developing novel therapeutics for ophthalmic and dermal diseases, announced that the US Patent Office has issued a composition-of-matter patent covering SCO-116, a novel Nrf2 activator being developed by Kuria for prevention and treatment of eye and skin diseases.

US Patent 11,518,763 covers a novel series of macrocyclic molecules discovered by Scohia Pharma, including SCO-116, which activate Nrf2 and are useful for a broad array of diseases involving oxidative stress and inflammation. The Nrf2 pathway is widely recognized as the master regulator of the antioxidant response, and plays a key role in cellular defense against external insults and pathogens, as well as the regulation of the inflammatory response.

Source: pharmabiz.com

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TECHNOLOGY /NDDS

1. The Growth and Emergence of Technology in the Outsourcing Space

Outsourcing has become a crucial part of the biopharmaceutical industry, with many contract manufacturing organizations (CMOs) being the only facilities with the ability to produce vaccines and therapies in the vast volumes requested. Other reasons for outsourcing include the need to control costs/minimize internal staff and resources, getting a product out to the market in an efficient way, and having no alternative ways to complete manufacturing capabilities.

For the near future, CMOs are hoping to grow outsourcing to significantly higher levels in many different areas, with a focus on analytical testing,toxicity testing, and fill/finish operations. In addition to these predictions, CMOs are already making shifts in their operations to have more options and advanced services.

Source: Pharmtech.com

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2. Teleflex launches UroLift System in India to treat benign prostatic hyperplasia

Teleflex Incorporated, a leading global provider of medical technologies, has announced the commercial launch of the UroLift System in India for treating benign prostatic hyperplasia (BPH), or enlarged prostate.

BPH is a common condition marked by bothersome urinary symptoms that can cause loss of productivity, depression, interrupted sleep, and decreased quality of life. The UroLift System is a minimally invasive approach to treating BPH that can be performed as a same-day outpatient procedure. The UroLift System provides rapid symptom relief for men with BPH and allows a quick recovery time for patients. Men can return to their normal routine with minimal downtime and preserve sexual function. The UroLift System can also help improve quality of life.

Source: pharmabiz.com

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3. Datar Cancer Genetics gets US FDA breakthrough designation for blood test, TriNetra-Glio to help diagnose brain tumours

Datar Cancer Genetics Inc announced that the US Food and Drug Administration (FDA) has granted 'Breakthrough Device Designation' for its 'TriNetra-Glio', a blood test to help in the diagnosis of brain tumours. This is the third test from the company to have received the Breakthrough Device Designation from the US FDA. The company's early-stage breast and prostate cancer detection tests became the first liquid biopsies to receive the Breakthrough Device Designation.

In the United States, brain cancer is the 9th most lethal cancer, and each year, more than 18,000 adults die due to the disease. Diagnosis of brain tumours is risk-prone and brain biopsies are impossible to perform in almost 40% of advanced cases. Presently, no blood test is available for diagnosing brain cancers, and doctors have to rely on complex surgical procedures to obtain tumour tissue for histopathological evaluation. The TriNetra-Glio liquid biopsy is intended to detect the cells released in the blood from the brain tumour; these cells are extremely rare and hard to detect.

Source: pharmabiz.com

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4. Is machine learning the answer for long-acting injectable drugs?

A study from the University of Toronto is one of the first to apply machine learning to the design of polymeric long-acting injectable drug formulations.

Machine learning models used to guide the design of long-acting injectable drug formulations have been successfully tested by scientists at the University of Toronto. The research results signal the potential for machine to reduce reliance on trial-and-error testing, which slows the development of long-acting injectables (LAIs).

The study was published Nature Communications and is one of the first to apply machine learning techniques to the design of polymeric long-acting injectable drug formulations.

“This study takes a critical step towards data-driven drug formulation development with an emphasis on long-acting injectables,” declared Professor Christine Allen, Pharmaceutical Sciences at the Leslie Dan Faculty of Pharmacy, University of Toronto.

Source: europeanpharmaceuticalreview.com

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