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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

Key Parkinson's protein could offer new potential targets for treatment

Researchers from Johns Hopkins University School of Medicine have revealed new findings about a key pathological protein associated with Parkinson's disease (PD), which could lead to new treatments. Published in Science Translational Medicine, the study found that the pathological form of alpha-synuclein triggers cells to increase protein synthesis in the neurodegenerative condition.

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New study finds heathy cells 'push' cancer cells to resist treatment

Researchers from University College London (UCL) and Yale University have found that healthy cells 'push' cancer cells to grow more slowly in two bowel cancer studies. Responsible for the deaths of over 900,000 people a year, bowel cancer is the second highest cause of cancer mortality worldwide, accounting for 10% of all cancer deaths in the UK.

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New approach for synthesis of oligonucleotide conjugates

Researchers from Aarhus University and Novo Nordisk have discovered a new synthesis method for oligonucleotide conjugates, marking a step forward in development of more targeted RNA medicines. Specifically, the researchers discovered a synthesis method for oligonucleotide (ON) conjugates that incorporates built-in handles and a special linker, enabling easy linkage of ONs to a peptide marker by adjusting the pH.

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PHARMA INDIA

Maharashtra FDA revokes 320 licenses, makes seizures worth Rs. 2.85 crore in illicit drug trade

In a concerted effort to fortify pharmaceutical compliance and ensure the highest standards in the industry, the Maharashtra Food and Drug Administration (FDA) has initiated a massive crackdown, replete with license revocations, seizures, and legal actions. The regulatory body has cancelled a total of 320 licenses, encompassing 134 retail and 186 wholesale licenses, spanning the period from April to October. This decisive move comes in the wake of an exhaustive series of 6,779 inspections carried out by the FDA.

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India so far approved 15 vaccines and five booster doses: CDSCO

India has so far approved 15 vaccines as primary vaccination and five for booster dose, for restricted use in emergency situation against Covid-19, the pandemic that broke out in the country in early 2020. This is apart from the two vaccines - Covishield and the indigenously developed Covovax - which received complete approval for manufacture for sale or for distribution in the country.

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Ayush ministry to amend D&C Rules to add guidelines & standards for new dosage form of nasal spray

The CPhI & PMEC India The Union Ministry of Ayush is framing guidelines under the Drugs and Cosmetics Rules, 1945 for issuance of license to the Ayurveda, Siddha, Unani and Homoeopathy drugs with the new dosage form of nasal spray in these systems, that are different from the traditional Nasya treatment.

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REGULATORY ROUND-UP

DCC recommends formation of sub-committee to look into potential misuse of tapentadol & pregabalin

The Drugs Consultative Committee (DCC) has decided to look in-depth into the potential misuse of opioid pain-relief medicine tapentadol and anticonvulsant and analgesic drug pregabalin and consider measures including control on the sales of these drugs in the market.

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DCGI to frame rules for compounding of offences under Section 32B of D&C Act

The Central government is expected to soon come out with the draft rules for compounding of offences under Section 32B of the Drugs and Cosmetics Act, 1940, following the notification of the Jan Vishwas (Amendment of Provisions) Act, 2023 which was passed in both the Lok Sabha and Rajya Sabha earlier this year. One of the amendments under the Jan Vishwas Act is on the Section 32B, which is related to compounding of certain offences, adding "clause (d) of Section 27 and clause (ii) of Section 27A," to the subsection (1).

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FDA posts a flurry of voluntary drug recalls by Teva, Glenmark, Apotex and VistaPharm

The FDA posted a flurry of voluntary drug recalls by drug manufacturers on its website. Below are the companies and products being recalled.

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MERGERS / ACQUISITIONS / COLLABORATIONS

ICMR to collaborate with Indian companies for technology transfer for malaria detection

In a significant move towards advancing diagnostic capabilities in the fight against malaria, the Indian Council of Medical Research (ICMR) has announced its collaboration with eligible companies for the technology transfer of a diagnostic assay. The initiative revolves around the "Novel molecular diagnostic technique for malaria parasite species identification," developed by the ICMR-National Institute of Malaria Research (NIMR) Institute.

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IP Alliance collaborates with ELP Consultants to streamline RoDTEP data submission

The Indian Pharmaceutical Alliance (IP Alliance) has entered into a collaboration with Economic Law Practice (ELP) Consultants to assist the industry in submitting data for the Remission of Duties and Taxes on Exported Products (RoDTEP) scheme, according to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) director general Uday Bhaskar.

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BioMed X and Ono Pharmaceutical enter joint cancer research project

The BioMed X Institute and Ono Pharmaceutical have announced a new joint research collaboration for cancer research. The project, 'New Strategies to Engage Neutrophils in Solid Tumors', will help to design next-generation immunotherapies by advancing the antitumour effects of neutrophils.

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DRUGS: APPROVALS AND LAUNCHES

MHRA authorises Mounjaro for weight management

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has authorised diabetes medicine, Mounjaro (tirzepatide), for weight loss and weight management in adults aged 18 and over. Mounjaro is now authorised for adults with a BMI of 30kg/m^2 or more (obesity), as well as those with a BMI between 27-30kg/m^2 (overweight) who also have weight-related health problems eg, prediabetes, high blood pressure, high cholesterol, or heart problems.

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EC approves treatment for rare haematological disorder

The European Commission has approved Blueprint Medicines' Ayvakyt® (avapritinib) for treatment of adult patients with the haematological disorder indolent systemic mastocytosis (ISM). "Ayvakyt represents an important treatment breakthrough as the first medicine approved for patients living with ISM, and the only therapy designed to selectively target the primary genetic driver of the disease," declared Jens Panse, Deputy Director of the Department of Haematology/Oncology of the University Hospital RWTH Aachen in Germany.

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FDA approves first cell-based gene therapies for sickle cell disease

The US Food and Drug Administration (FDA) has approved two landmark cell-based gene therapies for treatment of inherited blood disorder sickle cell disease. Casgevy (exagamglogene autotemcel) a cell-based gene therapy, is approved for the treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises (VOCs).

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Microbiome-based therapy shows potential in graft-versus-host disease

Data presented at the 2023 American Society of Hematology (ASH) Annual Meeting suggest that the off-the-shelf microbiome therapeutic could offer a "potentially life-saving approach" in graft-versus-host disease (GvHD). According to MaaT Pharma, there were 111 patients with steroid-refractory (SR) or steroid-dependent (SD) gastrointestinal acute graft-versus-host disease (GI-aGvHD) who were given MaaT013.

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Positive results for mRNA vaccine in melanoma patients

A personalised mRNA cancer vaccine in combination with MSD's Keytruda cut the risk of cancer recurrence by almost half in melanoma patients. The randomised study, KEYNOTE-942, evaluated the treatment in patients with high-risk stage III/IV melanoma. Analysis shows that after three years, treatment with mRNA-4157 (V940) in combination with checkpoint inhibitor Keytruda reduced the risk of recurrence or death by 49 percent compared with Keytruda alone.

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Psilocybin-assisted therapy reduces depressive symptoms in cancer patients

Results from a Phase II clinical trial indicate that psilocybin-assisted therapy could benefit individuals with cancer and major depression. Findings from a small Phase II clinical trial indicate that psilocybin, a hallucinogenic chemical found in certain mushrooms of the genus Psiloybe, may benefit individuals with cancer and major depression.

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TECHNOLOGY / NDDS

European regulators prepare for AI in pharma

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMAs) have published a plan, which sets out a "collaborative and coordinated strategy" to maximise the benefits of artificial intelligence in regulation.

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New technique efficiently offers insight into gene regulation

Researchers from the group of Jop Kind developed a new technique called MAbID. This allows them to simultaneously study different mechanisms of gene regulation, which plays a major role in development and disease. MAbID offers new insights into how these mechanisms work together or against each other.

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Absci and AstraZeneca Collaborate on AI-Driven Oncology Candidate

Absci, a generative artificial intelligence (AI) drug creation company, announced on Dec. 4, 2023 that it is collaborating with AstraZeneca to deliver an antibody to treat cancer that is designed with AI. AstraZeneca will use Absci's Integrated Drug Creation platform to accelerate the discovery of potential cancer treatments.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

After issuing Form 483, FDA classifies Aurobindo plant as only needing 'voluntary' action

The FDA has issued its final inspection report for an Aurobindo plant in India after a September inspection and a subsequent Form 483. The agency classified the plant as needing "voluntary" action, prompting investors to bid shares up. Aurobindo disclosed the FDA's classification of the site as "Voluntary Action Indicated" in a filing with the National Stock Exchange and the BSE.

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FDA hits Torrent Pharma with a Form 483, 5 observations

After an FDA inspection of a Torrent Pharmaceutical manufacturing facility in Gujarat, India, the agency has handed the company a Form 483 filing citing several production shortfalls. The regulatory agency cited five "procedural" observations that inspectors turned up during a pre-approval inspection of the oral dosage manufacturing plant between Dec. 5 and Dec. 11, the company said in a filing with the BSE.

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Cipla unit recalls one lot of anti-seizure drug because of faulty packaging

Cipla subsidiary InvaGen issued a voluntary recall of one lot of the oral anti-seizure drug vigabatrin due to problems with seal integrity in its packaging. The recalled lot of the medication, which is typically used to treat infantile spasms and refractory complex partial seizures, is NB301030 with an expiration date of March 2025. The medicine was distributed nationwide in the U.S.

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