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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

NHS campaign urges over 900,000 young adults to catch up on missed MMR vaccine

The NHS has announced it is targeting young adults to catch up on their missed measles, mumps and rubella (MMR) vaccines as part of the NHS catch-up campaign.

Following on from the national health service's recent reminder for 200,000 16- to 19-year-olds to receive the MMR vaccine, the NHS campaign will target young adults in areas more at risk: the West Midlands, Greater Manchester and London.

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Strand Therapeutics develops new class of mRNA molecules for cancer

Strand Therapeutics, a Massachusetts Institute of Technology (MIT) spinout, has developed a new class of advanced mRNA molecules for more targeted and powerful treatments for cancer.

The new class of mRNA molecules is designed to sense what type of cells they encounter in the body and express therapeutic proteins once they have entered diseased cells.

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Biologics driving continuous bioprocessing market expansion

According to research by InsightAce Analytic Pvt. Ltd., the global continuous bioprocessing market is expected to value $1,067.8 million by 2031. While the market was valued at $255.9 million in 2023, the report predicted it will witness a CAGR of 19.72 percent between 2024-2031. Overall, the market is expanding due to a greater demand for biologics, technological advancements, plus regulatory support for continuous manufacturing approaches, the report noted.

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PHARMA INDIA

Gujarat sets new benchmarks in pharmaceutical quality

Gujarat, which has earned a global reputation as a quality hub for medicines, renowned for its adherence to international standards, robust regulatory framework, and commitment to excellence in manufacturing practices, is continuously striving for innovation and improvement, ensuring that it remains at the forefront of pharmaceutical manufacturing.

Gujarat boasts of a significant number of pharmaceutical companies that have attained certifications such as WHO-GMP and USFDA compliance, indicating their dedication to maintaining high-quality standards.

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AstraZeneca Pharma India Ltd and Mankind Pharma partner to accelerate access to asthma medicine for patients in India

Bangalore, India: March 11 2024 - AstraZeneca Pharma India Limited (AstraZeneca India) (BSE : 506820, NSE : ASTRAZEN) and Mankind Pharma Limited (BSE: 543904 | NSE: MANKIND) entered into an agreement for exclusive distribution of AstraZeneca's budesonide and formoterol fumarate dihydrate (inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) combination) brand Symbicort in India. AstraZeneca will retain the intellectual property rights to budesonide and formoterol fumarate dihydrate and will continue to be the Marketing Authorisation Holder (MAH) and import license.

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Domestic drug firms to witness 8-10 pc revenue growth in FY25: Report

The domestic market, on the other hand, is expected to see a stable growth of 6-8 per cent, while the emerging markets may log an 8-10 per cent rise in FY25, against 16-18 per cent in FY24, the rating agency said.

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REGULATORY ROUND-UP

Regulatory information – adjusted fees for applications to EMA from 1 April 2024

The European Medicines Agency (EMA) reminds applicants and marketing authorisation holders that adjusted fees for all applications, except for pharmacovigilance procedures, will be coming into effect on 1 April 2024.

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MHRA approves Marinus Pharmaceuticals' Ztalmy for CDKL5 deficiency disorder

The Medicines and Healthcare products Regulatory Agency (MHRA) has approved Marinus Pharmaceutical's Ztalmy (ganaxolone) to treat cyclin-dependant kinase-like 5 (CDKL5) deficiency disorder (CDD).

The approval marks Ztalmy as the first anti-seizure medication to be used in the UK to treat the rare epileptic seizure disorder.

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FDA Approves First Interchangeable Biosimilar to Prolia and Xgeva

The FDA approved Jubbonti (denosumab-bbdz) injection as an interchangeable biosimilar to U.S.-licensed Prolia (denosumab), and Wyost (denosumab-bbdz) injection as an interchangeable biosimilar to U.S.-licensed Xgeva (denosumab). These are the first interchangeable biosimilars for RANKL inhibitors.

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MERGERS / ACQUISITIONS / COLLABORATIONS

Novartis acquisition to address inflammation-driven diseases

Novartis' new acquisition aims to advance first-in-class STING treatments for inflammation-driven diseases.

Under a new deal, Novartis has agreed to acquire US-based biopharma company IFM Therapeutics, for a total of up to $835 million. As part of this new agreement, Novartis has exercised its option to acquire all outstanding capital stock of IFM Due, a subsidiary company of IFM. Therefore, under the acquisition, Novartis has full rights to IFM Due's portfolio of small molecule Stimulator of Interferon Genes (STING) antagonists, IFM confirmed.

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AbCellera to Collaborate with Biogen to Discover Therapeutic Antibodies for Neurological Conditions

AbCellera and Biogen Inc. have entered into a strategic collaboration to discover antibodies for a novel target that enables the delivery of biotherapeutics to the brain for indications in neuroscience.

"Delivering biologics across the blood brain barrier is one of the most important and long-standing problems in neuroscience," said Murray McCutcheon, Ph.D., SVP, Partnering at AbCellera.

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Celanese and Secarna Pharmaceuticals Enter into RNA Research Collaboration for Long-Acting Antisense Therapies

Celanese Corporation, a specialty materials and chemical company, and Secarna Pharmaceuticals GmbH & Co. KG, a European antisense drug discovery and development company, announced a research collaboration for the development of long-acting implants that deliver antisense oligonucleotides (ASOs).

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DRUGS: APPROVALS AND LAUNCHES

Sandoz granted novel biosimilars approval

The US Food and Drug Administration (FDA) has approved the first and only FDA-approved denosumab biosimilars, to treat all indications of the reference medicines.

The approval authorises the interchangeability of denosumab biosimilars in the US to treat primary and secondary bone loss.

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New antibody drug formulation wins novel MHRA approval

The Medicines and Healthcare products Regulatory Agency (MHRA) has authorised the first product via its new International Recognition Procedure (IRP). The approval was for a new formulation for XGEVA (denosumab), to prevent serious bone-related complications caused by bone metastasis in adults and to treat giant cell tumour of bone in adults and adolescents.

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AstraZeneca India receives dual CDSCO approval for trastuzumab deruxtecan

AstraZeneca Pharma India has received permission to import for sale and distribution of trastuzumab deruxtecan lyophilized powder for concentrate for solution for infusion 100mg from the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India for two additional indications.

Trastuzumab deruxtecan was earlier approved by Drug Controller General of India (DCGI), for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

NIHR reveals phase 1/2 trial to evaluate an investigational vaccine for mpox in the UK

The National Institute for Health and Care Research (NIHR) has announced a new phase 1/2 trial, delivered by the NIHR Clinical Research Network and sponsored by Moderna, to test the effectiveness of an investigational mRNA vaccine for mpox. The trial will evaluate the safety and immune response to mRNA-1769, which aims to protect against illness caused by the mpox virus.

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Next-gen Modern COVID-19 vaccine shows promise

Moderna's next-generation COVID-19 vaccine mRNA-1283 demonstrated a higher immune response against SARS-CoV-2, interim results from the company's Phase III trial show. These findings were based on data comparing the treatment to mRNA-1273.222 (Spikevax®), Moderna's licensed vaccine for the condition.

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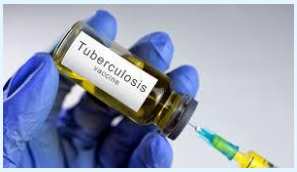
Bill & Melinda Gates Medical Research Institute Initiates Phase 3 Clinical Trial of Tuberculosis Vaccine Candidate



The Bill & Melinda Gates Medical Research Institute (Gates MRI) announced that a Phase 3 clinical trial to assess the efficacy of the M72/AS01E tuberculosis (TB) vaccine candidate is now underway, with first doses given in South Africa, where TB takes a heavy toll.

If shown to be well-tolerated and effective, M72/AS01E could potentially become the first vaccine to help prevent pulmonary TB in adolescents and adults, the most common form of the disease, and the first new TB vaccine in over a century.

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TECHNOLOGY / NDDS

VAV enters LatAM with high-purity lipids, eyes 40% share in five years

VAV Lipids, one of the world's leading lipid manufacturers, has announced its foray into Latin America. VAV Lipids will introduce its entire range of products through the company's distribution network in Latin America. The company will provide intense technical and marketing training to its distributors, customers with end-to-end technical support, including educational seminars and webinars. This includes technical assistance in selecting the proper grade of lecithins or phospholipids and guidance on formulations, applications, analytical procedures and stability.

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NHS to roll out AI to improve waiting times and reduce missed appointments

The NHS has announced that it's set to roll out artificial intelligence (AI) to help improve waiting times for elective care and reduce the number of missed appointments. New data has shown that 6.4% of over 125 million outpatient appointments across the NHS in England last year were not attended by the patient, specifically for physiotherapy, cardiology, ophthalmology, trauma and orthopaedics.

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Royal Marsden to implement RaySearch's online adaptive radiation therapy system

The Royal Marsden NHS Foundation Trust is set to implement online adaptive radiation therapy (OART) with RaySearch's treatment planning system, RayStation, and oncology information system, RayCare. OART is a novel treatment for cancer patients that is increasingly emerging to assess patients' anatomy, with a treatment plan adapted from an original reference plan with the patient on the treatment couch.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Johnson & Johnson Submits sBLA to FDA Seeking Approval of TREMFYA® for Adults

Johnson & Johnson announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. FDA seeking approval of TREMFYA® (guselkumab) for treatment of adults with moderately to severely active ulcerative colitis (UC). Clinical data from the Phase 3 QUASAR induction study through 12 weeks were presented at the 2023 Digestive Disease Week (DDW) Annual Meeting2 and results from the Phase 3 QUASAR maintenance study through 44 weeks will be presented at an upcoming medical meeting.

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Parkinson's UK grants funding of up to nearly £450,000 to four new research projects

Parkinson's UK has announced that it is funding four new research projects, totalling £446,305, to explore ways to better manage Parkinson's disease (PD) symptoms and improve everyday life for patients. Focusing on cutting-edge technologies, the new projects aim to tackle some of the highest-priority symptoms for people living with the neurodegenerative condition.

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Immunic receives US patent covering the composition-of-matter of a specific polymorph of vidofludimus calcium

Immunic, Inc., a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, announced that it has received a Notice of Allowance from the United States Patent and Trademark Office for patent application 16/981,122, entitled, "Calcium salt polymorphs as anti-inflammatory, immunomodulatory and anti-proliferative agents," covering the composition-of-matter of a specific polymorph of vidofludimus calcium (IMU-838) and a related method of production of the material. The claims are expected to provide protection into 2039, unless extended further. The patent was previously granted to the company in Australia, Canada, Indonesia, Japan and Mexico.

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