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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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CONTENTS PAGE

GLOBAL NEWS

Researchers identify new treatment target for genetic epilepsy

Researchers from the Francis Crick Institute have identified a new treatment target for cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD), a common form of genetic epilepsy.

CDD is a rare neurodevelopmental condition that is characterised by early-onset epilepsy, low muscle tone and developmental challenges in children.

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Researchers discover new cell that remembers allergies

The discovery gives scientists and researchers a new target in treating allergies and could lead to new therapeutics. The research, published in Science Translational Medicine on Feb.

"We've discovered a type of memory B cell that had unique characteristics and a unique gene signature that has not been described before," says Josh Koenig, assistant professor with McMaster's Department of Medicine and co-lead of the study.
"We found allergic people had this memory B cell against their allergen, but non-allergic people had very few, if any."

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MSU researchers find early, promising glioblastoma treatment

A team of Michigan State University scientists has unveiled a potential game-changer in the fight against glioblastoma, the most common and currently incurable form of brain cancer.

Their weapon of choice? A drug-like compound named Ogremorphin, or OGM. In laboratory experiments, OGM showed a remarkable ability to kill glioblastoma cells while leaving normal cells unharmed.

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PHARMA INDIA

Health minister urges all countries to join hands on digital health

Dr Mansukh Mandaviya, Union minister of health and family welfare urged all member countries of World Health Organisation (WHO) to join hands to strengthen the global digital health framework, which will empower countries in their journey towards ensuring universal health coverage.

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Prime Minister inaugurates AIIMS Jammu

Prime Minister Narendra Modi inaugurated the All India Institute of Medical Sciences (AIIMS), Jammu along with launch of various other development works in the region.

Addressing the gathering, the Prime Minister said, "The number of medical colleges in J&K has increased from 4 to 12 in the last 10 years. Similarly, in the same time period, MBBS seats in J&K has more than doubled from 500 to 1,300." He said that there were no PG medical seats in J&K before 2014, but today there are 650 PG medical seats in the Union Territory.

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Govt panel to review if nutraceuticals should be brought under CDSCO

The government has formed a panel to examine the possibility of bringing nutraceuticals under the ambit of the apex drug regulator CDSCO instead of the food regulator FSSAI to address regulatory challenges and promote consumer safety Presently, the Food Safety and Standards Authority of India (FSSAI) regulates the usage of health supplements and nutraceuticals under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022.

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REGULATORY ROUND-UP

JCVI announces advice for 2024 spring COVID-19 vaccine programme

The Joint Committee on Vaccination and Immunisation (JCVI) has announced its advice to the UK government in relation to the 2024 spring COVID-19 vaccine programme. The JCVI has advised that adults aged 75 and over, residents in care homes for older adults and individuals aged six months and over who are immunosuppressed should be offered the COVID-19 vaccine this spring.

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US legislation to benefit small molecule drug innovation

According to the Biotechnology Innovation Organization (BIO), the bipartisan Ensuring Pathways to Innovative Cures (EPIC Act) passed last week in the US, is a "critical" step for incentivising small molecule drug innovation. Representative Congressman Dr Greg Murphy, alongside Don Davis and Brett Guthrie, introduced the US legislation to fix the "pill penalty", BIO confirmed.

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EMA Annex 1 Q&A discusses bioburden considerations

In its recent responses to FAQs relating to Annex 1, the European Medicines Agency (EMA) discusses bioburden guidelines for good manufacturing practice (CGMP) and good distribution practice (GDP). These are discussed in EU GMP guide annexes: Supplementary requirements: Annex 1: Manufacture of sterile medicinal products.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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MERGERS / ACQUISITIONS / COLLABORATIONS

ALTURiX acquires exclusive UK rights to three new products

ALTURiX has announced that it has acquired exclusive rights to three new products within the fields of gastrointestinal and respiratory medicine for commercialisation in the UK. The new agreements align with the British pharmaceutical company's aim to reliably and affordably supply important products to prescribers, patients, families and the NHS. Across the past five years, ALTURiX has acquired several new products to add to its pipeline and has made subsequent effective market introductions.

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Novo Nordisk $11b acquisition to support manufacturing capacity

Novo Nordisk is set to acquire three fill-finish manufacturing sites from Novo Holdings A/S (Novo Holdings) for $11 billion. This agreement is part of a transaction in which Novo Holdings agreed to acquire the contract development and manufacturing organisation (CDMO) Catalent.

The three manufacturing sites in Anagni in Italy, Brussels in Belgium and in Bloomington, Indiana in the US, specialise in the sterile filling of drugs.

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BioNTech agrees collaboration to accelerate autologous CAR-T therapies

The collaboration between BioNTech SE and Autolus Therapeutics utilises manufacturing and commercial infrastructure, supporting a shared goal of advancing autologous CAR-T programmes towards potential market authorization.

Under the terms of the agreement, BioNTech will pay $50 million to Autolus, granting the immunotherapy company rights including the option to access Autolus' commercial and clinical site network, manufacturing capacities in the UK and commercial supply infrastructure.

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DRUGS: APPROVALS AND LAUNCHES

Vertex secures European approval for CRISPR cell therapy

The first CRISPR/Cas9 gene-edited therapy has been granted a marketing authorisation by the European Commission (EC). Vertex Pharmaceuticals' CASGEVY™ (exagamglogene autotemcel [exa-cel]) is conditionally approved individuals 12 years and over with severe sickle cell disease characterised by recurrent vaso-occlusive crises or transfusion-dependent beta thalassemia.

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Novel immunotherapy approved for melanoma

Amtagvi (lifileucel) is the first tumour-derived autologous T cell immunotherapy therapy to be approved by the US Food and Drug Administration (FDA) for certain adults with unresectable or metastatic melanoma. It is also the first non-CAR-T adoptive cell therapy to reach the market.

Based on the FDA's approval, lifileucel is indicated in those who have previously has been treated with other therapies (a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor).

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NICE recommends first medicine for severe alopecia areata

The National Institute for Health and Care Excellence (NICE) has recommended LITFULO® (ritlecitinib) for treating certain patients with severe alopecia areata.

This is "an important milestone" according to Lynn Clay, Specialty Care Lead at Pfizer UK. The once daily oral capsule is indicated as a treatment option in individuals who are 12 years and older.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Elicio's vaccine shows promise as potential cancer treatment in phase 1 trial

Elicio Therapeutics has announced positive phase 1 clinical data suggesting that its cancer vaccine could be a viable option for the treatment of pancreatic and other cancers.
Results showed robust responses in human patients with pancreatic and colorectal cancer: 84% had an average 56-fold increase in the number of antitumour T cells and 24% had complete elimination of blood biomarkers of residual tumours.

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Next-in-class combination treatment shows potential in cystic fibrosis

Phase III trials have found CFTR modulator vanzacaftor/tezacaftor/deutivacaftor (vanza triple) to be non-inferior to TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in improving cystic fibrosis lung function. Vertex Pharmaceuticals' once-daily small molecule vanzacaftor/tezacaftor/deutivacaftor (vanza triple) for cystic fibrosis (CF) has gleaned positive results in Phase III trials.

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New chemotherapy treatment could benefit multiple cancer types

A clinical trial in malignant pleural mesothelioma (MPM) has demonstrated the first successful combination of chemotherapy with a drug targeting cancer's metabolism developed for the asbestos-induced disease in two decades. The anti-cancer treatment combines the new drug ADI-PEG20 and traditional chemotherapy.

The Phase III ATOMIC-meso trial was led by Queen Mary University of London in the UK and studied 249 patients with the disease.

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TECHNOLOGY / NDDS

Millions of people to view digital prescriptions via the NHS app

NHS England has announced that its new digital prescription service has been added to the NHS App. The launch of the service follows a successful trial last year that involved over a million users.

In alignment with the NHS campaign to encourage more people to use the app, the digital prescription service will allow millions of patients to see when their prescriptions have been issued and will allow them to view their prescribed medication.

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Scientists develop a low-cost device to make cell therapy safer

A plastic microfluidic chip can remove some risky cells that could potentially become tumors before they are implanted in a patient. A tiny device built by scientists at MIT and the Singapore-MIT Alliance for Research and Technology could be used to improve the safety and effectiveness of cell therapy treatments for patients suffering from spinal cord injuries.

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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

Novavax, Gavi reach settlement on 2021 Covid-19 vaccine advance purchase agreement

Novavax, Inc. and Gavi, the Vaccine Alliance (Gavi) announced they have reached a settlement related to the 2021 Advance Purchase Agreement (APA) for Novavax's prototype Covid-19 vaccine (NVX-CoV2373) and it brings the pending arbitration related to the APA to a close. "Novavax is pleased to have reached this agreement with Gavi as it gives us the ability to continue to work together toward our shared mission of ensuring equitable access to safe and effective vaccines," said John C. Jacobs, president and chief executive officer, Novavax.

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WHO, Medicines Patent Pool announce technology transfer license to enable greater patient access to multiple essential diagnostics

WHO and the Medicines Patent Pool (MPP) announce a license agreement with SD Biosensor Inc., a global in-vitro diagnostic company, to provide sublicensees with the right, know-how and material to manufacture SDB's rapid diagnostic testing (RDT) technology. The transparent, non-exclusive license agreement, negotiated under the auspices of the Covid-19 Technology Access Pool (C-TAP), represents an important milestone in the evolution of the C-TAP initiative as it enables the manufacture of diagnostics for Covid-19 as well as other diseases such as HIV, malaria and syphilis.

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AntiCancer Inc receives new patent for mouse models

AntiCancer Inc, a world leader in developing individualized cancer therapy, including contract research, using its proprietary PDOX mouse model which it has developed since 1987, announced it has just received US Patent 11,871,731 that describes a method to increase the rate of establishment of patient tumors in mice to close to 100%. The new method allows, for the first time, large scale and commercial success of establishing mouse models for each cancer patient to individualize and optimize their cancer therapy, as well as banking their tumors after establishment for future therapy.

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