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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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Clinical Research Update
NEWS LETTER
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GLOBAL NEWS

NHS roadshow to tour England for lung cancer awareness month

The NHS and the Roy Castle Lung Foundation have launched the Let's Talk Lung Cancer roadshow for lung cancer awareness month this November. Areas of England with significantly higher rates of lung cancer will be visited by the roadshow, which is part of the NHS' Help Us, Help You campaign, to help catch cancer earlier and raise awareness of its signs and symptoms.

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BHF and UKDRI announce first UK centre for vascular dementia research

The British Heart Foundation (BHF) and the UK Dementia Research Institute (UKDRI) have announced plans to establish the first research centre for vascular dementia research in the UK. The new centre will help discover new treatments to prevent, halt and cure the condition.

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Study suggests cognitive decline could be linked to hippocampus shrinkage

A new study published in the journal Neurology has suggested that as the hippocampus area of the brain shrinks, the faster the decline in cognitive functions. These new findings could be important when treating patients with Alzheimer's disease (AD) as well as other neurodegenerative conditions.

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PHARMA INDIA

Four drugs for three rare diseases are under approval process in India, says report

The ministry of health and family welfare (MoHFW) has revealed that the drug regulator is considering four drugs for three rare diseases for approval while medicines for another four rare diseases have already been made available by Indian manufacturers, according to an agency report.

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DCC recommends to DCGI inclusion of details of all excipients in QR code

The Drugs Consultative Committee (DCC) of the Union health ministry has recommended to the national drug regulator to amend the regulation mandating Quick Response (QR) code for the top 300 brands in order to include the information on all the excipients used in the drug formulation.

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CPhI & PMEC India Expo to be held from Nov 28-30 in Delhi

The CPhI & PMEC India Expo, orchestrated by Informa Markets in India, is slated to unfold from November 28 to November 30, 2023, at the India Expo Centre in Greater Noida, Delhi.

By embracing modernisation, CPhI & PMEC India stands as the conduit to the global supply chain, converging diverse elements under one expansive roof. The event, along with its ancillary programmes, spotlights technological strides pivotal in propelling India's pharmaceutical machinery, technology, and ingredients sectors.

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REGULATORY ROUND-UP

MHRA launches online eligibility checker tool via the IRP

Medicines & Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) has announced the launch of an online Eligibility Checker tool as part of the agency's new International Recognition Procedure (IRP).

The IRP will allow the agency to help bring life-saving medicines to patients in the UK from 1 January 2024, following the UK's exit from the EU.

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FDA takes action on updated mRNA COVID-19 vaccines to better protect against currently circulating variants

The U.S. Food and Drug Administration took action approving and authorizing for emergency use updated COVID-19 vaccines formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc.

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US FDA cautions public of safety issue with Philips' DreamStation 2 CPAP machines

As part of the US Food and Drug Administration's (FDA) continued commitment to protect and promote the public health, the agency is alerting patients and healthcare providers of an emerging safety issue involving Philips Respironics' DreamStation 2 Continuous Positive Airway Pressure (CPAP) machines used for treatment of obstructive sleep apnea.

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MERGERS / ACQUISITIONS / COLLABORATIONS

SMART and CAMP collaborate to develop safer T-cell therapies

Researchers from the Singapore-MIT Alliance for Research and Technology's (SMART) Critical Analytics for Manufacturing Personalized-Medicine (CAMP) Interdisciplinary Research Group have collaborated to develop safer T-cell therapies.
In partnership with the Singapore Centre for Environmental Life Sciences Engineering and the Massachusetts Institute of Technology (MIT), researchers have developed a novel method to identify contaminants in T-cell cultures within 24 hours.

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bit.bio and KCL to collaborate for neurodevelopmental disorders

bit.bio and King's College London's (KCL) Institute of Psychiatry, Psychology and Neuroscience (IoPPN) have collaborated to build multi-cell models of the human brain for neurodevelopmental disorders. The collaboration will share scientific protocols and provide novel multi-cell models of the brain to researchers worldwide.

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AbbVie agrees $10 billion oncology acquisition

AbbVie has agreed to acquire ImmunoGen and its first-in-class antibody-drug conjugate (ADC) ELAHERE ® (mirvetuximab soravtansine-gynx), for a total of approximately $10.1 billion.

Under its proposed acquisition of ImmunoGen, AbbVie will gain rights to ELAHERE®, the first antibody-drug conjugate (ADC) approved in ovarian cancer.

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DRUGS: APPROVALS AND LAUNCHES

Alladapt's allergy treatment receives FDA fast track designation

Alladapt Immunotherapeutics has announced that its investigational multi-food oral immunotherapy (mOIT), ADP101, has received Fast Track Designation from the US Food and Drug Administration (FDA).

The designation will endorse the development of ADP101 as a treatment for some of the world's most significant food allergens.

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EC approves first-line ovarian cancer treatment

The European Commission (EC) has authorised a Type II variation for the poly (ADP-ribose) polymerase (PARP) inhibitor Rubraca® (rucaparib). The small molecule treatment is indicated as a first-line maintenance treatment for individuals with advanced ovarian cancer regardless of their BRCA mutation status, who have responded to first-line platinum-based chemotherapy.

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EC approves lebrikizumab for atopic dermatitis

Monoclonal antibody, lebrikizumab, is approved in Europe for treatment of adults and adolescents with moderate-to-severe atopic dermatitis. Lebrikizumab represents a "significant step forward" in patients with moderate-to-severe atopic dermatitis not controlled with topical therapy due to its selective mechanism of action, proven short and long-term efficacy and safety and a monthly maintenance dosing for all patients.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Clinical trial reveals positive results for treating children with rare gliomas

University College London (UCL) and Great Ormond Street Hospital (GOSH) have published the successful results from a phase 2 clinical trial to treat BRAF-mutated low-grade paediatric gliomas. Mutations in the BRAF gene are present in around 15-20% of paediatric low-grade gliomas and around 5-10% of high-grade gliomas, a cancerous brain tumour, in children.

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Thousands of men to participate in UK trial for prostate cancer

The UK government and Prostate Cancer UK have announced a £42m screening trial to detect prostate cancer in hundreds of thousands of men across the UK. The TRANSFORM trial will use innovative screening methods, such as MRI scans, to detect prostate cancer in men before their cancer spread and save lives.

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Ferring reveals long-term data for cancer gene therapy

New data from a Phase III gene therapy trial has demonstrated a 90 percent three-year overall survival rate for its participants with a high-risk bladder cancer.
Adstiladrin is the first FDA-approved intravesical gene therapy to be authorised for adults with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

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TECHNOLOGY / NDDS

AI tools to speed up lung cancer diagnosis in NHS hospitals

The Department of Health and Social Care (DHSC) has announced that 64 NHS trusts across England are set to deploy artificial intelligence (AI) tools to speed up the diagnosis and treatment of lung cancer. Following the UK government's announcement of £21m to roll out AI across the NHS in June, the funding will allow NHS trusts to deploy AI tools that analyse X-rays and CT scans.

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Samay's AI-assisted wearable technology accurately diagnoses COPD

Samay has announced positive results that showed that its artificial intelligence (AI)-assisted wearable technology device, Sylvee, accurately diagnosed chronic obstructive pulmonary disease (COPD) in patients.
The US start-up's passive remote monitoring platform and its wearable device delivered a near equivalence to the current standard pulmonary function test (PFT).

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First CRISPR-based gene-editing therapy authorized

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted a world-first regulatory authorisation to a medicine based on Nobel Prize-winning technology. According to Vertex Pharmaceuticals and CRISPR Therapeutics, Casgevy is a genetically modified autologous CD34+ cell enriched population containing human hematopoietic stem and progenitor cells edited ex vivo by CRISPR/Cas9 at the erythroid-specific enhancer region of the BCL11A gene.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Acquisition deal to back European biosimilars market

Biocon Biologics Ltd has successfully completed integration of Viatris' biosimilar business in 31 European countries. Following the acquisition of substantially all global biosimilar business of Viatris in November 2022, and the related integration of over 70 emerging market countries in July 2023 and North America in September 2023, now that Viatris' biosimilars operations have fully transitioned to Biocon Biologics Ltd in Europe, the company declared that this "represents another significant milestone."

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EU pharma legislation key in tackling AMR

efpia European Federation of Pharmaceutical Industries and Associations

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the EU general pharmaceutical legislation has potential to shape the future of EU actions against antimicrobial resistance (AMR).

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Avilar Therapeutics' novel extracellular protein degraders receives US patent

AVILAR THERAPEUTICS

Avilar Therapeutics, a biopharmaceutical company focused on extracellular protein degradation, announced that the US Patent and Trademark Office issued US Patent 11,819,551 on November 21, 2023.

The issued patent provides broad protection for Avilar's first wave of extracellular proteins degraders called ATACs (ASGPR Targeting Chimeras) with therapeutic applications in a wide range of human diseases.

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