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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

Lambda's BA-BE Centre in India Successfully clears GCC Inspection with Zero Observations

Lambda Therapeutic Research, a leading global clinical research organization, is thrilled to announce the successful conclusion of the Gulf Cooperation Council (GCC) inspection at its BA-BE Centre in India. The inspection, which took place from May 1st to May 4th, 2023, resulted in zero observations, highlighting Lambda's adherence to the highest quality standards.

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India emerging as favorable destination to conduct global clinical trials

A joint report by PwC India & US-India Chamber of Commerce (USAIC) has revealed that India is emerging as a favourable destination to conduct clinical trials. The report was released at the USAIC BioPharma & Healthcare Summit held virtually on May 3.

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International clinical trial to evaluate new combinations of generic antibiotics for treating neonatal sepsis

NeoSep1, an international clinical trial to evaluate much-needed new antibiotic combinations for newborn babies with sepsis, has started in three hospitals in South Africa and Kenya. The trial will be expanded to other countries and regions next year, with a target of recruiting up to 3,000 newborns overall.

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PHARMA INDIA

India Makes Cough Syrup Testing Mandatory for Exports

The Indian government has made it compulsory for cough syrup makers to get samples tested before exporting their products. Starting 1 June, these companies will have to get a certificate of analysis from a government-approved laboratory.

The rule change comes after some Indian-made cough syrups were linked to deaths in The Gambia and Uzbekistan.

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Biophore, its subsidiary Zenara Pharma, receive first approval for Cannabidiol in India

Biophore India Pharmaceuticals has received CDSCO approval for manufacturing and marketing of Cannabidiol active ingredient in India and its subsidiary, Zenara Pharma, has received the approval for the final product, Can nabidiol Oral Solution 100mg/ml, for neuro disorders. This is the first time ever that a Cannabidiol-based product has been approved in India, delivering a unique therapy option.

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Reducing regulatory intervention in system a priority: DCGI

Drugs Controller General of India (DCGI) Rajeev Singh Raghuvanshi has called for bridging the "huge gap" between biology and technology interface for out-of-the-box research, so that the country can come out of its 'generic' mindset. During a talk delivered at the CSIR-Indian Institute of Chemical Technology (IICT) on National Technology Day.

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REGULATORY ROUND-UP

ICMR issues draft policy on Research Infrastructure Sharing Ecosystem

This policy envisions to establish a mechanism to provide access to the centralized network of scientific research infrastructure within ICMR to fulfil the research needs of all researchers across the country thereby ensuring optimal use of available research facilities & promote health research.

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FDA publishes paper on Artificial Intelligence and Machine Learning (AI/ML) in drug development

The US Food and Drug Administration (FDA) has released a discussion paper to complement and inform future guidance on artificial intelligence (AI) and machine learning (ML) in drug development..

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EMA guidance aims to prevent medicine shortages

The European Medicines Agency (EMA) has made recommendations for industry on how to prevent medicine shortages and reduce their impact. A new document published by European Medicines Agency (EMA) makes ten recommendations and outlines good practices "to ensure continuity in the supply of human medicines, prevent shortages and reduce their impact."

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MERGERS / ACQUISITIONS / COLLABORATIONS

uBriGene Expands into US Market with Acquisition of Mustang Bio's CGT Manufacturing Facility

uBriGene Biosciences will acquire Mustang Bio's Worcester, Mass., CGT manufacturing facility in a deal worth up to $11 million, expanding its operations into the US market.

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Abbott Announces New Partnerships and Programs to Advance its Diversity in Clinical Trials Initiative

Abbott announced a series of new programs within its multi-million-dollar initiative to increase diversity in clinical trials and improve care among under-represented populations. The new additions to Abbott's Diversity in Clinical Trials initiative build on the partnerships, scholarships, and the focus on diversified participants in the company's own clinical trials during the initiative's first year.

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India a global pharma hub: Dr. Mandaviya invites Japanese collaboration

The union health minister Dr. Mansukh Mandaviya on Monday sought Japanese collaboration on research and innovation in emerging technologies like precision medicine, cell and gene therapy, biological products, and on the utilization of digital tools.

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DRUGS: APPROVALS AND LAUNCHES

FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease

The U.S. Food and Drug Administration is announcing the supplemental approval of Rexulti (brexpiprazole) oral tablets for the treatment of agitation associated with dementia due to Alzheimer's disease. This is the first FDA-approved treatment option for this indication.

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First redosable gene therapy approved by US FDA

Krystal Biotech, an organization focused on developing and commercializing genetic medicines for patients with rare diseases, is officially receiving FDA approval for Vyjuvek, a treatment geared towards patients aged six months or older with dystrophic epidermolysis bullosa (DEB).

The "landmark approval" of a redosable gene therapy for dystrophic epidermolysis bullosa "ushers in a whole new paradigm to treat genetic diseases.

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US FDA approves Lexicon Pharma's drug for heart failure

Lexicon Announces FDA Approval of Inpefa™ (Sotagliflozin) for treatment of Heart Failure.

INPEFA granted broad label across full range of left ventricular ejection fraction, including HFpEF and HFrEF, and for patients with or without diabetes.

INPEFA reduced the risk of total occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits by 33% compared to placebo in the SOLOIST-WHF study.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Nanoparticle HIV vaccine shows potential in trial

Positive first-in-human trial results have highlighted potential of a nanoparticle vaccine towards broadly neutralising against HIV.

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AstraZeneca's drug combo shows positive results in late-stage cancer trial

A combination of AstraZeneca's cancer drugs Imfinzi and Lynparza when added to platinum-based chemotherapy showed positive results in a late-stage trial in patients with advanced or recurrent endometrial cancer.

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Bayer receives US FDA Fast Track Designation for asundexian atrial fibrillation program

Bayer announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its investigational drug asundexian (BAY2433334) as a potential treatment to prevent stroke and systemic embolism in people with atrial fibrillation (AF). This news follows asundexian's first U.S. FDA Fast Track Designation for the prevention of stroke in patients after a non-cardioembolic ischemic stroke, which was granted in 2022.

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TECHNOLOGY / NDDS

Improved gene editing method could power the next generation of cell and gene therapies

A new approach to the genetic engineering of cells promises significant improvements in speed, efficiency, and reduction in cellular toxicity compared to current methods. The approach could also power the development of advanced cell therapies for cancers and other diseases, according to a study from researchers in the Perelman School of Medicine at the University of Pennsylvania.

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Novel device opens blood-brain barrier to deliver chemotherapy

The blood-brain barrier (BBB) in glioblastoma patients was opened temporarily using a novel, skull-implantable ultrasound device to deliver chemotherapy to the brain in a first in-human trial. Two chemotherapy drugs, paclitaxel and carboplatin were injected intravenously during the four-minute procedure.

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Insilico Medicine delivers preclinical candidate targeting ENPP1 for cancer immunotherapy and the treatment of rare disease using generative AI

Insilico Medicine (Insilico), a clinical-stage generative artificial intelligence (AI)-driven drug discovery company, has nominated a potentially best-in-class preclinical candidate targeting ENPP1 for cancer immunotherapy and the potential treatment of Hypophosphatasia (HPP).

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Pfizer, Moderna hit with new Alnylam patent lawsuits over COVID-19 vaccines

The new lawsuits mark the third time Alnylam has sued Pfizer and Moderna in Delaware for allegedly violating its patent rights in lipid nanoparticle (LNP) technology, which the vaccines use to deliver genetic material into the body.

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Amgen, J&J Settle Patent Dispute Over Stelara Biosimilar

After the recent high-profile loss of exclusivity for AbbVie's mega-blockbuster immunology drug Humira, industry watchers' eyes moved to Johnson & Johnson's Stelara as one of the next major drugs expected to face biosimilar competition.

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India to seek pharma IPR waiver for future pandemics at WTO meet: Report

After obtaining a five-year patent waiver for Covid-19 vaccines in 2022, India is likely to push for a global waiver for vaccines, therapeutics, & diagnostics to combat future pandemics at the mini-ministerial meeting of the World Trade Organization (WTO) in Paris on June 7.

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