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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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Dr. Tausif Monif
President - Global operations
tausifmonif@lambda-cro.com

Dr. Mrinal Kammili
Executive Director – Global Head, BD
mrinal@lambda-cro.com

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Clinical Research Update
NEWS LETTER
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GLOBAL NEWS

AstraZeneca's Tagrisso delivers positive results

AstraZeneca's Tagrisso has delivered positive results from its pivotal ADAURA phase 3. The study demonstrated a clinically meaningful improvement in overall survival (OS), compared to the placebo among patients with early-stage epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after complete tumour resection with curative intent.

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Leucine Rich Bio launches oral microbiome firm, Crown Biome in US

Headquartered in Bengaluru Leucine Rich Bio Pvt Ltd, South Asia's first microbiome company, is all set to foray into US healthcare with the establis hment of Crown Biome Inc, a visionary US-based entity dedicated to revolutionizing oral healthcare through cutting-edge products and solutions. Crown Biome Inc will be helmed by its CEO Bryan Toton.

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Salve Pharma establishes new manufacturing facility at Reliance MET, Haryana

Salve Pharmaceuticals, a leading company in the pharmaceutical and skincare sector, has recently unveiled its plans to establish a new manufacturing facility at the Reliance Modern Economic Township (Reliance MET) in Jhajjar, Haryana.

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PHARMA INDIA

Zydus Lifesciences' subsidiary, ZAHIL acquires stake in Mylab Discovery Solutions

Zydus Lifesciences, a discovery-driven, global life sciences company, through its wholly owned subsidiary Zydus Animal Health & Investments Limited (ZAHIL), has acquired 6.5% stake in Mylab Discovery Solutions from Rising Sun Holdings, an investment company owned by Adar Poonawalla.

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Sun Pharma presents data from first-in-human phase 1 studies of GL0034 at ADA 83rd scientific sessions

Sun Pharmaceutical Industries Ltd. announced results from two phase 1 studies evaluating the tolerability, safety, pharmacokinetics and pharmacodynamics of GL0034, a novel long-acting GLP-1 receptor agonist, in non-obese and obese adults without diabetes. The data highlighted in poster presentations at the American Diabetes Association's (ADA) 83rd Scientific Sessions held from June 23-26, 2023, in San Diego, California.

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Dr Reddy's enters the trade generics business in India

Hyderabad-based drug major Dr Reddy's Laboratories has announced its entry into the trade generics business in India with the launch of its new dedicated division 'RGenX'.

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REGULATORY ROUND-UP

EMA recommends approval of GSK's daprodustat for symptomatic anaemia associated with CKD in adults.

GSK plc announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued a positive opinion recommending authorisation of daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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FDA Accepts Pfizer's Application for Hemophilia B Gene Therapy Fidanacogene Elaparvovec

Pfizer Inc. announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Biologics License Application (BLA) for fidanacogene elaparvovec for the treatment of adults with hemophilia B. In parallel, the European marketing authorization application (MAA) for fidanacogene elaparvovec has also been accepted and is under review by the European Medicines Agency (EMA).

Pfizer

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US FDA issues first draft guidance on clinical trials with Psychedelic Drugs

The US FDA published a new draft guidance to highlight fundamental considerations to researchers investigating the use of psychedelic drugs for potential treatment of medical conditions, including psychiatric or substance use disorders.

FDA U.S. FOOD & DRUG ADMINISTRATION

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MERGERS / ACQUISITIONS / COLLABORATIONS

CORONA remedies buys Sanofi India's ortho brand Myoril

Ahmedabad-based pharmaceutical company CORONA Remedies has acquired leading muscle relaxant brand Myoril from Sanofi India, for Rs. 234 crore. Corona has acquired Myoril (Thiocolchicoside) and its extensions such as Myoril Plus (Ketoprofen + Thiocolchicoside), said people aware of the development.

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Chinook Therapeutics Acquired by Novartis AG

Chinook Therapeutics, Inc. announced on June 12, 2023 that it has entered into an agreement and a merger plan with Novartis AG where Novartis will acquire Chinook for $40 per share in cash, for a total of $3.2 billion. Additionally, Chinook shareholders will receive contingent value rights providing for payment of up to $4 per share upon the achievement of certain future regulatory milestones, according to the company press release.

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iNova Pharma acquires consumer healthcare brands from Mundipharma

iNova Pharmaceuticals, a multinational pharmaceutical and consumer health care company, is expanding its leading consumer healthcare platform through the acquisition of a portfolio of trusted, well-known consumer healthcare brands, anchored by the iconic Betadine product range.

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DRUGS: APPROVALS AND LAUNCHES

DCGI approves Akums perampanel oral suspension for treatment of epilepsy

Akums announced the approval of perampanel oral suspension by the Drug Controller General of India (DCGI). The perampanel oral suspension is a bioequivalent formulation to the US FDA-approved FYCOMPA (perampanel) oral suspension.

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EC approves Bristol Myers Squibb's Camzyos

The European Commission (EC) has granted approval for Bristol Myers Squibb's (BMS) Camzyos (mavacamten, 2.5mg, 5mg, 10mg, 15mg capsules) to treat adults with symptomatic obstructive hypertrophic cardiomyopathy.

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EDQM grants C2 PHARMA CEP approval for commercial sale of cyclopentolate hydrochloride

C2 PHARMA, the global leader in manufacturing and supplying ophthalmic APIs, is pleased to confirm the approval of a Certificate of Suitability (CEP) for cyclopentolate hydrochloride by the Quality of Medicines & Health Care (EDQM). This is the second ever CEP granted by the European Directorate for cyclopentolate hydrochloride, allowing C2 PHARMA to make the API commercially accessible to customers throughout Europe, Southeast Asia, Oceania and beyond.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Lupin achieves key milestone for its phase 1 clinical stage MALT1 inhibitor programme

Global pharma major Lupin Limited (Lupin) announced the achievement of a key milestone for its novel MALT1 (Mucosa-Associated Lymphoid Tissue Lymphoma Translocation Protein 1) inhibitor programme that is partnered with AbbVie Inc.

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Bayer begins phase III studies with novel contrast agent gadoquatrane

Bayer, a global leader in radiology, has started the phase III clinical development programme QUANTI, aiming to evaluate the efficacy and safety of gadoquatrane, a next-generation, extracellular, macrocyclic, gadolinium-based contrast agent (GBCA) for use in magnetic resonance imaging (MRI). Gadoquatrane is a highly stable MRI contrast agent featuring high relaxivity that has the potential to enable a substantially lower gadolinium (Gd) dose for patients.

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Astellas Pharma announces positive results from phase 3b trial of fezolinetant to treat VMS due to menopause.

Astellas Pharma Inc. announced positive topline results from the phase 3b DAYLIGHT clinical trial for fezolinetant, an investigational oral, nonhormonal compound being studied for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause.

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TECHNOLOGY / NDDS

ICMR invites applications for subscription based online IP management software to manage complete IP life cycle

The Indian Council of Medical Research (ICMR) has invited Expression of Interest (EoI) from experienced Intellectual Property (IP) management software companies for subscription based online IP management software for effectively managing the complete life cycle of the Intellectual Property, right from invention, disclosure to filing and licensing of the IP.

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Zeon Lifesciences disrupts probiotic manufacturing with Intelicaps technology

Zeon Lifesciences, the leading manufacturer of nutraceutical and herbal products, has announced a significant breakthrough in the manufacturing process of probiotics, utilizing the latest Intelicaps technology.

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Pixelgen Technologies introduces first Molecular Pixelation Kit for 3D spatial analysis of cell surface proteins

Pixelgen Technologies, the single cell spatial proteomics company, announced the commercial launch of its first kit, based on the company's proprietary Molecular Pixelation (MPX) technology for spatial analyses of immune cell surface proteins in 3D.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Origiin IP sees Unitary Patent System in EU bringing benefits of cost, ease of filing for Indian pharma

Origiin IP sees the recent Unitary Patent System in EU having the potential to completely transform patent registration, filing, enforceability and renewal if implemented smoothly for Indian pharma.

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Astellas confirms unfavourable District Court decision in myrbetriq US patent trial

Astellas Pharma Inc. confirmed that the US District Court for the District of Delaware issued a decision on June 9 finding US Patent No. 10,842,780 (the "'780 Patent", which expires in March 2030) invalid.

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OBiO Technology adds scale-X and NevoLine Upstream Platform to accelerate gene therapy manufacturing

OBiO Technology Corp., Ltd. (OBiO), a leading gene and cell therapy CDMO in China, and Univercells Technologies, a leading provider of novel biomanufacturing technologies for flexible and scalable advanced therapies and vaccine production, have entered into a strategic agreement to deploy novel technologies in Shanghai.

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