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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

AstraZeneca's gets European approval for myasthenia gravis.

Soliris (eculizumab) has been approved in the European Union (EU) for expanded use to include the treatment of refractory generalised myasthenia gravis (gMG) in children and adolescents aged six to 17 years who are anti-acetylcholine receptor (AChR) antibody-positive (Ab+). This is the first and only targeted therapy approved for the treatment of paediatric patients with the disease in the EU.

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WHO issues on NGS for diagnosis of drug-resistant TB.

Targeted next generation sequencing (NGS) for the detection of drug-resistant TB is a new class of diagnostic technology. It provides an option for rapid and accurate genetic analysis and detection of mutations associated with resistance in a fraction of the time required for culture-based methods for detecting resistance.

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Baxter introduces PERCLOT absorbable hemeostatic powder

Baxter Inter national Inc., a global leader, announced the launch of PERCLOT absorbable haemostatic powder in the US. PERCLOT is a passive, absorbable haemostatic powder that is ready to use and designed for patients with intact coagulation to address mild bleeding.

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PHARMA INDIA

Lupin gets TGA approval for tiotropium powder for inhalation for COPD

Lupin Limited announced that its wholly owned subsidiary in Australia, Generic Health Pty Ltd, has received approval for tiotropium 18 micrograms powder for inhalation in capsules for use with LupinHaler, from the Australian drug regulatory agency Therapeutic Goods Administration (TGA).

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GARDP & Bugworks to development of a novel antibiotic for bacterial infections

The Global Antibiotic Research & Development Partnership (GARDP) has teamed up with Bugworks Research Inc., an innovative clinical-stage biopharmaceutical company with research and development facilities in Bengaluru, to accelerate the development of a new broad-spectrum antibiotic compound aimed at treating serious infections caused by multidrug-resistant bacteria.

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Akums to diversify its portfolio into nutraceutical gummy formulations.

Akums Drugs and Pharmaceutical Limited announced that it is actively expanding its presence in the nutraceutical gummies market, responding to the escalating demand for gummy supplements among health-conscious consumers. The gummy supplement will cater to the general wellness and nutritional requirements of adults, paediatrics, and geriatric populations.

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REGULATORY ROUND-UP

US FDA facilitate innovation for devices to treat opioid use disorder.

The US Food and Drug Administration (FDA) announced new steps to help facilitate innovation in devices intended to treat opioid use disorder (OUD). The draft guidance, to help sponsors design clinical studies to evaluate these devices, furthers the FDA's Overdose Prevention goal of advancing evidence-based treatment for those with substance use disorders.

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EMA recommends authorization to ViiV Healthcare's cabotegravir for HIV

GSK plc announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, welcomed a positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use recommending marketing authorisation for cabotegravir long-acting injectable and tablets for HIV prevention.

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CDSCO asks applicants for testing of veterinary vaccines & drugs to submit Form

The Central Drugs Standard Control Organisation (CDSCO) has switched to online the procedure for submission of form for test license. The Drugs Controller General of India (DCGI) has said that the submission of applications for issuance for Form 11 for veterinary vaccines and drugs is now functional on the online system of Sugam portal.

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MERGERS / ACQUISITIONS / COLLABORATIONS

SRAM & MRAM collaborates with Cellaax to advance stem cell treatment in India.

In a major development in the field of healthcare, SRAM & MRAM Group has announced a joint venture with Cellaax. Cutting-edge technologies and exceptional medical know-how will be harnessed to deliver innovative solutions for patients grappling with diverse diseases and disorders in the region.

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Lupin collaborate to revolutionize in-home CV care in India with Digital Therapeutics

Lupin Digital Health, announced a first-of-its-kind collaboration to deliver in-home cardiovascular care with Digital Therapeutics (DTx) in India. Lupin Digital Health's DTx platform, Lyfe, also aims to give patients and their healthcare providers tools to manage heart diseases at home and help to ensure patients stay healthy after hospital discharge and reduce rehospitalization.

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Nona Biosciences announces update on antibody drug conjugate with DualityBio.

Nona Biosciences, a wholly owned subsidiary of HBM Holdings Limited, announced that, DualityBio, a collaborator of Nona Biosciences, and BeiGene entered into an agreement for BeiGene to acquire an exclusive option for a global clinical and commercial license to an investigational, preclinical ADC programme for patients with select solid tumours.

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DRUGS: APPROVALS AND LAUNCHES

US FDA approves Harm Reduction Therapeutics' RiVive, an OTC naloxone nasal spray

The US Food and Drug Administration (FDA) approved RiVive, 3 milligram (mg) naloxone hydrochloride nasal spray for over the counter (OTC), nonprescription use for the emergency treatment of known or suspected opioid overdose. This is the second nonprescription naloxone product the agency has approved, helping increase consumer access to naloxone without a prescription. The timeline for availability and the price of this nonprescription product will be determined by the manufacturer.

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Perrigo receives US FDA approval for Opill OTC daily oral contraceptive

Perrigo Company plc, announced that, a progestin-only daily oral contraceptive, for over-the-counter (OTC) use for all ages. Opill is the first ever birth control pill available over the counter in the United States.

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Aurobindo Pharma's receives US FDA approval for single dose plerixafor injection.

Aurobindo Pharma Limited announced that its wholly owned subsidiary company, Eugia Pharma Specialities Limited, has received a final approval from the US Food & Drug Administration (FDA) to manufacture and market plerixafor injection, 24 mg/1.2 mL (20 mg/mL), single-dose vial. The drug is a bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mozobil injection, 24 mg/1.2 mL (20 mg/mL) of Genzyme Corporation.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Asieris completes phase III bridging trial of Hexvix for diagnosis of bladder cancer.

Asieris Pharmaceuticals announced the completion of patient enrollment for its phase III bridging clinical trial of Hexvix, a drug used for the diagnosis of bladder cancer.
The study aimed at investigating the additional detection rate and safety of Hexvix in patients with non-muscle invasive bladder cancer (NMIBC) including tumours with stage carcinoma in situ (CIS), Ta, and T1

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AstraZeneca announces phase III trial of Imfinzi + Imjudo demonstrates sustained OS benefit in advanced liver cancer.

Updated results from the HIMALAYA phase III trial showed AstraZeneca's Imfinzi (durvalumab) + Imjudo (tremelimumab) demonstrated a sustained, clinically meaningful overall survival (OS) benefit at four years for patients with unresectable hepatocellular carcinoma (HCC) who had not received prior systemic therapy and were not eligible for localised treatment.

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BrainStorm's phase 3 trial data shows treatment with NurOwn significantly reduces NfL.

These new biomarker data from the phase 3 trial show that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light (NfL) over time compared to placebo in all trial participants.

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TECHNOLOGY / NDDS

Sanofi and Scribe Therapeutics Expands Genomics Collaboration

The agreement will see Sanofi receive an exclusive license to use Scribe's CRISPR X-Editing (XE) genome editing technologies for the development of in vivo therapies, including sickle cell disease. This agreement builds on the companies' existing collaboration, which is focused on ex vivo editing of natural killer (NK) cell therapies for cancer treatment.

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Upperton Completes New Development of GMP Manufacturing Facility

Upperton Pharma Solutions has finished the construction of GMP manufacturing facility in Nottingham, UK, as of July 12, 2023. According to the press release, the new building can house 10 new GMP manufacturing suites, quality control laboratories, and formulation development with pilot plant capabilities. Additionally, it is capable of handling highly potent and controlled drugs, clinical trial supplies, and support for early formulation development.

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TCS expands partnership with GE HealthCare for IT operations

Tata Consultancy Services (TCS) has expanded its partnership with GE HealthCare Technologies to transform the American multinational firm's IT operating model.The transformation will bring intelligent care solutions to one billion patients across more than 160 countries where GE HealthCare operates, TCS said.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Catalyst Pharma acquires exclusive North American license for vamorolone for DMD from Santhera Pharma

Catalyst Pharmaceuticals, Inc. announced the completion of its acquisition from Santhera Pharmaceuticals. The license is for exclusive commercial rights in the US, Canada, and Mexico, as well as the right of first negotiation in Europe and Japan.

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USPTO grants patent to Femasys' product, FemBloc for female permanent birth control.

Femasys Inc., a biomedical company focused on meeting women's unmet needs worldwide, announced that the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for US Patent Application 16/402,193 further strengthening Femasys' intellectual property position and coverage for the company's therapeutic product candidate, FemBloc permanent birth control.

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US District Court rules in favour of Orexo in patent litigation against Sun Pharma on Zubsolv patent.

Orexo AB (publ.), a company announces that the District of New Jersey ruled in favour of Orexo in its patent litigation against Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma Global, Inc., and Sun Pharmaceutical Industries, Inc. (collectively "Sun") regarding Zubsolv (buprenorphine and naloxone) sublingual tablets (CIII) in the US.

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