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LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

Mitochondrial protein plays key role in glioblastoma and therapeutic resistance

Glioblastoma is the most common type of brain tumor that affects adults and, unfortunately, remains incurable. In a new study, researchers have demonstrated that a specific mitochondrial protein plays an important role in glioblastoma, and can therefore be used as a potential target to reduce tumors.

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Researchers reveal link between Alzheimer's and sex hormones

Researchers have shown female sex hormones play a significant role in how Alzheimer's manifests in the brain. The study also highlights the importance of developing therapeutic strategies focused on these hormonal connections. The research indicates a need to better understand the role of estradiol -- a form of the female sex hormone estrogen, used therapeutically to mitigate menopause symptoms -- in Alzheimer's disease.

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King Faisal Specialist and Research Centre achieves world-first fully robotic liver transplant

The Organ Transplant Center of Excellence (OTCoE) team at King Faisal Specialist Hospital and Research Centre (KFSH&RC) has announced that it has successfully performed the world’s first fully robotic liver transplant.The medical milestone marks KFSH&RC’s, a tertiary and quaternary healthcare provider in the Middle East, position as a global leader in minimally invasive transplant surgery.

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PHARMA INDIA

India joins mission to harmonise pharmacopoeial standards

The Indian Pharmacopoeia Commission (IPC) is now a member the Pharmacopoeial Discussion Group (PDG). The PDG was established by the European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the US Pharmacopeia (USP) in 1989.

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India mammography equipment market to grow 12% through 2033

Driven by increasing focus on advancing women's health and facilitating timely breast cancer diagnosis, India's mammography equipment market is projected to grow at a compound annual growth rate of around 12% between 2023 and 2033, forecasts GlobalData, a data and analytics company.

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NPPA fixes retail price of 29 new drugs, exempts two drugs from DPCO, 2013

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail price of 29 new drugs under the provisions of Drugs (Prices Control) Order, 2013 for fixing retail price of a new drug for existing manufacturers of scheduled formulations. The Authority considered 30 applications seeking retail price fixation of 30 new drugs in its latest meeting and approved the prices for 29 drugs, while differing fixation of price for one formulation observing that necessary clarifications are required from the company before finalising the price.

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REGULATORY ROUND-UP

WHO releases key regulatory considerations on AI for health?

The World Health Organization (WHO) has published new key regulatory considerations on artificial intelligence (AI) for health to emphasise the importance of establishing the safety and effectiveness of AI systems. The new considerations aim to help governments and regulatory authorities to develop new guidance or adapt existing guidance on AI at national or regional levels.

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FDA issues draft guidance on alternative tools for facility assessments

As part of the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA) reauthorisation negotiations, the US Food and Drug Administration (FDA) has issued new draft guidance on alternative tools for assessing drug manufacturing facilities. Fundamentally, this approach will establish whether facilities meet applicable requirements for FDA approval and licensure decisions.

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Pharma pushes for UK medicine scheme revision.

According to the Association of the British Pharmaceutical Industry (ABPI), a consultation by the UK Government proposing radical changes to the Statutory Scheme for branded medicines has been heavily criticised by the pharmaceutical industry. The fundamental concern, ABPI highlighted, is the proposed continuation of an arbitrary cap on growth for branded medicines in the UK, which has led to soaring revenue clawbacks in the country.

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MERGERS / ACQUISITIONS / COLLABORATIONS

Kyowa Kirin to acquire Orchard Therapeutics in deal worth $477m

Kyowa Kirin has announced it has agreed to acquire Orchard Therapeutics in a deal worth $477.6m to develop several biopharmaceutical candidates in areas including oncology and autoimmune diseases. As part of the definitive agreement, Japan-based biopharmaceutical company Kyowa will gain rights to Orchard's Libmeldy (atidarsagene autotemcel) for early-onset metachromatic leukodystrophy (MLD).

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Elligo Health Research expands Study Marketplace with Syneos Health

Elligo Health Research has announced it is expanding its IntElligo Study Marketplace platform with Syneos Health. The platform aims to make sales, site selection and application processes more transparent and efficient for clinical trial sponsors, clinical research organisations and sites, while also tracking progress.

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Kate Therapeutics and Capsida Biotherapeutics collaborate on gene therapies

Kate Therapeutics (KateTx) and Capsida Biotherapeutics have announced a strategic collaboration to manufacture KateTx's next-generation gene therapies. The partnership aims to advance KateTx's initial internal portfolio of muscle and heart disease programmes and leverage Capsida's expertise and adeno-associated virus (AAV) manufacturing capabilities.

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DRUGS: APPROVALS AND LAUNCHES

Approval-first for meningococcal vaccine

The first single vaccine to immunise against the five most common meningococcal disease serogroups in adolescents has been approved in the US. The first and only pentavalent vaccine that provides the broadest serogroup coverage of any meningococcal vaccine available in the US for meningococcal disease in individuals aged 10 to 25 years old, has been approved by the US Food and Drug Administration (FDA).

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First-in-class phosphate absorption inhibitor approved by FDA

A first-in-class treatment with a differentiated mechanism of action has been approved to reduce serum phosphorus in chronic kidney disease (CKD) in individuals for which phosphate binders are not suitable. Ardelyx's first-in-class oral treatment is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant to phosphate binder therapy.

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UK MHRA grants marketing authorisation to AbbVie's bispecific antibody therapy Tepkinly to treat diffuse large B-cell lymphoma in adult.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has authorised a new medicine called Tepkinly (epcoritamab), a treatment for diffuse large B-cell lymphoma (a type of blood cancer) in adults. It can be used to treat patients when the cancer has returned after previous treatment, or who have not responded to at least two previous treatments.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Sanofi treatment could slow type 1 diabetes progression

New Sanofi Phase III trial data adds to evidence of the treatment potential for the first disease modifying therapy in type 1 diabetes. Data from the Phase III PROTECT clinical trial, presented at the 2023 Annual ISPAD Conference, showed that superior beta cell preservation was observed compared to placebo.

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Roche multiple sclerosis subcutaneous injection: late-breaking data

OCREVUS subcutaneous injection was comparable to intravenous (IV) infusion in providing near-complete suppression of multiple sclerosis brain lesions over 24 weeks, Phase III study data shows. OCREVUS is a humanised monoclonal antibody designed to target CD20-positive B cells, which are thought to be a key contributor to myelin and axonal (nerve cell) damage, noted Roche. OCREVUS IV is the first and only therapy approved for both RMS and active, or relapsing secondary progressive MS [SPMS], as well as clinically isolated syndrome [CIS] in the US) and PPMS.

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Moderna reveals optimistic data for influenza-COVID-19 vaccine

Strong influenza and COVID-19 immunogenicity compared to approved standalone vaccines has been demonstrated in Moderna's combination vaccine, interim Phase I/II trial data shows.There are several benefits of the combination vaccine as a preventative measure against these respiratory conditions, according to the pharmaceutical company. For example: higher patient compliance, easier administration and greater convenience.

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TECHNOLOGY / NDDS

New technology 'game changing' for pregnant women with diabetes

New research shows that automated insulin delivery technology could be a game changer for pregnant women with type 1 diabetes. The technology -- known as 'hybrid closed-loop technology' -- gives insulin doses as informed by a smartphone algorithm. The new study shows that it could help pregnant women better manager their blood sugars compared to traditional insulin pumps or multiple daily injections.

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Researchers develop DANGER analysis tool for the safer design of gene editing

A team of researchers has developed a software tool that provides a way for the safer design of genome editing in all organisms with a transcriptome. For about a decade, researchers have used the CRISPR technology for genome editing. However, there are some challenges in the use of CRISPR. The new analysis system overcomes these challenges and allows researchers to perform safer on- and off-target assessments without a reference genome.

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UK launches its first national PET imaging platform for drug discovery

The Medicines Discovery Catapult (MDC), the Medical Research Council (MRC) and Innovative UK has announced the launch of the UK's first-of-its-kind total-body National positron emission tomography (PET) Imaging Platform (NPIP). NPIP will bring together research to transform medical research and technology to advance the quality and speed of drug discovery.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

NERA Economic Consulting raises concerns over DHSC's Statutory Scheme

The National Economic Research Associates (NERA) Economic Consulting has raised concerns about the analysis, assumptions and approach taken by the Department of Health and Social Care (DHSC) in its proposed changes to the Statutory Scheme.

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Roche to gain rights to novel antibody for IBD

Roche is set to gain rights to develop, manufacture and commercialise a novel antibody treatment with first-in-class and best-in-disease potential for inflammatory bowel disease (IBD), under a new acquisition agreement. Roche has agreed to acquire Telavant Holdings, Inc. (Telavant), a Roivant company, owned by Roivant Sciences Ltd. and Pfizer Inc for $7.1 billion.

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US FDA denies approval of Alvotech's Stelara biosimilar as manufacturing problems at site

The US FDA on October 12th denied to approve Iceland-based Alvotech's AVT04, which it was proposing as a biosimilar to Johnson & Johnson's Stelara (ustekinumab), marking the fourth regulatory rejection for the company since last year. Alvotech was expected to introduce biosimilars for top-selling immunology medicines, but repeated manufacturing problems at its Reykjavik plant have delayed the launching programme.

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