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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

UK government launches pathway for innovative technologies

The UK government has announced the launch of the Innovative Devices Access Pathway (IDAP) to support the rapid development of innovative technologies. The new pathway aims to address unmet clinical needs for patients and healthcare professionals. First announced in May, the government has launched the pilot phase of IDAP, and innovators are invited to submit expressions of interest for access to the pathway.

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Japan approves Alzheimer's treatment Leqembi by Eisai and Biogen

Japan's Eisai (4523.T) said on Monday its Alzheimer's treatment developed with Biogen (BIIB.O), Leqembi, was approved by the country's health ministry, making it the second nation after the United States to clear its use. It can now be used in Japan as a treatment for slowing progression of mild cognitive impairment and mild dementia due to Alzheimer's disease.

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Parkinson's UK calls on government to mark World Patient Safety Day.

Parkinson's UK has called on the government to take action to help people with Parkinson's disease (PD) get their medication on time in hospital, as part of its relaunched 'Get It On Time' campaign to mark World Patient Safety Day on 17 September. The charity, alongside Diabetes UK, Epilepsy Action, National Aids, Rethink Mental Illness and the Richmond Group, supported by the Royal College of Emergency Medicine and the Royal Pharmaceutical Society, outlined in a joint statement how the government can take action to help patients with PD.

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PHARMA INDIA

Gujarat FDCA attributes 45% of drug samples failing quality tests due to dissolution testing failure

The Gujarat Food and Drug Control Administration (FDCA) has attributed 45% of drug samples failing quality tests due to dissolution testing failure. The state drug regulator collects 15, 000 drug samples annually of which 2% samples fail quality tests related to content, disintegration, dissolution, description, variation in weight and sterility. Out of the failed samples, 45% alone are due to failure in dissolution testing.

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Kerala DCA prepares new guidelines to collect drug samples as the number of DTLs increases

Since the state has four drug testing laboratories and one more in the pipeline, the drug control administration (DCA) in Kerala has prepared new guidelines to drug inspectors for drawing drug samples from industry and retail shops. As per the new guidelines, one drug inspector has to collect 23 samples per month and this will likely increase when the fifth lab becomes operational. Kerala DCA is the only drug regulator in India having this much number of drug testing laboratories and large collection of drug samples.

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SEC recommends permission for phase I trial of Cadila Pharma's VZV vaccine

The Subject Expert Committee (SEC) on vaccines, which reviews proposals and advice the Drugs Controller General (India) (DCGI) in matters for biologicals and post approval change proposals, has recommended to grant permission to Gujarat-based Cadila Pharmaceuticals to conduct phase I clinical trial for its chicken pox vaccine.

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REGULATORY ROUND-UP

Guidance recommending BMS cardiac myosin inhibitor published

The recommendation of Camzyos®(mavacamten) as an add-on treatment option for symptomatic obstructive hypertrophic cardiomyopathy (oHCM) in adults has been published in the National Institute for Health and Care Excellence (NICE)'s final guidance.

Bristol Myers Squibb's first-in-class treatment option is recommended for eligible oHCM patients on the NHS.

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CDSCO says samples labelled as Cipla's and Sun Pharma's drugs failed in July could be spurious

The Central Drugs Standard Control Organization (CDSCO) has declared the samples of Cipla's benign prostatic hyperplasia drug Urimax D it tested in July as spurious drug, and is investigating on Sun Pharma Laboratories' tip off that its bad cholesterol lowering drug Rosuvas 10 tablets failed during the test is spurious.

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DCGI issues alert on Abbott India's antacid Digene gel manufactured in Goa facility

Several FDA warning letters distributed to pharmaceutical manufacturers in 2023 have warned of numerous corrective and preventive action (CAPA) compliance concerns. In this paper, the US FDA highlighted that between 2018 and 2022, the quantity of warning letters issued were highest in the US in 2019 (55) and 2022 (47). Eight FDA warning letters were handed to European companies in 2018. In subsequent years, up to 2022, half this number or less were issued.

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MERGERS / ACQUISITIONS / COLLABORATIONS

Evaxion and Afrigen Biologics to develop mRNA vaccine for gonorrhea

Evaxion has announced that it has entered into a collaboration with Afrigen Biologics to develop an mRNA prophylactic vaccine against gonorrhoea. As part of the agreement, the Cape Town-based biotechnology company will utilise Evaxion's EDEN-discovered gonorrhoea targets. Gonorrhea is a sexually transmitted disease that stems from a bacteria called Neisseria gonorrhoeae and elevates the susceptibility to HIV.

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BeiGene & Nona Biosciences expand collaboration for antibody discovery

BeiGene and Nona Biosciences have announced an agreement to expand their strategic collaboration for antibody discovery. The collaboration will allow BeiGene to utilise Nona's Harbour Mice platform – a fully human transgenic mouse platform – to further improve therapeutic antibody discovery efficiency and flexibility. BeiGene first obtained the rights to use the proprietary Harbor Mice H2L2 platform for multiple antibody programs in 2018 as part of the now expanded collaboration.

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Salipro Biotech & Sumitomo Pharma collaborate for drug discovery

Salipro Biotech and Sumitomo Pharma have entered into a research collaboration to understand the pharmacological characteristics of a compound from Sumitomo's drug discovery programme. Both companies aim to reveal the mechanism of action and pharmacological characterisation of a drug candidate to advance Sumitomo's drug discovery programme by characterising the drug candidate with therapeutic properties against a selected target.

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DRUGS: APPROVALS AND LAUNCHES

FDA approves Pfizer/BioNTech and Moderna's adapted COVID-19 vaccines

The US Food and Drug Administration (FDA) has granted approval for Pfizer/BioNTech and Moderna's updated COVID-19 vaccines, to tackle currently circulating variants. As previously recommended by the FDA, both vaccines have been adapted to closely target the XBB.1.5. Omicron variant by including a monovalent component

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Anti-PD-1 antibody gains EU approval for oesophageal cancer

The European Commission (EC) has approved TEVIMBRA® (tislelizumab) as monotherapy for adults with oesophageal cancer. The humanised IgG4 anti-PD-1 antibody is indicated for unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (ESCC) after prior platinum-based chemotherapy.

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European Commission approves long-acting HIV drug option

The European Commission has authorized Apretude (cabotegravir long-acting (LA) injectable and tablets) for human immunodeficiency virus (HIV) prevention.
Cabotegravir LA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents (at least 12 years of age), weighing at least 35kg.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

NICE nod for Darzalex with lenalidomide and dexamethasone

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced that the National Institute for Health and Care Excellence (NICE) has recommended Darzalex – also known as daratumumab – in combination with lenalidomide and dexamethasone. The therapy concerns previously untreated multiple myeloma (MM) patients and will be available for routine use among adults across the NHS in England and Wales.

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Bristol Myers Squibb's Camzyos gets NICE recommendation

Bristol Myers Squibb (BMS) has announced that the National Institute for Health and Care Excellence (NICE) has published final guidance recommending its Camzyos drug for use across the NHS.
Also known as mavacamten, the therapy is a first-in-class treatment option among adult patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

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Eli Lilly therapeutic shows potential in thyroid cancer.

The first randomised trial comparing efficacy of a highly selective RET-kinase inhibitor with multikinase inhibitors (MKIs) in advanced medullary thyroid cancer (MTC) has delivered promising results. Eli Lilly and Company's highly selective and potent RET kinase inhibitor for advanced medullary thyroid cancer (MTC) has demonstrated superior progression-free survival (PFS) compared to approved multikinase inhibitors.

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TECHNOLOGY / NDDS

Evaxion validates its infectious disease AI vaccine platform

Evaxion Biotech has announced the validation of its artificial intelligence (AI)-powered vaccine discovery platform, Eden, marking a ground-breaking milestone in vaccine discovery.
Evaxion is the first organization to validate an AI model that outcompetes state-of-the-art vaccine development to combat antibiotic resistance.

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MIT's new technique to remotely evaluate cerebral palsy patients

Combining both computer vision and machine-learning techniques, the method analyses videos of patients in real-time and computes a clinical score of motor function based on patterns of poses that it detects in video frames.

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Eisai launches new digital business company for dementia

Eisai has announced that it has launched a digital business company, Theoria technologies, to accelerate the development of a "dementia ecosystem".
The new subsidiary will aim to relieve the anxieties of patients and their families, as well as address the social issues posed by dementia.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

First treatment for myelofibrosis with anemia approved

The first and only treatment for anemic patients with myelofibrosis has been approved by the US Food and Drug Administration (FDA). Ojjaara (momelotinib) is indicated for intermediate or high-risk myelofibrosis, a blood cancer, including primary myelofibrosis or secondary myelofibrosis (post-polycythaemia vera and post-essential thrombocythemia), in adults with anemia.

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FTC order could ease biopharma competition

According to the US Federal Trade Commission (FTC), Amgen is to be barred from leveraging its drug portfolio to disadvantage its industry competitors. The biopharma company will be required to seek prior approval before acquiring related products. The FTC has settled on a proposed consent order with Amgen Inc. to address the potential competitive harm Amgen's $27.8 billion acquisition of Horizon Therapeutics plc could bring.

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California sues organizations for touting abortion pill reversal

California on Thursday sued two anti-abortion organizations for telling patients that they can help reverse the effects of the abortion pill mifepristone, a potentially dangerous claim not supported by evidence. In a complaint filed in Alameda County Superior Court, California Attorney General Rob Bonta, a Democrat, accused Heartbeat International (HBI) and Real Options Obria of violating a state law against fraudulent business practices.

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