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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

Research shows new technique could cut time to detect polio in half

A new Medicines and Healthcare products Regulatory Agency (MHRA)-supported study has revealed that direct molecular detection and nanopore sequencing (DDNS) could significantly reduce the detection time for polio.
Researchers at the Institut National de Recherche Biomédicale in Kinshasa have proved, for the first time, that using DDNS to detect polio outbreaks can reduce detection time and reduce costs for public health authorities.

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Researchers fully sequence the Y chromosome for the first time

The National Human Genome Research Institute (NHGRI), a team of researchers at the National Institute of Standards and Technology (NIST) and many other organizations used advanced sequencing technologies to read out the full DNA sequence of the Y chromosome - a region of the genome that typically drives male reproductive development.

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DNA repair discoveries hold promise for new approaches to cancer treatment

DNA can be damaged by toxins, radiation, or even normal cell division, but human cells must continually fix DNA breaks to survive. In cells that cannot repair DNA effectively, changes (mutations) can occur that lead to cancer.
Most cells rely on a system called homologous recombination or HR, which uses proteins called BRCA1 and BRCA2 for accurate DNA repair.

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PHARMA INDIA

Maharashtra govt booster dose for bulk drugs industry

Maharashtra, the torch -bearer of the Indian pharma industry, is taking a slew of initiatives to propel the pharma and health care sector of the state. This includes the state government initiative to set up a bulk drugs park in Raigad, effective measures taken by Maharashtra Food and Drug Administration (FDA) to streamline the drug administration and also the initiatives taken by the corporate houses in the state to boost pharma exports.

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PharmaTech Expo to showcase futuristic tech trends

The 15th edition of PharmaTech Expo & LabTech Expo provides an opportunity to experience latest and futuristic trends in equipment & technologies as well as allied services. This mega fair dedicated to pharmaceutical innovation, technology and knowledge, has become India's premier business gathering of pharma product manufacturers, suppliers and buyers. It will be taking place from August 25 to 27, 2023 at Helipad Exhibition Center, Sector -17, Gandhinagar, Gujarat.

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India's generic drug prescription mandate faces execution challenges, says Fitch

The Indian government's mandate for physicians to prescribe only generic drug names is facing challenges in execution, according to Fitch Ratings. The report suggests that a significant decline in sales of branded generics will impact the profitability of Indian pharmaceutical companies, as lower prices will outweigh the benefits of reduced marketing costs. However, Fitch believes that the new guidelines are unlikely to result in an immediate shift away from branded generics.

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REGULATORY ROUND-UP

NICE rejection for CSL Behring gene therapy

The National Institute for Health and Care Excellence (NICE) has issued a draft appraisal consultation document, whichdoes not recommend CSL Behring's gene therapy treatment Hemgenix. Also known as etranacogene dezaparvovec, the drug is a treatment option for adults with severe and moderately severe haemophilia B without a history of factor IX inhibitors.

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CHMP to review MAA for geographic atrophy treatment

"This acceptance of our EU Marketing Authorisation Application is a key milestone in our global effort to help patients living with GA, a leading cause of blindness worldwide. We look forward to collaborating with Committee for Medicinal Products for Human Use (CHMP) throughout the review process and hope to make ACP available for patients in Europe," commented Dr Pravin Dugel, President of Iveric Bio, an Astellas company.

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FDA warning letters highlight CAPA concerns

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

EIP Pharma merges with CervoMed

CervoMed – a company focusing on treatments for degenerative brain conditions – has announced that it has finalized its merger with EIP Pharma.

The united company will still be known as CervoMed, and the merged business will concentrate on advancing lead drug candidate neflamapimod. The therapy is an oral stress kinase inhibitor, which is currently being developed for the treatment of dementia with Lewy bodies (DLB) and various other degenerative brain diseases.

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Mahana Therapeutics signs agreement with Consumer Health division of Bayer

Mahana Therapeutics, a leading provider of prescription digital therapeutics, announced today that the company has entered into a multi-million-dollar distribution and marketing partnership with the Consumer Health division of Bayer to commercialize digital therapeutics.

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Astex reveals partnership with MSD

Astex Pharmaceuticals, a company focused on the development of novel small molecule therapeutics for oncology and diseases of the central nervous system, has announced a global collaboration with MSD.

The aim of the partnership is to establish small molecule candidates with activity towards a tumour suppressor protein for treating cancer.

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DRUGS: APPROVALS AND LAUNCHES

Elfabrio receives vital MHRA authorization

Chiesi has announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for Elfabrio across Britain.

Also known as pegunigalsidase alfa, the treatment involves long-term enzyme replacement therapy (ERT) among adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase).Pegunigalsidase alfa is produced in plant cells using recombinant DNA technology and the treatment remains the only PEGylated ERT for Fabry disease.

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FDA approves first oral treatment for postpartum depression

The U.S. Food and Drug Administration approved Zurzuvae (zuranolone), the first oral medication indicated to treat postpartum depression (PPD) in adults. PPD is a major depressive episode that typically occurs after childbirth but can also begin during the later stages of pregnancy.

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Pfizer maternal RSV vaccine approved

The US Food and Drug Administration (FDA) has authorised an RSV vaccine for pregnant individuals, which in one study, reduced the risk of severe LRTD by 81.8 percent within 90 days after birth.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Theriva Biologics reveals positive VCN-01 study results

The study is a multi-location, phase 2b, randomised, open-label clinical trial researching VCN-01 when combined with standard-of-care chemotherapy (gemcitabine/nab-paclitaxel) as a first-line therapy among patients with metastatic pancreatic ductal adenocarcinoma (PDAC). VCN-01 is Theriva's systemic stroma-degrading oncolytic adenovirus and has been awarded orphan drug designations from the US Food and Drug Administration and the European Medicines Agency for treating pancreatic cancer.

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Atai Life delivers results from PCN-101 study

Atai Life Sciences, a company focusing on transforming the treatment of mental health disorders, has announced the results from Perception Neuroscience's intravenous-to-subcutaneous bridging study of its PCN-101 (R-ketamine) candidate.

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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

Scientists develop efficient spray technique for bioactive materials

Rutgers scientists have devised a highly accurate method for creating coatings of biologically active materials for a variety of medical products. Such a technique could pave the way for a new era of transdermal medication, including shot-free vaccinations, the researchers said.

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How artificial intelligence gave a paralyzed woman her voice

Researchers at UC San Francisco and UC Berkeley have developed a brain-computer interface (BCI) that has enabled a woman with severe paralysis from a brainstem stroke to speak through a digital avatar.

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Nanotechnology's triple threat: Advancing precision cancer treatment

In a recent review published in Natures Signal Transduction and Targeted Therapy Journal, a group of authors explored current and future strategies in the design of tumor tissue-, cell-, and organelle-targeted cancer nanomedicines, emphasizing the latest advances in hierarchical targeting technologies to maximize therapeutic efficacy while minimizing off-target toxicity.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Glenmark settles drug pricing case with US Dept. of Justice

US-based Glenmark Pharmaceuticals Inc, a subsidiary of the company, has entered into a three-year deferred prosecution agreement with DOJ involving historical pricing practices by former employees relating to the generic drug pravastatin between 2013 and 2015.

Glenmark
A new way for a new world

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Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy

Sixth and Seventh Companies to Admit to Price-Fixing Charges Affecting Critical Generic Drugs; First Resolutions to Require Divesting Drug Product Lines; Teva USA to Pay $225 Million and Donate $50 Million in Drugs; Glenmark USA to Pay $30 Million

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