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CLINICAL RESEARCH UPDATE

LAMBDA RESEARCH NEWSLETTER

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GLOBAL NEWS

Fertilised chicken eggs could be viable for use in cancer imaging research

Researchers from King's College London (KCL) have identified that fertilised chicken eggs could provide a low-cost opportunity for cancer imaging studies and radiotracer development. Dr Tim Witney, reader in molecular imaging, school of biomedical engineering and imaging sciences, KCL, said: "12 fertilised eggs cost just £45, with zero maintenance costs – a 97% saving compared to standard mouse xenografts."

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Researchers improve blood tests' ability to detect and monitor cancer

The advance makes it easier to detect circulating tumor DNA in blood samples, which could enable earlier cancer diagnosis and help guide treatment. The researchers developed two different types of injectable molecules called as "priming agents," which can transiently interfere with the body's ability to remove circulating tumor DNA from the bloodstream. In a study of mice, these agents could boost DNA levels enough that % of detectable early-stage lung metastases leapt from less than 10 % to above 75 %.

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Smart skin bacteria are able to secrete and produce molecules to treat acne

International research led by the Translational Synthetic Biology Laboratory of the Department of Medicine and Life Sciences (MELIS) at Pompeu Fabra University has succeeded in efficiently engineering Cutibacterium acnes -a type of skin bacterium- to produce and secrete a therapeutic molecule suitable for treating acne symptoms. This finding opens the door to broadening the way for engineering non-tractable bacteria to address skin alterations and other diseases using living therapeutics.

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PHARMA INDIA

Venus Remedies gets coveted GMP certification from Libya

Venus Remedies, a globally recognised pharmaceutical company, has been awarded the Good Manufacturing Practices (GMP) certification for its facilities from the Ministry of Health, Libya. This accomplishment is a testament to the company's commitment to quality, safety and efficiency in the production of injectable pharmaceuticals, including oncology, antibiotic and anticoagulant medications.

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Indian Immunologicals launches India's first indigenously developed hepatitis A vaccine

Indian Immunologicals Ltd (IIL) a wholly owned subsidiary of National Dairy Development Board (NDDB) and a leading biopharmaceutical company, launches India's first indigenously developed hepatitis A vaccine "Havisure". The vaccine represents a significant step forward in India's fight against hepatitis A and is poised to make a substantial contribution to public health.

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Indian Drug Manufacturers' Association organises Pharma Live Expo & Summit

The Pharma Live Expo & Summit, organized by the Indian Drug Manufacturers' Association, ignites the future of the pharma industry. This electrifying event promises three days of inspiration, collaboration, and limitless potential at the Bombay Exhibition Centre, Nesco Mumbai, from January 17th to 19th. The inaugural ceremony of the Pharma Live Expo & Summit shone under the illustrious presence of key industry leaders and dignitaries. The Summit was inaugurated by Dr Arunish Chawla, IAS – Department of Pharmaceuticals, Government of India.

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REGULATORY ROUND-UP

FDA guidance highlights E&L considerations for ophthalmic drug products

In draft guidance on quality considerations for topical ophthalmic drug products, the US Food and Drug Administration (FDA) provided recommendations for E&L testing. This document is revised from a version published in October 2023.

In addition to approaches evaluating E&L, the draft guidance also discussed evaluation of impurities and degradation products.

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Revised ISO guideline highlights toxicological evaluation of extractables and leachables

In the guideline published in 2023, the process and requirements for toxicological risk assessment of medical device constituents is outlined. Also covered in the guideline are "the methods and criteria used to assess whether exposure to a constituent is without appreciable harm". As highlighted by the International Organization for Standardization (ISO), the process described in the standard is relevant to chemical characterisation, such as extractable data or leachable data (E&L), information obtained in line with ISO 10993-18.

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EMA releases major revision of user guide for SMEs in pharma sector

The European Medicines Agency (EMA) has released a major revision of its user guide for micro, small, and medium-sized enterprises (SMEs) in the pharmaceutical sector. The revised user guide offers comprehensive information on the EU legislative framework for medicines, outlining requirements for the development and authorisation of medicines for human and veterinary use.

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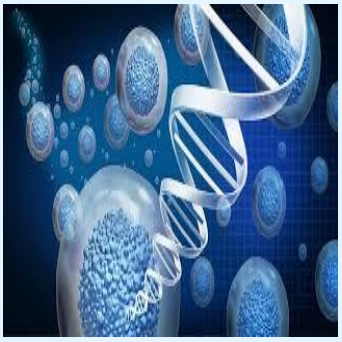
MERGERS / ACQUISITIONS / COLLABORATIONS

Deepcell and NVIDIA collaborate to advance AI in single cell research



Deepcell has entered into a research collaboration with NVIDIA to accelerate the use of generative artificial intelligence (AI) in single cell research for cancer, stem cells and cell therapies.

Both companies aim to advance understandings of cell morphology and advance the use of AI-powered cellular analysis in cell biology and translational research.

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Owkin and Evotec partner to accelerate therapeutics in oncology and I&I

Owkin and Evotec have entered into an artificial intelligence (AI)-powered strategic partnership in oncology, immunology and inflammation (I&I). Both companies will collaborate to accurately select targets, discover and develop new therapeutics.

As part of the agreement, the French-American techbio company, Owkin, will identify indication-relevant targets and subgroups using AI applied to multimodel patient data with its cutting-edge target discovery engine.

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ERS Genomics and StemSight Enter into CRISPR/Cas9 Licensing Agreement

ERS Genomics Limited, a company focused on CRISPR licensing and formed to facilitate broad access to the foundational CRISPR/Cas9 intellectual property co-owned by Dr. Emmanuelle Charpentier, has entered into a non-exclusive CRISPR/Cas9 license agreement with StemSight Oy. StemSight is a biotechnology firm working on developing stem cell-based therapies for corneal blindness.

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DRUGS: APPROVALS AND LAUNCHES

UCB announces MHRA approval for UCB's Zilbrysq

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for Zilbrysq as an add-on to standard therapy. Zilucoplan is the first once-daily subcutaneous, targeted peptide inhibitor of complement component 5 (C5 inhibitor) and the only self-administered gMG therapy for use by adult patients with AChR antibody positive gMG.

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ZILBRYSQ® (zilucoplan) Injection

First European ustekinumab biosimilar to Stelara approved

The European Commission (EC) has granted a marketing authorisation for Uzpruvo® (AVT04) in Europe, a biosimilar candidate to Stelara® (ustekinumab). Ustekinumab is a human IgG1κ monoclonal antibody (mAb).

Uzpruvo is produced in Sp2/0 cells via perfusion, in the same way that the reference product Stelara is. The biologic targets the p40 protein, which has key roles in treating immune-mediated diseases like Crohn's disease, psoriasis as well as psoriatic arthritis, Alvotech highlighted.

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MHRA approves 'safer' medicine alternative for rare disease

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved Agamree® (vamorolone), as a safer alternative to corticosteroids, for Duchenne muscular dystrophy (DMD).
"In addition to its anti-inflammatory efficacy, both the EMA and the MHRA recognise the benefits of treatment with Agamree for bone health and growth," Dr Shabir Hasham, Chief Medical Officer of Santhera Pharmaceuticals shared.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

Study reveals antibiotic use is not the only driver of antibiotic resistance

In the UK and Norway, researchers compared the impact of antibiotic use on the treatment-resistant bacteria Escherichia coli (E. coli) over the last two decades.Results showed that the increase in treatment-resistant bacteria varied depending on the type of broad-spectrum antibiotic used. Specifically, the rate of resistance to a commonly used antibiotic to treat urinary tract infections caused by E. coli ranged from 8.4% to 92.9%, depending on the country.

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First-of-a-kind psoriasis study outcomes revealed

Phase III data for Janssen's innovative IL-23 inhibitor has revealed that the biologic is effective for adults with moderate to severe plaque psoriasis (PsO) across all skin tones.
The topline data from Cohort B of the Phase IIIb VISIBLE study presented at the Maui Derm Hawaii 2024 conference, showed that at Week 16, after three doses of Tremfya, patients achieved significantly greater improvements versus placebo. A nearly 90 percent improvement (87.6 percent compared to 37.8 percent placebo) was observed from baseline in Psoriasis Scalp Severity Index (PSSI) and in Scalp Surface Area (SSA) (86.6 percent versus 33.4 percent for placebo).

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Immunotherapy drug achieves trial-first in fifty years

Results from a Phase III, randomised, placebo-controlled clinical trial for the first time in fifty years, demonstrated an overall survival benefit from an adjuvant therapy in kidney cancer. Pembrolizumab targets a “checkpoint” pathway that is key in enabling cancer cells to avoid being destroyed by the immune system. As a result, the immunotherapy drug supports the immune system's T cells fight tumours, the researchers highlighted.

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TECHNOLOGY / NDDS

Inhalable sensor to make lung cancer screening more accessible worldwide

Engineers from the Massachusetts Institute of Technology (MIT) have designed a diagnostic system to make lung cancer screening more accessible globally. The new technology could replace or supplement low-dose computed tomography (CT), the current gold standard for diagnosing lung cancer. Based on nanosensors, sensors produce signals when detecting cancer-linked proteins in the lungs, which accumulate in the urine, where they can be detected with a simple paper test strip.

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AlcoChange app to help alcohol-related liver disease patients stay sober

University College London (UCL) and the Royal Free Hospital researchers have revealed that their mobile phone app successfully helped patients living with alcohol-related liver disease abstain from alcohol. Alcohol-related liver disease is an increasing global health problem that is estimated to kill three million people worldwide every year.

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New Novo Nordisk AI hub for drug discovery to open in London, UK

Danish pharmaceutical giant Novo Nordisk will be opening an AI-based research facility in the heart of London to advance drug discovery operations. The hub will be situated in the Kings' Cross Knowledge Quarter among world-leading science institutions and companies including AstraZeneca, GSK, the Wellcome Trust, and the Francis Crick Institute.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

Cyclo Therapeutics receives US patent for treatment of Alzheimer's disease

Cyclo Therapeutics, Inc., a clinical stage biotechnology company, announced that the company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) regarding Cyclo Therapeutics' US Patent Application No. 17/289,137 titled, "Methods for Treating Alzheimer's Disease."

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Kane Biotech Files New Patent on revive

Kane Biotech Inc. (TSX-V:KNE OTCQB:KNBIF) (the "Company" or "Kane Biotech" or "Kane") announces that it has filed a patent on its revyve™ Antimicrobial Wound Gel Spray, a follow-on product to its FDA 510(k) cleared revyve™ Antimicrobial Wound Gel, and will be introducing it today at the Boswick Burn and Wound Care Symposium.

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Longeveron gets US patent for technology behind its lead investigation product Lomecel-B

Longeveron Inc., a clinical stage biotechnology company developing cellular therapies for life-threatening and chronic aging-related conditions, announced it has received a notice of patent allowance from the United States Patent and Trademark Office (PTO) for Medicinal Signalling Cells (MSCs), the technology behind its lead investigational product Lomecel-B. The allowance impacts patients with aging-related frailty receiving vaccines for conditions such as Covid and the flu.

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