Lambda Research Newsletter

February 2023

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NEWS letter

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GLOBAL NEWS

1. University of Sydney discovers new protein that hinders Covid-19

Researchers at the University of Sydney in Australia have announced the discovery of a new protein in the lung that can hinder Covid-19 infection.

The leucine-rich repeat-containing protein 15 (LRRC15) also forms a natural protective barrier in the body of human beings.

It is an inbuilt receptor that attaches to the SARS-CoV-2 virus and drags it away from the target cells. This research from the University of Sydney is said to offer a pathway for developing new drugs for preventing infection from coronaviruses such as Covid-19 or dealing with lung fibrosis, where the tissue becomes thickened and scarred.

Source: pharmaceutical-technology.com

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GLOBAL NEWS

2. New antibiotic cures superbugs without bacterial resistance

In a potential game changer for the treatment of superbugs, a new class of antibiotics was developed that cured mice infected with bacteria deemed nearly "untreatable" in humans -- and resistance to the drug was virtually undetectable.

The discovery was serendipitous. The U.S. Army had a pressing need to charge cell phones while in the field -- essential for soldier survival. Because bacteria are miniature power plants, compounds were designed by Bazan's group to harness bacterial energy as a '"microbial"' battery. Later the idea arose to re-purpose these compounds as potential antibiotics.

Source: sciencedaily.com

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GLOBAL NEWS

3. Hope for Parkinson's disease and Lewy body dementia patients

University of Nottingham experts – led by Dr Helen Miranda Knight – have discovered that the modification of ribonucleic acid (RNA) in human brain tissue is disrupted among neurodegenerative diseases. These conditions include Lewy bodies dementia and Parkinson's disease.

Published in Neuropathology and Applied Neurobiology, the research has established modified m6A RNAs as a novel molecular mechanism that is altered in Lewy body disease and which may drive the formation of neurotoxic protein aggregates known as Lewy bodies.

Researchers also used microscopy and machine learning to investigate the spatial location and abundance of modified RNA in human cells in brain regions. In particular, it targeted the functions important for cognitive and memory ability, such as frontal and cingulate cortices.

Source: pharmatimes.com

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GLOBAL NEWS

4. Important milestone for Valneva's chikungunya vaccine

VLA1553 is a single-dose, live-attenuated vaccine candidate targeting the highly dangerous chikungunya virus

Valneva – a company focused on global vaccines – has revealed that the US Food and Drug Administration (FDA) is reviewing its biologics license application for the company's single-shot chikungunya vaccine candidate.

Indeed, it has been decided that the application connected with VLA1553 is sufficiently complete to permit a substantive review, with the review classification established as 'priority'.

Source: pharmatimes.com

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PHARMA INDIA

1. NPPA approves ceiling prices of 128 more scheduled formulations from revised Schedule I of DPCO, 2013

The National Pharmaceutical Pricing Authority (NPPA) has revised the ceiling price of 111 scheduled formulations and fixed the ceiling price of 17 new ones in its latest Authority meeting as part of fixing the prices of the formulations listed in the National List of Essential Medicines (NLEM), 2022, which has been amended as the new Schedule I of the Drugs (Prices Control) Order, 2013 recently.

The Authority meeting, held on January 11, considered the 134 formulations for which the draft calculation sheet of ceiling prices were uploaded in the NPPA website from December 13 to 23, 2022. The drug price regulator has invited comments from the stakeholders within 10 working days on the draft calculation sheets and the period for representations on the formulations uploaded on December 23 ended on January 6, 2023.

Source: pharmabiz.com

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PHARMA INDIA

2. Dr Reddy's to buy US generic products portfolio of Mayne Pharma

Dr Reddy's Laboratories has signed a definitive agreement to buy Australian company Mayne Pharma Group's US generic prescription product portfolio in a deal valued at approximately $105m.

Under the deal, the company will buy the portfolio for around $90m in an upfront cash payment.

It will also make contingent payments of up to $15m towards inventory and credits for certain accrued channel liabilities that will be determined on the closure date.

Source: pharmaceutical-technology.com

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PHARMA INDIA

3. First G20 Health Working Group meeting to commence on January 18 at Thiruvananthapuram, Kerala

The first Health Working Group meeting after India assumed the presidency of the G20 on December 1, 2022, is scheduled to be held from January 18 to 20, 2023 in Thiruvananthapuram, Kerala. India is currently part of the G20 Troika comprising Indonesia, India and Brazil, marking the first time that the troika consists of three developing and emerging economies.

The Health Track of the G20 India Presidency will comprise four Health Working Group (HWG) Meetings and one Health Ministerial Meeting (HMM). The meetings will be held in different locations across the country including Thiruvananthapuram (Kerala), Goa, Hyderabad (Telangana) and Gandhi Nagar (Gujarat), highlighting the Prime Minister Narendra Modi's call to action to showcase India's rich and diverse cultures.

Source: pharmabiz.com

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PHARMA INDIA

4. SEC recommends to waive off Phase IV study on Tocilizumab Injection for GCA

Cipla

The expert committee, that recommends the nation's drug regulator on approval of new drugs and clinical trials among others, has recommended to waive off the condition for conduct of Phase IV study on Tocilizumab Injection, indicated for Giant Cell Arteritis (GCA) imported and marketed by Cipla Ltd, considering it is very rare disease and there is challenge in recruitment of patients.

The company justified its proposal stating that it is facing challenges in recruitment of patients of GCA as it is an extremely rare disease with very low prevalence in India.

"After detailed deliberation,the committee recommended to waive off the condition for conduct of Phase IV study as mentioned in import and marketing permission of the drug considering that Giant Cell Arthritis is very rare disease and there is challenge in recruitment of patients," said the SEC after the meeting.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. WHO report shows more countries eliminate neglected tropical diseases but investments key to sustain progress

World Health Organization

On World Neglected Tropical Disease (NTD) Day (January 30), WHO releases a new progress report, entitled “Global report on neglected tropical diseases 2023” highlighting the progress and challenges in delivering NTD care worldwide, against a backdrop of Covid-19-related disruptions.

The new progress report shows that the number of people requiring NTD interventions fell by 80 million between 2020 and 2021, and eight countries were certified or validated as having eliminated one NTD in 2022 alone. As of December 2022, 47 countries had eliminated at least one NTD and more countries were in the process of achieving this target.

Accomplishments made in 2021-2022 build on a decade of significant progress. In 2021, 25% fewer people required interventions against NTDs than in 2010, and more than one billion people were treated for NTDs each year between 2016 and 2019 through mass treatment interventions

Source: pharmabiz.com

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REGULATORY ROUND-UP

2. US FDA accepts Regeneron's pozelimab BLA for priority review

The US Food and Drug Administration (FDA) has accepted a priority review of the biologics license application (BLA) for Regeneron Pharmaceuticals' pozelimab to treat children and adults with ultra-rare CHAPLE disease.

Currently, there are no approved treatments for CHAPLE, a life-threatening hereditary immune disease caused by an overactivation of the complement system.

The investigational, fully human monoclonal antibody, Pozelimab has been designed to block the complement factor C5 activity.

Source: pharmaceutical-technology.com

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REGULATORY ROUND-UP

3. Other Countries Refused 47 FDA-Approved Drugs in the United States

A recent assessment of FDA-approved drugs between 2017 and 2022 determined that other countries refused to approve or discouraged reimbursement for 47 drugs approved in the United States. In the US, the FDA is the primary regulatory agency for food, medication, and medical devices. Each year the organization approves an average of 38 drugs, accepting only 12% of drugs submitted for clinical testing. Despite low acceptance rates, the organization has been critiqued for inadequate regulation.

Looking at the 206 new drugs approved by the FDA between 2017 and 2020, the study concluded that less than 79% were approved or granted market authorization by another regulatory agency.

Source: pharmanewsintel.com

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REGULATORY ROUND-UP

5. Legalizing Recreational Cannabis May Reduce Some Opioid Distribution

CENTERS FOR DISEASE CONTROL AND PREVENTION

An article published in Health Economics found that legalizing recreational cannabis may reduce the demand for opioids, thus reducing distribution and its potential risks.

According to the CDC, in 2020, the opioid prescription rate was 43.3 prescriptions per 100 individuals, accounting for nearly 1.5 million opioid prescriptions. While this rate is significantly lower than the 81.3 prescriptions per 100 people observed in 2012, it is still considerably high, considering the available pain management options. These prescription rates have contributed to opioid-involved deaths, which make up 75% of all drug overdoses in the United States.

Source: pharmanewsintel.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

1.GenScript ProBio and RVAC partner for Covid-19 vaccine pDNA

GenScript ProBio has announced a strategic collaboration with RVAC Medicines to manufacture GMP-grade plasmid DNA (pDNA) for the latter's RVM-V001, an mRNA Covid-19 vaccine candidate.

Under the agreement, GenScript ProBio will offer GMP plasmid manufacturing service for the RVM-V001 programme.

This collaboration is expected to help expedite the clinical manufacturing of RVM-V001 and future mRNA-based vaccines that target infectious diseases such as Clostriodioides difficile infection (CDI) and Respiratory syncytial virus (RSV).

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Moderna partners with Life Edit for mRNA gene editing therapies

Moderna has entered a strategic research and development partnership with ElevateBio's Life Edit Therapeutics to discover and develop new in-vivo mRNA gene editing therapies.

The collaboration will combine the mRNA platform of Moderna with the gene editing technologies suite, including the base editing capabilities of Life Edit for the development of curative therapies to treat challenging genetic diseases.

Under the deal, both companies will partner on the research and preclinical studies, which will be funded by Moderna.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. AstraZeneca Enters License Agreement with KYM Biosciences for Antibody Drug Conjugate

AstraZeneca and KYM Biosciences Inc. have agreed to a global exclusive license for CMG901, an antibody drug conjugate (ADC) targeting Claudin 18.2, a promising therapeutic target in gastric cancer. AstraZeneca will be responsible for the research, development, manufacture, and commercialization of CMG901 globally. CMG901 is currently in Phase I clinical trials for the treatment of Claudin 18.2-positive solid tumors, including gastric cancer, and has shown early signs of anti-tumor activity.

The agreement includes an upfront payment of $63 million to KYM Biosciences, as well as additional milestone payments of up to $1.1 billion and tiered royalties up to low double digits. The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearances. This agreement strengthens AstraZeneca's pipeline of antibody drug conjugates and supports their ambition to expand treatment options for patients with gastrointestinal cancers.

Source: americanpharmaceuticalreview.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. AbbVie and Capsida Biotherapeutics Expand Strategic Collaboration

AbbVie and Capsida Biotherapeutics Inc. ("Capsida") today announced an expanded strategic collaboration to develop genetic medicines for eye diseases with high unmet need. AbbVie's extensive capabilities will be paired with Capsida's novel adeno-associated virus (AAV) engineering platform and manufacturing capability to identify and advance three programs. The collaboration builds upon the neurodegenerative disease partnership announced in 2021.

"This expanded collaboration with Capsida has the potential to develop transformative therapies for patients with serious eye diseases," said Jonathon Sedgwick, Ph.D., vice president and global head of discovery research, AbbVie. "In pursuing the promise of genetic medicine-based therapeutics, AbbVie continues to expand our capabilities, and we are pleased to have Capsida as a partner."

Source: news.abbvie.com

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DRUGS: APPROVALS AND LAUNCHES

1. FDA grants Fast Track status for Biohaven's taldefgrobep alfa to treat SMA

The US Food and Drug Administration (FDA) has granted Fast Track designation for Biohaven's new anti-myostatin adnectin, taldefgrobep alfa, to treat spinal muscular atrophy (SMA).

The new myostatin-targeting biologic investigational agent has been designed for specific binding to myostatin (GDF-8) to reduce overall levels of myostatin

It also works as a receptor antagonist to block myostatin signalling in skeletal muscles. Taldefgrobep is a complete human anti-myostatin recombinant protein that is developed for lowering free myostatin.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

2. FDA Approves Apellis' Syfovre as First Treatment for Geographic Atrophy

The FDA approved Apellis Pharmaceuticals' Syfovre (pegcetacoplan) as the first treatment for geographic atrophy (GA), a leading cause of blindness.

GA causes areas of the retinal cells to waste away and die in some patients with age-related macular degeneration. The condition affects over five million worldwide and, until now, progressed relentlessly without any treatments to slow the decline in patient's vision.

On average, the lesions caused by the condition begin impacting central vision within 2.5 years.

Source: biospace.com

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DRUGS: APPROVALS AND LAUNCHES

3. UK MHRA approves Takeda's dengue vaccine Qdenga

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for Takeda's dengue virus vaccine candidate, Qdenga (Dengue Tetravalent Vaccine [Live, Attenuated]).

The vaccine candidate has been approved for active immunisation against the infection in people from four years of age.

Qdenga has been developed based on a live-attenuated dengue serotype 2 virus that offers the genetic backbone for four dengue virus serotypes.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

4. CSL's first gene therapy for haemophilia B approved

CSL has revealed that the European Commission (EC) has granted conditional marketing authorisation for HEMGENIX.

It is a treatment for severe and moderately severe haemophilia B (congenital Factor IX deficiency) in adults who have not had a history of Factor IX inhibitors. It also becomes the first approved gene therapy for haemophilia B in the EU and European Economic Area.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Positive results for Ipsen's Cabometyx in combination with nivolumab

Benefits were identified with Cabometyx in combination with nivolumab across all efficacy measures Ipsen has revealed follow-up results from its phase 3 CheckMate-9ER trial. The study demonstrated that Cabometyx in combination with nivolumab provides survival benefits after three-years of treating advanced renal cell carcinoma (RCC), compared to sunitinib.

CABOMETYX® (cabozantinib) tablets 60 mg | 40 mg | 20 mg

During the CheckMate -9ER trial, overall survival benefits were maintained during three-years of follow-up. Meanwhile, median overall survival was significantly higher for patients on Cabometyx (also known as cabozantinib) together with nivolumab versus sunitinib.

IPSEN Innovation for patient care

Accounting for around 90% of cases, RCC is the most common type of kidney cancer. When detected at an early stage, the five-year survival rate is high, but for people living with advanced or late-stage metastatic RCC the survival rate is considerably lower – around 12%.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Sangamo Therapeutics Announces Evidence of Clinical Benefit in Phase 1/2 STAAR Study

Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicine company, today announced updated preliminary data as of the October 20, 2022. These data, which present new biomarker data and results from the first kidney biopsies in this study, indicate evidence of clinical benefit for isaralgagene civaparvovec in Fabry disease.

As of the November 15, 2022 supplemental cutoff date, 13 patients across the dose escalation and expansion phases exhibited supraphysiological levels of α-Gal A activity, sustained for over two years for the patient with the longest follow-up. All five patients who began the dose escalation phase on ERT had been successfully withdrawn from ERT and continued to exhibit supraphysiological levels of α-Gal A activity following withdrawal. No patient has required the resumption of ERT treatment to date.

Source: businesswire.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Merck delivers vital data on evobrutinib

Merck has announced updated four-year safety and efficacy data for its relapsing multiple sclerosis (RMS) therapy, evobrutinib.

The treatment, which is an investigational BTK inhibitor, has demonstrated a sound safety and tolerability profile. In addition, results have been consistent with an earlier double-blind period clinical trials.

Meanwhile, the data also continues to demonstrate the treatment's benefit in reducing annualised relapse rates over the four-year period in subjects with RMS. Data from the ongoing phase 2 open-label extension study of evobrutinib also showed that benefits were maintained, with no new safety signals.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. LEO Pharma Announces Positive Phase 3 Topline Results From DELTA 2 Trial

LEO Pharma A/S, a global leader in medical dermatology, today announced positive results of the DELTA 2 trial. DELTA 2 is the second of two pivotal phase 3 clinical trials with delgocitinib cream, an investigational topical pan-Janus kinase (JAK)-inhibitor, for the potential treatment of adults with moderate to severe chronic hand eczema (CHE).

The trial met its primary endpoint with a statistically significant improvement in CHE after 16 weeks of treatment with delgocitinib cream compared to cream vehicle, and the treatment was well-tolerated. All or most of the signs and symptoms of CHE were cleared early in the treatment period for a significantly larger proportion of patients treated with delgocitinib cream compared to subjects treated with cream vehicle. DELTA 2 is the second phase 3 trial to achieve its primary and all key secondary endpoints, confirming the positive results of the DELTA 1 trial.

Source: globewirenews.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Patent wars: What's behind Amgen's possible win over Sanofi at the US Supreme Court

Amgen could be the winner of a high-stakes patent spat with Sanofi as tensions run high weeks before the March 27 US Supreme Court hearing. While some courts were previously on Sanofi's side, it is possible that Amgen's case could win this time, some legal experts say. However, Sanofi's side also has significant support, highlighting the dispute's contentious nature.

The patent battle between Amgen and Sanofi over their cholesterol-lowering antibodies has divided big pharma in the past months. Not even two weeks ago, the likes of AstraZeneca and Pfizer voiced their support of Sanofi's side through amicus briefs submitted to the Court. But Amgen received support from other players, including AbbVie, at the start of the year.

Source: pharmaceutical-technology.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Global Pharma Healthcare Recalls Artificial Tears Due to Contamination

After the CDC identified bacterial infections, the FDA announced that Global Pharma Healthcare had voluntarily recalled its artificial tears due to contamination by Pseudomonas aeruginosa.

According to the CDC, most of the patient population was linked to four clusters of healthcare facilities. Patient infections were identified between May 2022 and January 2023 through various testing methods, including but not limited to blood tests, urine tests, and phlegm cultures. The testing identified a dangerous and rare version of Pseudomonas aeruginosa, VIM-GES-CRPA, a drug-resistant bacteria.

Source: pharmanewsintel.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. CDC Analyzes Sleep Medication Usage by Adults in the United States

In a study by the National Center for Health Statistics, the CDC analyzes sleep medication use by adults in the US, noting that 18.4% have used sleep medication in the past 30 days.

The study collected data in 2020 to make conclusions about adults' general use of sleep medication across the US. Additionally, the researchers looked at usage and differences across different socio-demographic characteristics.

According to the article, sleep medications treat insomnia and other sleep-related conditions. Sufficient and quality sleep is critical for physical and mental health. Insufficient sleep is correlated with many conditions, including but not limited to heart disease, diabetes, obesity, multiple sclerosis, depression, and more. Despite many varying theories surrounding sleep, the consensus by healthcare professionals is that sleep is a vital health factor.

Source: pharmaceutical-technology.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Reckitt Recalls Plant-Based Infant Formula Due to Health Risk

Reckitt recalled two select batches of Enfamil 12.9 oz ProSobee Simply Plant-Based Infant Formula due to potential health risks caused by bacterial contamination.

According to the company's recall notice, the infant formula has yet to cause any adverse reactions; however, out of caution, the company is voluntarily recalling two batches of its plant-based formula.

In the recall notice, Reckitt revealed that batches ZL2HZF and ZL2HZZ of the infant formula might have been cross-contaminated with Cronobacter sakazakii, an opportunistic pathogen that can survive in arid environments.

Source: pharmanewsintel.com

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TECHNOLOGY /NDDS

1. Long-Acting Injectable Antiretroviral Therapy Suppresses HIV

A study supported by the NIH concluded that long-acting injectable antiretroviral therapy effectively suppresses HIV in communities that have previously not had access to HIV treatments.

According to the NIH press release, Monica Gandhi, MD, MPH, professor of medicine and associate division chief at the University of California, San Francisco, and medical director of the Ward 86 HIV clinic at San Francisco General Hospital, and her team recruited over 200 participants who are part of historically underserved communities in San Francisco.

Over half of the participant population (58%) reported having unstable housing, with an additional 8% reporting homelessness. Beyond housing insecurity, 38% of patients had a mental illness, and 33% reported substance use.

Source: pharmanewsintel.com

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TECHNOLOGY /NDDS

2. Bio-Rad's New StarBright Blue and Yellow Dyes Enhance Multiplex Flow Cytometry

Bio-Rad Laboratories introduced its new StarBright Blue and StarBright Yellow dyes in February 2023. The dyes are designed to promote flexibility in conventional and full spectrum flow cytometry applications. Dyes in the Starbright series are conjugated to flow validated antibodies, supporting flow cytometry panel design in immunology design.

The two new variations in the Starbright series are intended to expand research capabilities across blue (488 nanometers) and yellow (561 nanometers) lasers. According to a Feb. 13, 2023 press release, the new dyes offer exceptional brightness in conjunction with narrow excitation and emission profiles, allowing for precise resolution.

Source: pharmtech.com

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TECHNOLOGY /NDDS

3. CN Bio launches single-organ higher throughput system PhysioMimix

CN Bio – a company that focuses on microphysiological systems (MPS) – has announced the commercial launch of PhysioMimix.

The technology is the company's single-organ higher throughput (HT) system and has been created to overcome adoption obstacles which are currently reducing the use of predictive human liver models within drug discovery.

It can also be incorporated in earlier stages where larger-scale comparative studies are concerned with investigating the disposition, efficacy or safety of candidate drugs.

Source: pharmatimes.com

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TECHNOLOGY /NDDS

4. Thermo Fisher Scientific Collaborates to Introduce Fully Automated Cell Line Automation Platform

Thermo Fisher Scientific and Celltrio announced on Feb. 6, 2022 their collaboration to bring a fully automated cell culture system to biotherapeutics customers. The collaboration will integrate the Thermo Scientific Momentum workflow scheduling software with the Celltrio RoboCell cell line automation platform to address the critical unmet market need for high-throughput automated cell line culturing and maintenance.

Thermo Fisher will also immediately take on exclusive responsibility for sales, installation, and support of the RoboCell system in Europe. Celltrio's RoboCell systems distributed in Europe will now use Momentum software for work scheduling and date management.

Source: pharmtech.com

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