Lambda Research Newsletter

March 2023

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NEWS letter

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GLOBAL NEWS

1. First mixed race woman potentially cured of HIV

A female patient, who had leukaemia and HIV has been potentially cured by a stem cell transplant from cord blood, scientists say.

Using stem cells from cord blood rather than compatible adult donors, as has been done previously, increases the potential to cure HIV via stem cell transplantation in people of all racial backgrounds.

Preliminary details on the case study were presented in February 2022 at the 29th annual Conference on Retroviruses and Opportunistic Infections. The researchers have now shared the full results in the journal Cell.

Source: europeanpharmaceuticalreview.com

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GLOBAL NEWS

2. Scientists develop novel approach to enhance drug delivery for brain tumors in children

Mount Sinai Health System and Memorial Sloan Kettering Cancer Center researchers have developed a new drug delivery approach that uses nanoparticles to enable more effective and targeted delivery of anti-cancer drugs to treat brain tumors in children.

The technology allows for the enhanced delivery of anti-cancer drugs to the specific locations of brain tumors while sparing normal brain regions.

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. Researchers unraveled new mechanisms behind articular cartilage healing after injury

Understanding how the knee joint environment affects cartilage cells is crucial for joint health. Knowledge of cell-driven cartilage degeneration mechanisms can support the development of effective pharmaceutical interventions for osteoarthritis.

These models could also open new avenues for model-guided pharmaceutical research aiming to mitigate osteoarthritis progression. This model considers different forms of cell death, oxidative stress, and pro-inflammatory biomolecules. As in previous biological experiments, the model predicted that injurious loading causes aggressive cell damage and cartilage degeneration near cartilage lesions, whereas inflammation induces widespread degeneration also in the intact regions.

Source: sciencedaily.com

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PHARMA INDIA

1. Fortis Healthcare MD & CEO Dr Ashutosh Raghuvanshi appointed as new president of Nathealth

Nathealth (Healthcare Federation of India), the apex body representing the ecosystem of the Indian healthcare industry, has announced the appointment of Dr Ashutosh Raghuvanshi, managing director and CEO of Fortis Healthcare Ltd as its new president.

He takes charge from Dr. Shravan Subramanyam, erstwhile president of Nathealth during FY 2022-23. The announcement was made in the Annual General Meeting after the 9th Nathealth Annual Summit 2023, held last week.

Source: pharmabiz.com

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PHARMA INDIA

2. Merck India conducts student engagement programme in Bengaluru to attract right talent into workforce

To attract the right talent into the workforce, drug maker Merck India has been continually partnering with industries and academia – for training, skill development and research. The drugmaker's university relations team has recently held its first-ever student engagement programme at New Horizons Engineering College in Bengaluru to understand their expectations from their future workforce.

The event was organised by Merck IT Centre (MITC) in partnership with the company's university relations team on March 17. With a strong background of academic advancement and being at the forefront, Merck is strengthening ties with educational institutions to expand the industry.

Source: pharmabiz.com

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PHARMA INDIA

3. Thalassemics India celebrates 35 years of service in thalassemia

Thalassemics India, the first NGO for thalassemia established in 1987 in India, recently celebrated its 35th anniversary at Le Meridian, New Delhi. The event witnessed a historic journey of Thalassemics India gracing the theme “LAKSH” highlighting the mission of “Sampoorn Chikitsa" and “Thalassemia Mukt Bharat”.

The event was graced to award doctors, patient achievers and caregivers who have worked tirelessly in the field of thalassemia across the country recognizing them for their achievements.

Source: pharmabiz.com

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PHARMA INDIA

4. Indian healthcare providers and pharma companies speed up to combat TB as drug resistance concerns emerge

Indian healthcare providers and pharma companies pace up their efforts with early detection and research for new medicines to combat the spread of tuberculosis as drug resistance concerns emerge.

TB is a significant public health threat, with an estimated 10 million annual cases. India shares the highest TB burden with 2.69 million cases and 4.5 lakh fatalities every year.

On the occasion of the World TB Day observed annually on March 24, this year's theme is 'Put a Full Stop on TB'. Medical experts and pharma industry see the need to research for new drugs and accurate point-of-care diagnostics.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. ICMR releases draft consensus document for management of urinary bladder cancer

The Indian Council of Medical Research (ICMR) has released the draft consensus document for management of urinary bladder cancer.

This draft consensus document has been formulated by ICMR's expert group and is available on website for seeking comments from a wider section of the scientific community for a period of 4 weeks from March 17, 2023 to April 14, 2023.

INDIAN COUNCIL OF MEDICAL RESEARCH
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This consensus document represents the current thinking of experts on the topic based on available evidence. This document has been developed by national experts in the field and does not in any way bind a clinician to follow this guideline verbatim. One can use an alternative mode of therapy on the basis of discussions with the patient and institution and national or international guidelines. The mention of pharmaceutical drugs for therapy does not constitute endorsement or recommendation for use but serves as a guide for clinicians in complex decision-making processes

Source: pharmabiz.com

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REGULATORY ROUND-UP

2. MHRA revamps UK clinical trial regulation with the promise of faster timelines

The MHRA introduces new changes to UK clinical trial regulation in hopes of recovering the UK's clinical research space.

The MHRA hopes this new framework "will remove obstacles to innovation" and "streamline the regulation of clinical trials" amongst other things. These changes come following a public consultation with the Healthcare Research Authority, to which a government response was published on March 21.

Source: pharmaceutical-technology.com

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REGULATORY ROUND-UP

3. FDA Requires Anaphylaxis Warning for All Allergenic Extracts

In a recent safety communication, the FDA announced that it would require an anaphylaxis warning for all allergenic extracts used to diagnose food allergies.

According to the safety communication, all manufacturers will be required to include the following warning on their Prescribing Information label under an “Anaphylaxis Following False Negative Food Allergen Skin Test Results” heading:

“False negative skin test results associated with anaphylaxis from subsequent exposure to the allergen have been reported during postmarketing diagnostic use of some food allergenic extracts. Based on the patient’s clinical history and the index of suspicion, healthcare providers should consider confirming negative skin testing with serologic testing by measuring specific serum IgE or with a medically-supervised oral food challenge.”

Source: pharmanewsintel.com

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REGULATORY ROUND-UP

4. FDA issues continuous manufacturing advice to build an agile pharma industry

The FDA issued the International Council for Harmonisation (ICH) final guidance on the use of continuous manufacturing in drug production. This publication marks the FDA's proactive steps to ease the pharmaceutical's industry transition to these advanced processes, states the announcement.

While not binding, the document covers the regulatory and scientific considerations needed for the development and implementation of continuous manufacturing in pharma, and the guidelines are meant for both new and pre-existing products.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Jacobio enters clinical collaboration with Merck to evaluate CD73 monoclonal antibody

Jacobio Pharma announced it has entered into a clinical collaboration with Merck & Co., Inc., Rahway, New Jersey, USA to evaluate the combination of Jacobio's CD73 monoclonal antibody JAB-BX102 in combination with Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy, Keytruda (pembrolizumab).

The clinical study will evaluate the clinical effect of JAB-BX102 in combination with Keytruda for the treatment of advanced solid tumours. Under the terms of the agreement, Merck & Co., Inc., Rahway, NJ, USA will provide Keytruda.

"The CD73 monoclonal antibody is Jacobio's first large molecule project to enter the clinic. CD73 is an important target in the tumour immune pathway. We believe the combination of CD73 and anti-PD-1, an inhibitor on the same tumour immune pathway, can potentially relieve immunosuppression in the tumour microenvironment, stimulate the proliferation and activation of killer immune cells, enhance tumour immunity," said Dr. WANG Yinxiang, chairman and CEO at Jacobio. "We look forward to exploring the potential benefit of CD73 in combination with an anti-PD-1 in tumour immunotherapy through this collaboration with Merck & Co., Inc., Rahway, NJ, USA and potentially giving patients new treatment options."

Source: pharmabiz.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. InvisiShield and Gladstone partner to develop intranasal preventatives

Pre-clinical-stage biotechnology firm InvisiShield Technologies has partnered with Gladstone Institutes to develop intranasal preventatives against airborne viral infections including influenza, respiratory syncytial virus (RSV) and SARS-CoV-2.

Under the partnership terms, InvisiShield will offer technical support, as well as funding to develop the intranasal preventatives.

Scientists at Gladstone Institutes will be responsible for carrying out preclinical studies to assess the efficacy and safety of the product. Tests of live virus can take place in its advanced Biosafety Level 3 (BSL-3) facility.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. California Partners with Civica to Make Affordable Insulin Available

Governor Gavin Newson announced that CalRx, a program through the California Department of Healthcare Services, is partnering with Civica to make affordable insulin available state-wide.

Under this new partnership, California can offer insulin vials for $30 for 10 mL. Five packs of 3 mL pre-filled insulin pens should also be offered at roughly $55. These are approximately 10% of the initial prices of vials and pre-filled pens, usually $300 and $500, respectively.

Source: pharmanewsintel.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Pfizer signs agreement to acquire Seagen for $43bn

Pfizer has entered a definitive merger agreement to purchase biotechnology firm Seagen in a deal valued at $43bn. Under the deal, the company would pay $229 per Seagen share in cash.

Both companies' boards of directors have unanimously approved the transaction. The company's portfolio includes four approved medicines, including three ADCs, Adcetris (brentuximab vedotin), Padcev (enfortumab vedotin), and Tivdak (tisotumab vedotin).

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. US FDA approves Novartis' Tafinlar and Mekinist combination therapy

The US Food and Drug Administration (FDA) has granted approval for Novartis' combination therapy, Tafinlar (dabrafenib) and Mekinist (trametinib), to treat BRAF V600E low-grade glioma (LGG) in paediatric patients as young as one year.

The liquid formulations of Tafinlar and Mekinist also received approval for ease of administration across several approved indications.

This marks the first time a BRAF/MEK inhibitor has been developed in a formulation that is suitable for these patients as young as one year.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

2. First mild asthma combination reliever approved in UK

The Medicines and Healthcare products Regulatory Agency (MHRA) has approved the first dual-combination, inhaled corticosteroid and long-acting beta2-agonist reliever therapy for mild asthma.

The marketing authorisation has been given to budesonide/formoterol (Symbicort Turbohaler 200/6) as a reliever therapy for patients over 12 years old.

The combination therapy, delivered as a formulation in a single inhaler contains budesonide, an inhaled corticosteroid (ICS) and formoterol, a long-acting beta2-agonist bronchodilator (LABA).

Source: europeanpharmaceuticalreview.com

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DRUGS: APPROVALS AND LAUNCHES

3. US FDA approves Acadia Pharmaceuticals' Rett syndrome therapy

The US Food and Drug Administration (FDA) has granted approval for Acadia Pharmaceuticals' Daybue (trofinetide) to treat Rett syndrome in adult and paediatric patients aged two years and above.

Trofinetide is a synthetic version of the tripeptide glycine-proline-glutamate (GPE) naturally occurring molecule.
It increased the branching of dendrites and synaptic plasticity signals in animal trials.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

4. MHRA approves prostate cancer combination therapy

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for Lynparza (olaparib) as combination therapy with abiraterone and prednisone or prednisolone.

AstraZeneca and MSD's treatment is indicated for adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.

Olaparib is the first poly (ADP-ribose) polymerase (PARP) inhibitor to demonstrate clinical benefit in combination with a new hormonal agent in first-line mCRPC.

Source: europeanpharmaceuticalreview.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Astellas presents positive results from phase 3 GLOW trial of zolbetuximab plus Capox

Astellas Pharma Inc. presents detailed results from the phase 3 GLOW trial evaluating first-line treatment with zolbetuximab, an investigational first-in-class Claudin 18.2 (CLDN18.2) targeted monoclonal antibody, plus Capox.

In the study, investigational treatment zolbetuximab plus Capox demonstrated a statistically significant improvement in progression-free survival (PFS) compared to placebo plus Capox. Specifically, zolbetuximab plus Capox reduced the risk of progression or death by 31.3% (n=507; hazard ratio [HR]=0.687; [95% confidence interval [CI]: (0.544-0.866)]; p=0.0007) compared to placebo plus Capox, meeting GLOW's primary endpoint. Median PFS was 8.21 months (95% CI: 7.46–8.84) in the treatment arm and 6.80 months (95% CI: 6.14–8.08) in the placebo arm.

The study also showed that zolbetuximab plus Capox significantly prolonged overall survival (OS), a key secondary endpoint, reducing the risk of death by 22.9% (HR=0.771; 95% CI: 0.615-0.965; p=0.0118). Median OS was 14.39 months (95% CI: 12.29-16.49) and 12.16 months (95% CI: 10.28-13.67) for the treatment arm and placebo arm, respectively.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Phase 1 Clinical Trial Achieves Leukemia Remission in 18 Patient

In a study published in Nature on March 15, 2023, researchers achieved complete or nearly complete remission in 18 patients with KMT2A-rearranged or NPMI-mutant leukemia. The phase 1 clinical trial recruited 68 patients and dosed them with revumenib (SNDX-5613), an inhibitor of the menin-KM2A interaction.

KMT2A, also called lysine methyltransferase 2A, and NPM1, also called nucleophosmin 1, are critical genetic components linked to leukemia. According to the Nature study, 80% of acute lymphoblastic leukemia (ALL) cases are associated with a rearrangement of KMT2A. Beyond that, up to 15% of all acute leukemias exhibit this rearrangement. The five-year survival rate of leukemia with KMT2A is less than 25%.

Source: pharmanewsintel.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Agenus' Botensilimab in Combination with Balstilimab Shows 33% Durable Responses in Ovarian Cancer

Agenus Inc., an immuno-oncology company announced results from a cohort of 24 evaluable patients in an expansion of the Company's Phase 1b study of botensilimab (multifunctional CTLA-4 antibody) in combination with balstilimab (PD-1 antibody) in patients with recurrent platinum resistant/refractory ovarian cancer. These findings, presented in an oral plenary session at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting on Women's Cancer, showed a 33% overall response rate (ORR).

"These results add to the growing body of data showing deep and durable efficacy signals for botensilimab across nine cold and treatment-resistant cancers," said Steven O'Day, M.D., Chief Medical Officer of Agenus. "Botensilimab is designed with a unique mechanism of action that stimulates both innate and adaptive immune responses against cancer, resulting in an improved benefit compared to what has been reported for other checkpoint therapies."

Source: biospace.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Novartis releases long-term data for SMA gene therapy

Data from LT-001, Novartis' ongoing 15-year long-term follow-up (LTFU) study of one-time gene therapy Zolgensma® (onasemnogene abeparvovec), revealed significant milestone achievements for spinal muscular atrophy (SMA) patients. The latest data from two LTFU studies LT-001 and LT-002 was presented at the 2023 MDA Clinical & Scientific Conference. Highlights included:

Sustained durability up to 7.5 years post-dosing; 100 percent achievement of all assessed milestones in children treated prior to SMA symptom onset

Children in LT-001 treated after SMA symptom onset maintained or achieved additional milestones up to 7.5 years post one-time intravenous (IV) infusion

All children (100 percent) in the pre-symptomatic intravenous cohort of LT-002 maintained or achieved all assessed motor milestones, including independent walking

Additionally, children with SMA Type 2 treated with investigational intrathecal OAV101 maintained or achieved new development gains.

NOVARTIS

Source: europeanpharmaceuticalreview.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Sequana Medical's DSR programme receives additional patents from China & United States

Sequana Medical NV, a pioneer in the treatment of fluid overload in liver disease, heart failure and cancer, announces further strengthening of the intellectual property portfolio for its DSR (Direct Sodium Removal) programme. A key composition of matter patent was allowed in China and an additional patent on the method of operation was granted in the US.

sequanamedical

Chinese patent application number 201880045801.6 was allowed on 7 March 2023. This key patent entitled "Direct sodium removal method, solution and apparatus to reduce fluid overload in heart failure patients" has already been granted in the US and Europe and is pending in other regions such as Australia, Canada and Japan. It protects the use of a sodium-free or low-sodium infusate that is administered into a patient's peritoneal cavity to directly remove sodium, and thereby fluid from the body to alleviate fluid overload in heart failure patients with residual renal function.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Evofem Biosciences Announces FDA Orange Book Listing of Two Additional U.S. Patents for Phexxi

Evofem Biosciences, Inc. today announced that two additional U.S. patents which cover Phexxi® (lactic acid, citric acid and potassium bitartrate) and its labeled indication are now listed in the U.S. Food and Drug Administration (FDA) publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

"The Orange Book listing of these two patents covering Phexxi's composition of matter and its method of use in contraception is an important step in further strengthening our patent portfolio," said Evofem Biosciences CEO Saundra Pelletier. "We plan to further expand our intellectual property estate in the U.S. and overseas as we continue to iterate our vaginal pH modulator platform and seek entry into global markets."

Source: prnewswire.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Patent office refuses review petition of Sun Pharma for its anti-dengue botanical drug

The Indian Patent Office has upheld its earlier decision refusing patent rights to Sun Pharmaceuticals for its botanical drug to treat dengue following a review petition, as the company representatives neither attended nor filed submissions against the hearing notice issued by the authority.

The patent application, initially filed by Ranbaxy Laboratories and took over by its acquirer Sun Pharmaceutical, was to seek exclusive rights for its invention related to anti-dengue activity of Cissampelos pereira extracts, which is also known as Velvet Leaf and Patha in Hindi, and an ayurvedic medicinal plant used traditionally for the treatment of irregular heartbeat, acute diarrhoea, cancer and irritable bowel syndrome among others.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Combined Therapeutics' mRNA vaccine platform receives US patent

Combined Therapeutics Inc. (CTx), a privately held biotechnology company, announced its intellectual property position reinforcement in mRNA vaccine technology with the issue of US Patent 11,596,685 by the United States Patent and Trademark Office (USPTO) on March 7, 2023.

This patent recognizes significant innovative research and development advances by Combined Therapeutics in the mRNA vaccine field and covers its vaccine compositions which include its proprietary mRNA MOPCTx (Multi-Organ Protection) technology to deliver viral or bacterial antigens in combination with a panel of molecular adjuvants. These mRNA-expressed antigens and adjuvants together are formulated in a delivery vehicle and can be used to develop both preventive as well as therapeutic vaccines against serious infectious diseases and cancer.

Source: pharmabiz.com

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TECHNOLOGY /NDDS

1. New data show remote monitoring technology like Abbott's CardioMEMS HF System helps improve survival in heart failure patients

Abbott announced new data that found monitoring patients remotely with hemodynamic pressure sensing technology, such as with its CardioMEMS HF System, can significantly improve survival in heart failure patients with reduced ejection fraction (HFrEF). The analysis is the first to give doctors specific insight into how remotely monitoring patients with technology like CardioMEMS can provide an early warning against worsening heart failure and significantly reduce mortality risk by 25% at two years in HFrEF patients.

The meta-analysis of three randomized, controlled trials (CHAMPION, GUIDE-HF and LAPTOP-HF) was presented at the Technology and Heart Failure Therapeutics (THT) Conference in Boston, Mass. (March 20-22, 2023). The data reinforce that – in addition to providing an early warning system against worsening heart failure – remote monitoring technology like CardioMEMS can help doctors more proactively make changes to a patient's treatment plan before the disease advances, often resulting in repeat hospitalizations. A patient's risk of mortality significantly rises with each heart failure-related hospitalization, making it critical that treatment plans aim to manage the disease and keep patients out of the hospital.

Source: pharmabiz.com

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TECHNOLOGY /NDDS

2. Vertex to use ImmunoGen technology to discover conditioning agents

ImmunoGen has announced an agreement granting rights to Vertex Pharmaceuticals to carry out research using antibody-drug conjugate (ADC) technology for the discovery of new targeted conditioning agents.

After completion of the research period for each target, Vertex can obtain a global and exclusive license for their research, development, and commercialisation employing the technology for that target.

Vertex is also responsible for the related costs.

Exclusive rights to the technology will remain with ImmunoGen for all targets not covered by the Vertex licence.

Source: pharmaceutical-technology.com

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TECHNOLOGY /NDDS

3. New Nature Study Analyzes Temperature-Stable Tuberculosis Vaccine

A new study published in Nature on March 6, 2023, analyzed the safety and immunogenicity of a temperature-stable tuberculosis vaccine.

According to the NIH, the study — posted on March 6, 2023 — is based on phase 1 clinical trial results.

The trial, supported by the National Institute of Allergy and Infectious Diseases (NIAID), recruited 48 patients who met exclusionary criteria for six months. Although 93 participants were screened, many patients were excluded from the study due to concurrent medical conditions, poor health, and abnormal lab results.

Source: pharmanewsintel.com

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TECHNOLOGY /NDDS

4. New InnoGenomics Technology Revolutionizes DNA Testing of Sexual Assault Samples

Addressing a long-term shortcoming in DNA evidence for rape and sexual assault cases, New Orleans-based InnoGenomics has developed a nanotech method, SpermX™ that drastically increases usable results to solve more crimes.

The novel nanotechnology-derived polymer outperforms conventional methods, capturing male DNA from as few as 25 sperm cells while minimizing DNA contribution from the victim. The method can also be automated for labs with larger caseloads.

Source: biospace.com

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