veeda clinical research

The Veeda Newsletter

NOVEMBER 2023: ISSUE 11

Veeda's Mehsana Clinical Research Unit (CRU)

Partners in Creating

a healthier tomorrow

Veeda News

Latest news from event visits and implementation of a Smart Document Management System

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Indian Pharma

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VEEDA NEWS

Glimpse of our team who attended the 16th EBF Open Symposium in Barcelona

Veeda experts attended the 16th EBF Open Symposium in Barcelona from November 14th to 17th, 2023.

Know More!

Glimpse of the implementation of a Smart Document Management System for protocol generation

We understand the importance of creating high-quality protocols that meet regulatory and ethical requirements while also simultaneously meeting the specific expectations of our sponsors and investigators from the outset.

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Glimpse of our team who attended the BIO-Europe 2023

Our experts navigated various (Bio)pharma companies to discover our integrated approach and expertise at every stage of development.

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FDA Approves First Therapy for Rare Type of Non-Cancerous Tumors

The U.S. Food and Drug Administration approved Ogsiveo (nirogacestat) tablets for adult patients with progressing desmoid tumors who require systemic treatment. Ogsiveo is the first drug to be approved for the treatment of patients with desmoid tumors, a rare subtype of soft tissue sarcomas. Desmoid tumors are non-cancerous but can be locally aggressive.

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UK MHRA issues safety advice on specific batches of carbomer-containing lubricating eye gels branded Aacarb, Aacomer & Puroptics

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has issued precautionary safety advice regarding possible contamination of certain eye gels and has told patients and users of the affected products to stop using them immediately. They should return their product to the place of purchase. Anyone feeling unwell, for example with symptoms of eye infection, such as reduced vision, red and painful eye, should contact a healthcare professional and tell them that they have been using a recalled eye gel.

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FDA Clears First COVID-19 Home Antigen Test

The U.S. Food and Drug Administration cleared for marketing the first over-the-counter (OTC) antigen test for COVID-19. ACON Laboratories' Flowflex COVID-19 Antigen Home Test, originally authorized for emergency use in 2021, is now the second home COVID-19 test to successfully complete a traditional FDA premarket review pathway, and the first indicated for use in children under 18. Today's announcement follows clearance of a molecular home test earlier this year.

FDA U.S. FOOD & DRUG ADMINISTRATION

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CDC and FDA Expedite the Availability of Additional Doses of New RSV Immunization for Infants

CDC announced the release of more than 77,000 additional doses of Beyfortus™ (nirsevimab-alip (100 mg), a long-acting monoclonal antibody designed to protect infants against severe respiratory syncytial virus (RSV) disease. These additional doses will be distributed immediately to physicians and hospitals through the Vaccines for Children Program and commercial channels – improving the availability of nirsevimab-alip for parents seeking to protect their eligible children, particularly those at highest risk of severe illness.

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Global measles threat continues to grow as another year passes with millions of children unvaccinated

Following years of declines in measles vaccination coverage, measles cases in 2022 have increased by 18%, and deaths have increased by 43% globally (compared to 2021). This takes the estimated number of measles cases to 9 million and deaths to 136,000 – mostly among children – according to a new report from the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC).

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NPPA notifies retail price for 33 new drugs, special prices for injections

The National Pharmaceutical Pricing Authority (NPPA) has notified the retail price of 33 new drugs based on applications filed by the pharma companies including Sun Pharmaceuticals, Zydus Healthcare, Cipla, Torrent Pharmaceuticals, J B Chemicals and Pharmaceuticals, Sanofi India, among others.The NPPA, based on the 118th Authority meeting held on November 8, 2023, under the chairmanship of Kamlesh Kumar Pant, chairman of NPPA, has also notified the extension of special ceiling prices applicable for the IV fluid injection formulations in non-glass packaging with special features for different dosage forms of products from Biosynergy Lifecare Pvt Ltd, and IV fluid sodium chloride 0.9% 100 ml of Puerto Life Science Pvt Ltd.

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NPPA fixes ceiling price of nine scheduled formulations including a brain cancer drug

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price of nine more formulations, taking the total number of formulations notified with revised prices under the National List of Medicines (NLEM), 2022-based revised Schedule I of the Drugs (Prices Control) Order (DPCO), 2013 to 700.The Authority, in its latest meeting, decided to apply monopoly provisions under the DPCO, 2013 while fixing the prices of brain cancer drug formulations temozolomide 20 mg and 250 mg, with around 27.8 per cent and 21.15 per cent price cut, respectively.

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Rusan Pharma opens new API facility in Pithampur with Rs 300 crore investment

Rusan Pharma, the Mumbai-based drug maker that specialises in de-addiction and pain management products, said it has launched a new active pharmaceutical ingredient (API) facility in Pithampur, Special Economic Zone (SEZ), Madhya Pradesh. Rusan said the total investment over two phases on setting up of the factory will be upto Rs 300 crores.

Rūsan
A TECHNOLOGY DRIVEN ENTERPRISE

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Cipla stocks slump 8% after US FDA warning letter

Pharmaceutical giant Cipla on Thursday reassured stakeholders that there was no significant risk to its existing commercial product portfolio after it received a warning letter from the United States Food and Drug Administration (US FDA) following a routine Good Manufacturing Practices (GMP) inspection.The company said it is actively implementing a de-risking plan for new products while addressing the observed concerns.

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NPPA revises prices of 438 formulations to rectify anomaly in calculating revised prices based on WPI

The National Pharmaceutical Pricing Authority (NPPA) has notified revised ceiling price of 438 scheduled formulations in order to rectify an anomaly that took place while calculating the revised prices based on the Wholesale Price Index (WPI) increase of 12.1218 per cent.The prices of these scheduled formulations have been increased by 0.01 per unit. The ceiling prices for the scheduled formulations are revised with effect from April 1, 2023, said the notification.It has also notified the revised price for Bare Metal Stents also, with a marginal price increase of 0.01 paise, in tune with the decision.

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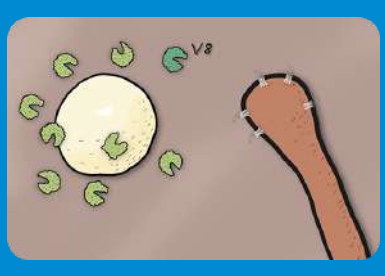
CLINICAL RESEARCH

Researchers find new clues into the head-scratching mystery of itch

Scientists at Harvard Medical School have shown for the first time that a common skin bacterium — Staphylococcus aureus — can cause itch by acting directly on nerve cells.The findings, based on research in mice and in human cells, are reported November 22 in Cell.The research adds an important piece to the long-standing puzzle of itch and helps explain why common skin conditions like eczema and atopic dermatitis are often accompanied by persistent itch.



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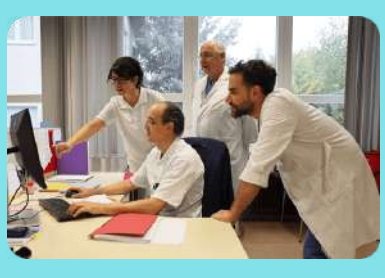
New immunotherapy for small cell lung cancer impresses in phase II clinical trial

Results from a recently published phase II clinical trial of an immunotherapeutic agent (Tarlatamab) for the treatment of small cell lung cancer have demonstrated anti-tumour activity and a promising extension of overall survival in patients. The international study (DeLLphi-301) was conducted at 56 clinical centres in 17 countries. The University Hospital Krems of the Karl Landsteiner University of Health Sciences (KL Krems) played a particularly active role, treating numerous patients from Austria, Switzerland and the Czech Republic.



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JCVI recommends chickenpox vaccine in childhood immunisation programme

The Joint Committee on Vaccination and Immunisation (JCVI) has recommended a vaccine against varicella, commonly known as chickenpox, should be added to the UK's routine childhood immunisation programme.The vaccine would be offered to all children in 2 doses, at 12 and 18 months of age.The committee has submitted its recommendations to the Department of Health and Social Care (DHSC), which will take a final decision on whether to implement a programme.

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Alimentiv, AcelaBio & PharmaNest unite to revolutionize precision medicine and AI digital pathology for NASH/MASH trialss

Alimentiv Inc., AcelaBio Inc., and PharmaNest Inc. announced their collaborative effort aimed at revolutionizing precision medicine and artificial intelligence (AI)-enabled digital pathology solutions for metabolic dysfunction-associated steatohepatitis (MASH), previously known as nonalcoholic steatohepatitis (NASH) clinical trials. This collaboration will enable clinical trial sponsors to quantify the histological effects of compounds and gain deeper insight into underlying mechanisms in MASH-targeted therapies using state-of-the-art spatial transcriptomics and AI-powered single-fiber and single-cell digital pathology.

Read More

Araris Biotech enters research collaboration with Taiho Pharma to develop next-generation ADCs using Araris' proprietary linker-conjugation technology

Araris Biotech AG (Araris), a Swiss oncology biotech company developing next-generation antibody drug conjugates (ADCs), announced they have entered a collaboration agreement under which Araris will use its proprietary linker-conjugation platform to generate novel ADCs against undisclosed targets provided by Taiho Pharmaceutical Co., Ltd., a Japanese R&D-driven specialty pharma company with a focus on oncology.ADCs delivered by Araris will be further tested and evaluated by Taiho. The financial terms of the collaboration agreement were not disclosed.

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Broncus to acquire 100% equity interest in Hangzhou Jingliang

Broncus, a medical device company specializing in the global development and distribution of innovative lung solutions, announced that, on November 23 2023 Broncus Hangzhou (a wholly owned subsidiary of Broncus, as Transferee) has entered into the Equity Transfer Agreement with the shareholders of the Hangzhou Jingliang, to acquire 100% equity interest in it.

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Telix Pharma to acquire US-based clinical stage company, QSAM Biosciences and its lead therapy candidate, CycloSam

Telix Pharmaceuticals Limited, a biopharmaceutical company, announces it has signed a conditional Term Sheet to acquire QSAM Biosciences, Inc. (QSAM) and its lead asset, CycloSam (Samarium-153-DOTMP).QSAM is a United States (US) based clinical stage company developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer.CycloSam is highly synergistic with Telix's existing therapeutic development activity in both prostate cancer and sarcoma. The proposed acquisition, subject to customary completion terms, will further enhance and differentiate Telix's innovation position to provide a continuum of care to patients from diagnosis and staging, systemic treatment of metastatic disease, to palliative care.

Telix

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Halozyme, Acumen Pharma ink global collaboration and license agreement to develop subcutaneous formulation of ACU193 with Enhanze technology in AD

Halozyme Therapeutics, Inc. announced a global collaboration and non-exclusive license agreement with Acumen Pharmaceuticals that provides Acumen access to Halozyme's Enhanze drug delivery technology, a proprietary recombinant human hyaluronidase PH20 enzyme (rHuPH20) for rapid subcutaneous drug delivery, for a single target. Acumen intends to explore the potential use of Enhanze for ACU193, Acumen's clinical-stage monoclonal antibody (mAb) candidate to target Amyloid-ß Oligomers (AßOs) for the treatment of early Alzheimer's disease (AD).

Halozyme
ACUMEN

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Landmark Bio signs multi-year agreement to manufacture Galapagos' oncology CAR-T cell therapy clinical programmes at point-of-care

Landmark Bio, a collective endeavour bringing together leaders in industry, academia, and research hospitals to accelerate development and industrialization of next-generation genomic medicines, announced that it has signed a multi-year strategic manufacturing agreement with Galapagos NV, an innovative biotech company with operations in Europe and the US.Under the terms of the agreement, Landmark Bio will perform GMP manufacturing of clinical trial batches of Galapagos' development programmes of chimeric antigen receptor (CAR) T-cell therapies in haematology-oncology in the Boston metropolitan area.

LANDMARK BIO™
Galápagos

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BioCina expands partnership with GPN Vaccines

BioCina Pty Ltd., a global end-to-end biologics CDMO, announced the expansion of their partnership with GPN Vaccines Ltd.GPN Vaccines is a biotechnology company developing a proprietary engineered whole-cell vaccine called Gamma-PNTM against Streptococcus pneumoniae. This bacterium is responsible for causing life-threatening infections such as pneumonia, bacteraemia and meningitis, each year causing up to 2 million deaths worldwide.

BioCina

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DCC asks DCGI to issue advisory to all SLAs to ensure that only pharma grade excipients are used in drugs

In an effort to address the quality issues of the excipients including the propylene glycol used in cough syrups, the Drugs Consultative Committee (DCC) of the Union health ministry has recommended to the national drug regulator to ensure that only pharma grade excipients are used in manufacturing of drugs as per the Drugs and Cosmetics Act.A recent meeting of the DCC, convened under the chairmanship of Drugs Controller General of India (DCGI) Dr Rajeev Singh Raghuvanshi, opined, "that as per the Drugs and Cosmetics Act only pharma grade excipients shall be used and therefore proper enforcement need to be done to tackle the issue."

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CDSCO extends time limit for submission of EoI for SSPs under DDRS

The Central Drugs Standard Control Organisation (CDSCO) has decided to provide more time for the eligible Software Service Providers (SSPs) to submit their Expression of Interest (EoI) for developing the unified digital ecosystem Digital Drugs Regulatory System (DDRS) as a single window, single sign on and unified portal for all regulatory activities.The EoI was issued earlier with the start date of issuance of EoI document as November 2, fixing the last date of submission as November 30, 2023. With the extension, the last date of EoI submission is fixed as December 7, 2023.

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Philips keen to capitalize India potential of qualified talent for research and manufacture

Royal Philips, a global leader in health technology, is now keen to capitalize India's potential of qualified talent in research and manufacture. The company is building initiatives to transform India into a global design and manufacturing hub.The new Phillips Innovation Centre is a 650,000 sq. ft. campus in Yelahanka, Bengaluru. It will accommodate over 5,000 professionals working on innovative health technologies aimed at improving patient experiences, achieving better health outcomes and lowering the cost of care.The total global strength of the company is 10,000 staff of which 5,000 are in Bengaluru.

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USV, Biogenomics partner to launch biosimilar insulin aspart, InsuQuick for people with diabetes in India

USV Pvt Ltd, a leading healthcare company, and Biogenomics, a science-driven, biotechnology company, announced the launch of InsuQuick, India's first biosimilar insulin aspart, which will improve access for people with diabetes. Diabetes is a growing healthcare concern in India as nearly 11.4% of the country's adult population, which accounts for 101 million people, are living with diabetes. Besides this, there are an additional 136 million people who are pre-diabetic and who have a high propensity to convert into diabetes in a short time.

Read More

Lupin lunches rocuronium bromide Injection in US markets

Global pharma major Lupin Limited (Lupin) announced the launch of rocuronium bromide injection, 50 mg/5 mL (10 mg/mL) and 100 mg/10 mL (10 mg/mL) multiple-dose vials, after Lupin's alliance partner Caplin Steriles Limited (Caplin) received an approval for its ANDA from the United States Food and Drug Administration (FDA).

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For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

Corporate Office

VEEDA CLINICAL RESEARCH LIMITED
Satyamev House,
Nr. Shalin Bunglow,
Prahladnagar,
Ahmedabad 380015

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

OTHER ADDRESS:

- Sarkhej - Gandhinagar Highway
  Vedant Complex, S. G. Highway, nr. YMCA club,
  Ahmedabad, Gujarat 380051
- Insignia, Besides Auda Garden, Opp. Zenobia
  Residency, Sindhu Bhavan Road, Off. S. G. Highway,
  Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium
  Panchot Cir, Kunal, Mehsana, Gujarat 384002