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The Veeda Newsletter

FEBRUARY 2023: ISSUE 02

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MANAGING DIRECTOR,
VEEDA CLINICAL RESEARCH

"We now offer end-to-end modular technical services, encompassing both pre-clinical and clinical development of biosimilars addressing global regulatory requirements."

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Veeda News
Update on our latest webinar, upcoming event and recently concluded event

Regulatory
FDA Rejects Biocon Biologics, Viatris Avastin Biosimilar

Financial
Centre estimates 40% growth in budget allocation for DoP for fiscal year 2023-24

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Merger and Acquisition
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VEEDA NEWS

Veeda expert at PharmaSynergy 2023

Here's a glimpse of PharmaSynergy 2023, where our Veeda Expert, Mr. Pankaj Sojitra PMP®, had a great time networking with various industry professionals from pharma and biopharma companies, discussing drug development needs.

Know More!

Veeda Experts at ISCR 16th Annual Conference

We are pleased to share a glimpse of Veeda Experts attending the Indian Society for Clinical Research 16th Annual Conference, 2023, "Demystifying Innovations in Clinical Research".

Know More!

Our latest webinar on Bioequivalence Studies

Watch our latest webinar as our experts covered variety of topics like Regulatory pathways for approvals of Orally Inhaled Products (FDA and EMA), Challenges & Solutions in planning and execution of the studies and more.

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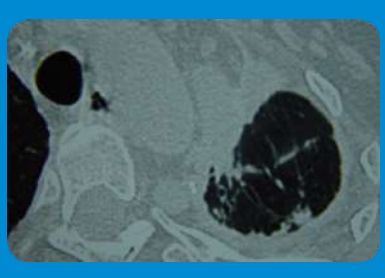
FDA clears Chemomab's IND for systemic sclerosis therapy trial

The US Food and Drug Administration (FDA) has granted clearance for Chemomab Therapeutics' investigational new drug (IND) application to commence the Phase II ABATE clinical trial of CM-101 in systemic sclerosis (SSc) adult patients.The double-blind, multicentre, proof-of-biology, randomised Phase II trial has been designed for assessing the activity, safety, and tolerability of CM-101 in these patients.A total of 45 people with clinically active dermatologic, vascular, or pulmonary SSc will be enrolled in the trial.



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FDA Advances Additional Activities to Prevent Drug Overdoses and Reduce Death

Addressing the drug overdose crisis and substance use disorder (SUD) is an issue of great concern for our nation and remains a top public health priority for the U.S. Food and Drug Administration. Upon returning to the FDA as Commissioner, I expressed my commitment to respond to all aspects of this ongoing crisis. As an agency focused on protecting public health, combatting this evolving emergency is an issue of particular urgency for us. Of note, a public health emergency, as a consequence of the opioid crisis, was declared by the U.S. Department of Health and Human Services in October 2017 and renewed on December 22, 2022.

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Dr PBN Prasad to hold charge as DCGI on temporary basis

Dr PBN Prasad will hold the charge of the post of Drugs Controller General of India from February 16 to 28 this year or until further orders, an official notice said on Wednesday.According to the official notice issued by Dr Kiran Kumar Karlapu, Deputy Secretary to the Government of India, "It has been decided with the approval of the Competent Authority, that Dr PBN Prasad, JDC(I) shall hold the charge of the post of Drug Controller of (India) under FR 49(v)wef 16.02.2023 till 28.02.2023 (date of his superannuation) or until further orders, whichever is earlier."

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FDA Rejects Biocon Biologics, Viatris Avastin Biosimilar

Biocon Biologics and Viatris have taken another blow from the FDA after receiving a complete response letter (CRL) for their bevacizumab biosimilar referencing Avastin. Biocon Biologics announced the news in a statement for its investors.The letter represents the second CRL in 2023 for the partners following the rejection of their insulin glargine biosimilar. Unlike the CRL for the insulin glargine biosimilar, which requested additional data to be submitted, the CRL for the bevacizumab candidate cited a failed manufacturing facility inspection.According to Biocon Biologics, it has submitted a "comprehensive" Corrective and Preventive Action (CAPA) plan to the FDA and is "confident of addressing the observations within the stipulated timeframe."

Biocon

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Sun Pharma's wholly owned subsidiary receives US FDA approval for generic lenalidomide capsules

Sun Pharmaceutical Industries Limited announced that one of its wholly owned subsidiaries has received final approval from US FDA for its Abbreviated New Drug Application (ANDA) for generic lenalidomide capsules, 5mg, 10mg, 15mg, 25mg and tentative approval for 2.5mg, 20mg. The respective product approval is based on Revlimid capsules, 5mg, 10mg, 15mg, 25mg and 2.5mg, 20mg as a reference product.

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NPPA proposes to bring down price of dobutamine injection 50 mg by 81%

The National Pharmaceutical Pricing Authority (NPPA) has proposed to bring down the ceiling price of anti-cardiac drug dobutamine injection 50 mg by around 81 per cent and snake venom antiserum by around 64 per cent through the ongoing process of revising the ceiling prices of scheduled formulations as per the revised Schedule I of the Drugs (Prices Control) Order, 2013.According to the draft calculation sheet of ceiling prices for 50 scheduled formulations, released as the 12th such lot of calculation sheets from the NPPA, the ceiling price of dobutamine injection 50 mg.ml, a medication to treat heart failure by strengthening the heart muscles and to treat low blood pressure, has been proposed at Rs. 8.05, with a reduction of 80.67 per cent as compared to the current ceiling price of Rs. 41.64 for each pack.

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NPPA addresses the issue of inter brand price variation in new scheduled drugs while fixing ceiling prices

The National Pharmaceutical Pricing Authority (NPPA) has decided to cap the prices of new scheduled drugs from the same company with significant inter-brand price variation, at the price of the lowest brand or pack size plus 10 percent based on the existing reference under the Drugs (Prices Control) Order (DPCO), 2013.The NPPA has released the National List of Essential Medicines (NLEM), 2022, with a total of 384 medicines of which 34 are new medicines added to the list while 26 from the previous list were deleted due to various reasons.

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NPPA refixes ceiling price of 400 scheduled formulations till Feb 6 with average reduction of 15.39%

The latest efforts by the National Pharmaceutical Pricing Authority (NPPA) to revise and fix the ceiling price of scheduled formulations has resulted in refixing the ceiling prices of 400 formulations till February 6 with an average reduction of 15.39 per cent in ceiling prices, says the ministry of chemicals and fertilisers.The Ministry said that the Department of Pharmaceuticals (DoP) notified Revised Schedule-I of Drugs (Prices Control) Order (DPCO) on November 11, 2022 incorporating the National List of Essential Medicines (NLEM), 2022 notified by the ministry of health and family welfare on September 13, 2022.There are 388 medicines (including 2 animal vaccines and 2 stents) consisting of approximately 954 formulations in the Revised Schedule-I of the DPCO, 2013.

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NPPA releases 10th lot of draft calculation sheets for ceiling price revision under revised Schedule I

The National Pharmaceutical Pricing Authority (NPPA) has released the tenth lot of draft working sheets for 55 scheduled formulations including 17 new formulations and strengths as part of fixing the ceiling prices for the formulations under the revised Schedule I of the Drugs (Prices Control) Order, 2013.The draft working sheets are published to collect response from the industry on the calculations and the revised ceiling prices, as part of its exercise to revise the prices based on the amended Schedule I, which replaced the National List of Essential Medicines (NLEM), 2015 with the NLEM, 2022, in November, 2022.

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Centre estimates 40% growth in budget allocation for DoP for fiscal year 2023-24

The budget outlay for the Department of Pharmaceuticals (DoP) and the schemes running under its aegis has been increased by around 40 per cent in the year 2023-24 as compared to the budget estimates for the previous year, mainly owing to the expected increase in allocation for promotion of bulk drug parks and medical devices parks, among others.According to the Demands for Grants released by the Union finance ministry for the next fiscal year, the Budget Estimate (BE) for the DoP for the year 2023-24 is Rs. 3,160.06 crore, up from Rs. 2,244.15 crore BE during the year 2022-23. The revised estimate for the year 2022-23 was Rs. 2,268.54 crore, a slight increase from the estimates for the year.

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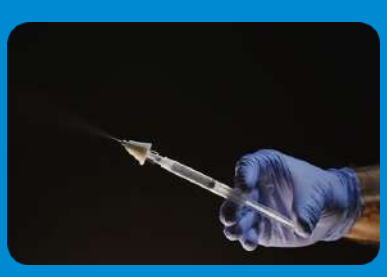
CLINICAL RESEARCH

Nasal Covid vaccine shows promise in early clinical trial

An experimental nasal vaccine provided strong protection against Covid infection, according to preliminary results from a Phase 1 clinical trial.The vaccine, developed by a startup called Blue Lake Biotechnology Inc., was found to reduce the risk of symptomatic Covid infections by 86% for three months in people who received it as a booster dose. Existing booster shots in the United States reduce symptomatic infections by 43% in people 18 to 49 over one to two months, according to a study published in November by the Centers for Disease Control and Prevention.



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eFFECTOR reports positive data from trial of zotatifin for Covid-19

EFFECTOR Therapeutics has reported positive top-line data from its Phase Ib clinical trial of zotatifin to treat Covid-19.The potent and sequence-selective small molecule eIF4A inhibitor zotatifin demonstrated favourable safety results and positive trends in multiple antiviral activity measures.In the double-blind, randomised, placebo-controlled dose escalation study of zotatifin, 27 subjects received the therapy at doses ranging from 0.01 to 0.035 mg/kg, and nine were given a placebo.

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DMT therapy appears effective for depression in phase 2 clinical trial

London-based biotech Small Pharma has released top-line data for its DMT-assisted therapy for major depressive disorder (MDD) — and the results are promising.The phase 2a trial, which administered their DMT candidate SPL026 intravenously, found a “statistically significant and clinically relevant” reduction in depressive symptoms, at least over the short term.The results suggest that “just one dose of SPL026, with supportive therapy, has marked antidepressant effects, all the way out to three months,” Carol Routledge, the chief medical and scientific officer of Small Pharma, tells Freethink, and a six-month, out-of-study follow up on trial participants is forthcoming.

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Formosa Pharma inks collaboration agreement with Eyenovia for development of novel ophthalmic therapeutics

Taiwan-based Formosa Pharmaceuticals (Formosa) announced that the company has entered into a collaboration agreement with Eyenovia, Inc. (Eyenovia) for the development of novel ophthalmic therapeutics. The foundation of the collaboration lies in the combination of Formosa’s APNT formulation platform with Eyenovia’s Optejet delivery system.Eyenovia’s Optejet delivery platform for ocular therapeutics utilizes Microdose Array Print (MAP) technology to deliver 6-8 mL of drug product, consistent with the capacity of the tear film of the eye.

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Moderna confirms progress in mRNA-3927 clinical trial

In a recent press release, Moderna confirmed that its Phase I/II study examining candidate mRNA-3927 is progressing. The pharmaceutical giant shared that encouraging data showed a decrease in the number of metabolic decompensation events (MDEs) in trials of mRNA-3927, and regulators seemed to support MDE as a primary endpoint for the study. Additionally, Moderna stated that all eligible participants elected to continue to the Open Label Extension study. According to GlobalData’s Pharma Intelligence Center, mRNA-3927 is one of five non-vaccine mRNA therapeutics currently in clinical trial development.

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MEI Pharma and Infinity Pharma ink all-stock merger deal

Oncology-focused clinical-stage biotechs MEI Pharma (NASDAQ:MEIP) and Infinity Pharmaceuticals (NASDAQ:INFI) announced a merger agreement Thursday to combine in an all-stock transaction.Per the terms, Infinity (INFI) will become a wholly owned subsidiary of MEI Pharma (MEIP) at the close of the deal, expected in mid-2023, subject to shareholder approval and other closing conditions.Three development programs will anchor the combined company's pipeline, which will be led by eganelisib, an oral, immuno-oncology drug candidate targeted at the head and neck squamous cell carcinoma (HNSCC) in combination with Merck's (MRK) Keytruda.

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MMS Partners with I-ACT to Advance Children's Clinical Trials

MMS Holdings, a data-focused contract research organization (CRO) – announced its partnership with the Institute for Advanced Clinical Trials (I-ACT) to accelerate the development of life-saving therapeutics, including vaccines, medicines, and medical devices for children. MMS is a sponsor of I-ACT's Spin Challenge, a creative way to raise funds to advance and accelerate children's clinical trials. The event officially launches in early March when scores of pediatricians, pediatric nurses, pediatric social workers, and others who care deeply about children will visit Disney World and set a world record by riding Disney's Spinning Tea Cups for three days.

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Sun Pharma acquires minority stake in 2 medical devices companies

Sun Pharmaceutical Industries announced the acquisition of minority stake in Agatsa Software Private Limited and Remidio Innovative Solutions Private Limited on February 18.The pharma major will hold a 26.09 percent stake in Agatsa Software, an early-stage digital diagnostic devices company. In Remidio Innovative Solutions, a company that provides innovative products for early detection of eye diseases, Sun Pharma will be acquiring 27.39 percent.

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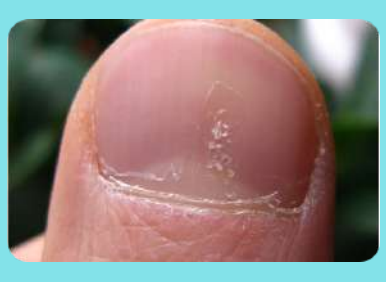
Takeda acquires Nimbus Therapeutics' subsidiary

Takeda has concluded the previously announced acquisition of the complete shares of Nimbus Therapeutics' tyrosine kinase 2 (TYK2) programme subsidiary Nimbus Lakshmi.The latest move comes following clearance from the United States Federal Trade Commission and after satisfaction of other conditions related to the deal closure.Takeda originally signed the acquisition agreement in December last year. According to the agreement and following the deal completion, Nimbus will receive nearly $4bn in upfront payment from Takeda.



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Abbott to acquire Minnesota-based Cardiovascular Systems for $890 million

Abbott and Cardiovascular Systems, Inc. (CSI), announced a definitive agreement for Abbott to acquire CSI, a medical device company with an innovative atherectomy system used in treating peripheral and coronary artery disease. Under terms of the agreement, CSI stockholders will receive $20 per common share at a total expected equity value of approximately $890 million. CSI is a leader in devices for atherectomy, a minimally invasive treatment for plaque build-up in arteries that can restrict blood flow.

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FOPE, RPMA jointly launch FPCR startup in Jaipur for commercialization of research in health & pharma

The Federation of Pharma Entrepreneurs (FOPE) and Rajasthan Pharmaceutical Manufacturers Association (RPMA) have jointly launched Foundation for Promotion of Commercialization of Research (FPCR) Startup in Jaipur for industry and academia to collaborate towards accomplishing commercialization of research already done or being done in health and pharma in India and globally. FPCR Startup was inaugurated by Vinod Kalani, president, FOPE in Jaipur recently.

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Government focussing on production of high value pharmaceuticals: Mansukh Mandaviya

The government is taking steps to produce "high value pharmaceuticals" in the country to reduce import dependency for such critical articles, Union Minister Mansukh Mandaviya said on Tuesday. Manufacturing of components of high-end medical devices in the country will be another big step in moving towards self reliance, the Union Minister for Chemicals and Fertilisers noted."Working on the vision of reducing import dependency through indigenous production, the government is focussing on production of high value pharmaceuticals and high-end medical devices," he said.

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Gujarat FDCA signs MoU with NIPER Ahmedabad for training and capacity building of state drug controllers

The Gujarat Food and Drug Control Administration (FDCA) has signed an MoU with National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad for knowledge sharing, training and capacity building of state drug controllers.The capacity building program for drug regulators: a step towards continual learning training program for drug regulators of Gujarat FDCA is jointly organized by NIPER-Ahmedabad and National Forensic Sciences University (NFSU), Gandhinagar, Gujarat.This will give a competitive edge to the state drug controllers (SDCs) in terms of doing the US FDA aligned audits in the Indian pharmaceutical industry in a timely manner for trust and compliance building with the manufacturers for safe and efficacious medicines.

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NIPER Hyderabad bags patent for nano formulation of lung cancer drug osimertinib

The Indian Patent Office has granted patent to National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad for its nano formulation of lung cancer drug osimertinib mesylate, which claims to address the risk of acquired resistance against the therapy in the first year of treatment.Osimertinib is an oral, third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) drug developed by AstraZeneca Pharmaceuticals and sold under the brand Tagrisso to treat metastatic non-small cell lung cancer (NSCLC). Tagrisso is one of the blockbuster drugs of AstraZeneca.

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Zydus Hospitals & Medtronic collaborate to launch India's first indigenous AI based stroke care network in Gujarat

Zydus Hospitals, Ahmedabad, and India Medtronic Private Limited, a wholly owned subsidiary of Medtronic plc, have announced their partnership to support stroke patients in Gujarat via a hub and spoke network. As part of the partnership, Medtronic will collaborate with Zydus Hospitals to build an ecosystem that can help in timely diagnosis and treatment of stroke patients by facilitating the use of indigenous AI-enabled technology and providing tools and technologies to support the education and training of doctors in select remote hospitals.

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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