The Veeda Newsletter

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Veeda Biopharma X Biobeams | 908 Devices

Veeda Biopharma is the only solution partner in India offering services on this Microcapillary based platform

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Partners in Creating

a healthier tomorrow

Veeda News

Latest news on an interview with our COO and Scientific Briefing

Financial

BSE Healthcare index jumps by 37% during 2023, Nifty Pharma index up by over 33%

Merger and Acquisition

Sanofi to acquire clinical-stage biopharma company, Inhibrx for approximately $1.7 billion

Regulatory

US FDA grants fast track designation to Kyverna Therapeutics' CD19 CAR T-cell product candidate, KYV-101 to treat refractory progressive MS

Clinical Research

AIM ImmunoTech starts patient enrolment in phase 1b/2 study of Ampligen in combo with AstraZeneca's Imfinzi to treat late-stage pancreatic cancer

Indian Pharma

Enzene Biosciences launches its first manufacturing base in the US

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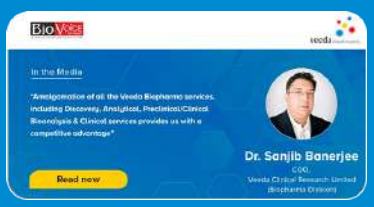
Our recent BioVoice News's interview with our COO, Dr. Sanjib Banerjee, Veeda Biopharma Division

This interview sheds light on the strategic vision behind Veeda Biopharma Solutions, emphasizing the company's commitment to delivering superior Quality, Precision, and Efficiency in every facet of Biopharmaceutical Drug Development.



Know More!

Our recent Scientific Briefing on Developing New Chemical Entities (NCEs) for the management of Plaque Psoriasis

Discover our recent Scientific Briefing, which delves into:
Study Objectives and Endpoints Considerations in
- Plaque Psoriasis Critical Factors to Consider in NCE Development
- Regulatory Compliance
- Veeda's Dermatology Experience and commitment to
- advancing Dermatology Research across various indications

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US FDA grants fast track designation to Kyverna Therapeutics' CD19 CAR T-cell product candidate, KYV-101 to treat refractory progressive MS

Kyverna Therapeutics, Inc. (Kyverna), a patient-centred clinical-stage biopharmaceutical company, announced it received fast track designation by the US Food and Drug Administration (FDA) for its autologous, fully human CD19 chimeric antigen receptor (CAR) T-cell product candidate, KYV-101, to be used for the treatment of multiple sclerosis (MS). Fast track designation is a program intended to facilitate and expedite the development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition.

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TN DCA issues stop production orders to three pharma firms after risk-based inspections

Following the mandate of the Drug Control General of India (DCGI), the department of drugs control administration (DCA) in Tamil Nadu, in association with the Central Drug Standard Control Organisation (CDSCO), conducted risk-based inspections of 10 manufacturing companies in the state in 2022 and in 2023. In the joint inspections, the regulators found irregularities in three companies out of the ten inspected and issued stop production orders. The seven companies were found to be fully compliant with GMP norms.

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US FDA updates label for Dupixent in atopic dermatitis with moderate-to-severe hand and foot involvement

The US Food and Drug Administration (FDA) has updated the label for Dupixent (dupilumab) in atopic dermatitis, adding efficacy and safety data for patients aged 12 years and older with atopic dermatitis with uncontrolled moderate-to-severe hand and/or foot involvement. These phase 3 data are from the first and only trial evaluating a biologic specifically for this difficult-to-treat population and have also been added to the Dupixent label in the European Union, with regulatory submissions underway in additional countries.

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US FDA approves Vertex's Casgevy to treat transfusion-dependent beta thalassemia

Vertex Pharmaceuticals Incorporated announced that the US Food and Drug Administration (FDA) has approved Casgevy (exagamglogene autotemcel [exa-cel]), a CRISPR/Cas9 gene-edited cell therapy, for the treatment of transfusion-dependent beta thalassemia (TDT) in patients 12 years and older.

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WHO launches appeal for US$ 1.5 billion for key emergencies in 2024

The World Health Organization (WHO) launched an appeal for US$ 1.5 billion to protect the health of the most vulnerable populations in 41 emergencies around the globe in 2024.

The appeal covers the emergencies that demand the highest level of response from WHO, with the aim to reach over 87 million people. It is being issued in a context of complex emergencies cutting across crises of conflict, climate change and economic instability, which continue to fuel displacement, hunger, and inequality.

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Granules India chief sees need for Budget 2024 to implement focused strategies: streamline regulatory pathways & create innovation zones

Granules India chief sees need for Budget 2024 to implement focused strategies. These include creating innovation zones offering incentives and infrastructural support, encouraging public-private partnerships to combine expertise-resources, and boosting funding for advanced drug research and development. Stating that streamlining regulatory pathways to expedite approvals for novel treatments and investing in educational initiatives to develop a workforce adept in pharmaceutical innovation are also key, Dr Krishna Prasad Chigurupati, chairman and joint managing director, Granules India said that these initiatives are expected to usher in a new age of Indian pharmaceutical leadership, characterized by groundbreaking R&D.

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Over 86% of NPPA's total demand against overcharging yet to be recovered

Over 86 per cent of the total demand raised by the National Pharmaceutical Pricing Authority (NPPA) from the pharma industry on alleged overcharging of prices over the years is yet to be recovered. Of the total amount to be recovered, around 71.52 per cent is under litigation in various forums, according to data from the Authority. As per the data available, till September, 2023, the drug price watchdog has reported a total of 2,433 cases of overcharging from the year 1979 to September, 2023 and raised demand for overcharging to the tune of Rs. 9,900.8 crore, including interest whenever updated.Myriad Genetics sets up comprehensive pan-cancer research platform to advance patient care.

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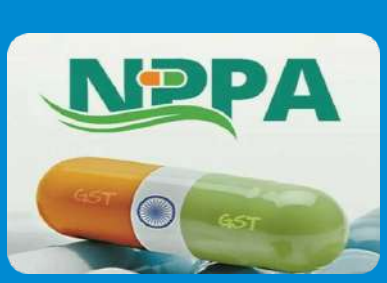
NPPA to fix ceiling price of over 200 formulations based on market data of October, 2023

The National Pharmaceutical Pricing Authority (NPPA) is looking at fixing the ceiling prices of over 200 scheduled formulations under the Revised Schedule I of the Drugs (Prices Control) Order, 2013 based on the price database for the month of October, 2023. The Authority has so far fixed the ceiling prices under the revised Schedule I of the DPCO, which was amended last year replacing the National List of Essential Medicines (NLEM), 2015 with the NLEM, 2022, notified by the Department of Pharmaceuticals (DoP) on November 11, 2022. Janaushadhi Pariyojana achieves target of Rs.1,000 crore sales in FY 2023-24



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BSE Healthcare index jumps by 37% during 2023, Nifty Pharma index up by over 33%

The pharmaceutical and healthcare scrip remained in limelight during the year ended 2023 on account of improved profitability in the first half of 2023-24, positive outcome from R&D investment, capex plans, higher ANDA approvals, new launches and entry into new international markets. The BSE Healthcare index of 94 scrips went up smartly by 37 per cent and closed at 31,549 points on the last trading day of 2023. Similarly, Nifty Pharma index of 20 companies went up by 33.6 per cent and closed at 16,831. The rally started after March 2023 and pharma shares moved up to new yearly high level. Markets closed on positive note with higher FIIs investments.

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ADMI asks govt to remove inverted duty structure & withdraw decision on refurbished devices in Budget for 2024-25

The Central government has to look at removing the inverted duty structure in the medical devices sector, disallowing the imports of refurbished medical devices which was allowed in the last budget, and chalk out a clear-cut path to remove the issues faced by the MedTech exporters among other measures in the upcoming Budget for the year 2024-25, says the Association of Diagnostic Manufacturers of India (ADMI)

admi
Association of Diagnostics Manufacturers of India
Voice of IVD industry

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AIM ImmunoTech starts patient enrolment in phase 1b/2 study of Ampligen in combo with AstraZeneca's Imfinzi to treat late-stage pancreatic cancer

AIM ImmunoTech Inc., an immuno-pharma company, announced that the first subject has been enrolled at Erasmus Medical Center (Erasmus MC) in a phase 1b/2 clinical trial combining AIM's Ampligen (rintatolimod) with AstraZeneca's anti-PD-L1 immune checkpoint inhibitor Imfinzi (durvalumab) for the treatment of late-stage pancreatic cancer (the "DURIPANC Study").

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Virios Therapeutics to advance development of IMC-2 as treatment for symptoms associated with long-Covid

Virios Therapeutics, Inc., a development-stage biotechnology company, announced its plans for advancing IMC-2 (combination of valacyclovir and celecoxib) as a treatment for the fatigue, orthostatic intolerance and other symptoms associated with LC, also known as post-acute sequelae of SARS-CoV-2 infection (PASC).

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BioNTech, DualityBio begins patient dosing in pivotal phase 3 trial of ADC candidate, BNT323/DB-1303 in metastatic breast cancer

BioNTech SE and Duality Biologics (Suzhou) Co., Ltd. (DualityBio) announced that the first patient with metastatic breast cancer has been treated in a pivotal phase 3 trial evaluating the efficacy and safety of the next-generation antibody-drug conjugate (ADC) candidate BNT323/DB-1303 targeting the Human Epidermal Growth Factor Receptor 2 (HER2), a cancer cell surface protein. Breast cancer is the most commonly diagnosed cancer worldwide and the leading cause of death from malignant tumours in women globally.

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Sensorion receives approval for CTA to initiate phase 1/2 trial of gene therapy candidate, SENS-501 in France

Sensorion a pioneering clinical-stage biotechnology company, announces that it has received approval for its Clinical Trial Application (CTA) to initiate a phase 1/2 clinical trial of SENS-501 (OTOF-GT), in France. The conclusion of the Part I of the assessment report according to regulation EU 536/2014 covering France, Italy and Germany is that the conduct of the clinical trial is acceptable.

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Rallybio announces preliminary phase 1 MAD data of RLYB116 to treat patients with complement-mediated diseases

Rallybio Corporation, a clinical-stage biotechnology company with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases, has announced preliminary phase 1 multiple ascending dose (MAD) data for RLYB116, an innovative, long-acting, low volume subcutaneously injected inhibitor of complement component 5 (C5), in development for patients with complement-mediated diseases.

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Sun Pharma to acquire remaining stake in Taro Pharma

Sun Pharmaceutical Industries Limited and Taro Pharmaceutical Industries Ltd. announced that they have entered into a definitive merger agreement in which Sun Pharma, Taro's controlling shareholder, has agreed to acquire all of the outstanding ordinary shares of Taro other than the shares already held by Sun Pharma or its affiliates for US$ 43.00 per share in cash without interest. Dilip Shanghvi, managing director of Sun Pharma, said, "Over the years, with Sun Pharma's strategic interventions, Taro has remained a key player in the generic dermatology market in a challenging environment. Post completion of the merger, the combined entity will firmly move forward, leveraging its global strengths and capabilities to better serve the needs of patients and healthcare professionals.

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Coherus BioSciences to divest Cimerli ophthalmology franchise to Sandoz for $170 million

Coherus BioSciences, Inc. (Coherus), a commercial-stage biopharmaceutical company, announced it has entered into an agreement to divest its Cimerli (ranibizumab-eqrn) ophthalmology franchise, inclusive of Cimerli and its supporting commercial infrastructure, to Sandoz for upfront, all-cash consideration of $170 million plus an additional amount for Cimerli product inventory and subject to customary working capital adjustments at the closing date. This divestiture includes Coherus' Cimerli biologics license application, ophthalmology sales and select field reimbursement teams, Cimerli product inventory on hand, and access to proprietary commercial software.

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Sanofi to acquire clinical-stage biopharma company, Inhibrx for approximately $1.7 billion

Sanofi and Inhibrx, Inc. (Inhibrx), a publicly traded clinical-stage biopharmaceutical company focused on developing a broad pipeline of novel biologic therapeutic candidates, have entered into a definitive agreement under which Sanofi has agreed to acquire Inhibrx following the spin-off of non-INBRX-101 assets into New Inhibrx.

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Processa Pharma to expand development of NGC-Cap programme into advanced or metastatic breast cancer

Processa Pharmaceuticals, Inc., a clinical-stage pharmaceutical company, announces it plans to expand the development of Next Generation Capecitabine (NGC-Cap) into the treatment of advanced or metastatic breast cancer beginning with its next phase 2 trial. Following the Processa meeting with the FDA, Processa has decided the next NGC-Cap trial would be a phase 2 trial in breast cancer. This decision was supported through discussions with the FDA where Processa agreed with the FDA that pursuing breast cancer will lead to a more efficient development programme while providing a greater likelihood of FDA approval. The FDA stated that the previously generated data in past and existing studies could be used to directly support the phase 2 trial in breast cancer.

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Cactus Communications collaborates with Indian Society of Cell Biology to empower researchers

Cactus Communications (Cactus), a science communication and technology company, has joined forces with the Indian Society of Cell Biology (Society). This two-year partnership aims to enhance academic growth and offer training support to students, postdocs, and researchers in various life sciences fields, highlighting a step forward in academic development.

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Enzene Biosciences launches its first manufacturing base in the US

Widely recognized as a pioneer in continuous manufacturing, Pune-based contract development & manufacturing organization (CDMO), Enzene Biosciences recently announced the launch of its first manufacturing site in the United States, located in Hopewell (near Princeton, New Jersey). The site is expected to be ready in June 2024, and customers have already started to reserve capacities for continuous manufacturing and/or fed batch.

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AstraZeneca gets CDSCO nod to import and market andexanet alfa in India for critical bleeding linked to novel anticoagulants

AstraZeneca Pharma India has received approval from Central Drugs Standard Control Organisation (CDSCO) in India for the import and marketing of andexanet alfa. This treatment addresses life-threatening or refractory bleeding associated with the use of Factor Xa (FXa) inhibitors. FXa inhibitors are increasingly employed for preventing and treating thrombotic events, such as deep vein thrombosis and pulmonary embolism, as well as in patients at high risk of stroke due to atrial fibrillation. While these medications effectively prevent unwanted clot formation, they also elevate the risk of major bleeding, which can be life-threatening

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Indian Drug Manufacturers' Association organises Pharma Live Expo & Summit

The Pharma Live Expo & Summit, organized by the Indian Drug Manufacturers' Association, ignites the future of the pharma industry. This electrifying event promises three days of inspiration, collaboration, and limitless potential at the Bombay Exhibition Centre, Nesco Mumbai, from January 17th to 19th. A kaleidoscope of vibrant booths showcasing the latest pharmaceutical aces, from potent APIs to sleek packaging machineries. The air crackles with excitement as 20,000 pharma professionals, representing every facet of the industry – from eagle-eyed QA specialists to meticulous production engineers – mingle and forge connections that will shape the future of healthcare.

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Indian pharma to grow 10 times in next 25 years aided by govt policies like PLI schemes: IDMA president

Indian pharma will grow 10 times in the next 25 years in sectors like biologics, large molecules, New Drug Delivery Systems (NDDS) and Complex Generics under the PLI-1 and PL-2 schemes. This will be complemented with research in Orphan Drugs and Drug-Device combinations under the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme, said Dr. Viranchi Shah, national president, Indian Drug Manufacturers' Association (IDMA).

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Abbott announces first global procedures in a clinical trial of its Volt PFA System to treat patients with abnormal heart rhythms

Abbott announced the first global procedures have been conducted using the company's new Volt Pulsed Field Ablation (PFA) System to treat patients battling common abnormal heart rhythms such as atrial fibrillation (AFib). Over 30 patients were recently treated in Australia as part of Abbott's Volt CE Mark study, a pre-market, multi-center clinical study designed to evaluate the safety and effectiveness of Abbott's Volt PFA System. In addition to upcoming procedures in markets across Asia Pacific and Europe, Abbott anticipates approval for its US clinical trial (IDE) for the Volt PFA System in the first half of this year.

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