The Veeda Newsletter

DECEMBER 2023: ISSUE 12

Discover our recent Scientific Briefing on

Higher-Order Structure Assessment

A Critical Step in Biosimilar Development

Read More

Partners in Creating

a healthier tomorrow

Veeda News

Latest news on event participation and Veeda Biopharma's infrastructure

Regulatory

Parliamentary panel recommends Centre to support new vaccine development to address Covid-19

Financial

Innova Captab's IPO to open on December 21, sets price band at Rs. 426 to Rs. 448 per equity share

Clinical Research

Gilead Sciences, Compugen ink licence deal for novel pre-clinical immunotherapy programme

Merger and Acquisition

Biocon Biologics partners with Sandoz for distribution of adalimumab BS subcutaneous injection in Japan

Indian Pharma

JB Pharma Enters Ophthalmology space, signs RS 1089 crore deal with Novartis for 10 Brands

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

VEEDA NEWS

Glimpse of Veeda Experts at the SCDM India Annual Conference 2023

The conference was a great opportunity for our team to demonstrate how Veeda's expertise and strategic methodologies in Clinical Data Management have the potential to expedite your research outcomes.

Know More!

Infrastructure: Veeda Biopharma

Explore our infrastructure driving research and development across a diverse range of solutions, advancing movement of molecules from discovery to market with remarkable Speed and Precision.

Know More!

veeda clinical research

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

US FDA approves LEO Pharma's Tralokinumab-ldrm to treat Atopic Dermatitis in paediatric patients

LEO Pharma Inc announced that the US Food and Drug Administration (FDA) has expanded the approval of Adbry (tralokinumab-ldrm) to include pediatric patients aged 12-17 years with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry is the first and only US FDA-approved biologic that specifically binds to and inhibits the interleukin (IL)-13 cytokine, one of the key drivers of AD signs and symptoms.

Read More

WHO adds the R21/Matrix-M malaria vaccine to its list of prequalified vaccines

WHO has added the R21/Matrix-M malaria vaccine to its list of prequalified vaccines. In October 2023, WHO recommended its use for the prevention of malaria in children following the advice of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization and the Malaria Policy Advisory Group. The prequalification means larger access to vaccines as a key tool to prevent malaria in children with it being a prerequisite for vaccine procurement by UNICEF and funding support for deployment by Gavi, the Vaccine Alliance.

Read More

Parliamentary panel recommends Centre to support new vaccine development to address Covid-19

A Parliamentary panel that looked into the vaccine development and distribution for Covid-19 has recommended to the Centre to encourage vaccine development on other newer and more efficient platforms and also evaluate the efficacy of the existing vaccines to address the future challenges.

Read More

US FDA grants priority review status to Roche's Xolair for children and adults with food allergies based on positive NIH phase III study results

Roche announced that the US Food and Drug Administration (FDA) has accepted, under Priority Review, the company's supplemental Biologics License Application (sBLA) for Xolair (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with an accidental exposure to one or more foods in adult and paediatric patients aged 1 year and older with food allergy. If approved, people taking Xolair would still need to avoid foods they are allergic to (commonly referred to as "food avoidance").

Roche

Read More

EMA & HMAs publish artificial intelligence workplan to guide use of AI in medicines regulation

European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMAs) have published an artificial intelligence (AI) workplan to 2028, setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks.

Read More

veeda clinical research

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

Innova Captab's IPO to open on December 21, sets price band at Rs. 426 to Rs. 448 per equity share

Innova Captab Limited has fixed the price band at Rs. 426 to Rs. 448 per equity share for its maiden initial public offer (IPO). The IPO of the company will open on December 21, 2023, for subscription and close on Tuesday, December 26, 2023. Investors can bid for a minimum of 33 equity shares and in multiples of 33 equity shares thereafter. Innova Captab is an integrated pharmaceutical company in India with a presence across the pharmaceuticals value chain including research and development, manufacturing, drug distribution and marketing and exports.

Read More

Myriad Genetics sets up comprehensive pan-cancer research platform to advance patient care

Myriad Genetics, Inc, a leader in genetic testing and precision medicine, has announced the launch of the Myriad Collaborative Research Registry (MCRR). Formerly known as the Precise Treatment Registry, the MCRR includes new data across germline and tumor testing results from Myriad's cancer products on more than one million patients. The latest enhancements make the MCRR one of the largest pan-cancer registries freely available for research use and supports transparent clinical data sharing to advance the field. The Myriad Collaborative Research Registry has more than one million patient cases.

Read More

Janaushadhi Pariyojana achieves target of Rs.1,000 crore sales in FY 2023-24

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) has achieved a target sales of Rs. 1,000 crore during the fiscal year 2023-24, said the ministry of chemicals and fertilisers.It has helped to save Rs. 5,000 crore to the people during the fiscal year so far, and approximately Rs. 25,000 crore have been saved through this Pariyojana in the last nine years. The government said that Jan Aushadhi Kendras are present in more than 785 districts of the country.In the financial year 2022-23, PMBJP has made sales of Rs. 1,235.95 crore (at MRP), with a growth of 38.3 per cent compared to Rs. 893.56 crore sales during the financial year 2021-22.

Read More

Steps by NPPA has resulted in price reduction of cancer drugs by 23%: Union minister

The steps taken by the National Pharmaceutical Pricing Authority (NPPA) to reduce the ceiling price of cancer drugs under the National List of Essential Medicines (NLEM) 2015 and 2022 has resulted in price reduction of around 23 per cent.The Union ministry of chemicals and fertilisers has also said that overall, the price control authority has notified retail price of around 2607 new drugs under Drugs (Prices Control) Order, 2013 till November 30, 2023.

Read More

CDSCO declares over 5% of drug samples tested in November as NSQs

The Central Drugs Standard Control Organisation (CDSCO) has declared almost 5.2 per cent of the total drug samples it has tested during the month of November, 2023 as Not of Standard Quality (NSQ). It has also declared one sample as spurious and another one as misbranded, during the month.According to the test results announced by the drug regulator for the month of November, 62 were declared as NSQs out of a total number of 1,197 samples tested. Out of the total, 1,133 samples were declared as of standard quality.

Read More

veeda clinical research

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

BioCardia enrolls first patient in CardiALLO phase I/II clinical trial of BCDA-03 to treat ischemic heart failure of reduced ejection fraction

BioCardia, Inc, a developer of cellular and cell-derived therapeutics for the treatment of cardiovascular and pulmonary disease, has announced that the first patient was enrolled and treated in its CardiALLO allogeneic mesenchymal cell therapy phase I/II clinical trial for the treatment of patients with New York Heart Association Class II and III ischemic heart failure of reduced ejection fraction (HFrEF).

Read More

Gilead Sciences, Compugen ink licence deal for novel pre-clinical immunotherapy programme

Gilead Sciences, Inc. an American biopharmaceutical company headquartered in Foster City, California, has announced an exclusive licence deal with Compugen Ltd, a clinical-stage cancer immunotherapy company and a pioneer in computational target discovery, headquartered in Holon, Israel, to license its potential first-in-class, pre-clinical antibody programme against IL-18 binding protein, including the COM503 drug candidate.

Read More

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.

Read More

Sanofi to discontinue phase 3 CARMEN-LC03 trial of tusamitamab ravtansine

Sanofi is discontinuing the global clinical development programme of tusamitamab ravtansine. The decision is based on the outcome of a prespecified interim analysis of the phase 3 CARMEN-LC03 trial evaluating tusamitamab ravtansine as monotherapy compared to docetaxel in previously treated patients with metastatic non-squamous (NSq) non-small cell lung cancer (NSCLC) whose tumours express high levels of carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5).

Read More

Akero Therapeutics enrolls first patients in efruxifermin phase 3 SYNCHRONY programme

Akero Therapeutics, Inc, a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, reported patients have received their first doses of efruxifermin (EFX) in the SYNCHRONY phase 3 programme.

Read More

veeda clinical research

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

Roche Expands Obesity Portfolio Through $2.7 Billion Carmot Acquisition

December 6, 2023 - On December 4, 2023, Roche revealed that it entered into definitive merger agreements with Carmot Therapeutics. According to the company's press release, it will acquire Carmot and its gamut of clinical-stage obesity drugs for $2.7 billion.

Read More

Cosmos Health signs agreement to acquire license and rights for DIABIT-IS X to treat type-2 diabetes

Chicago-based Cosmos Health Inc, a diversified, vertically integrated global healthcare group engaged in innovative R&D, owner of proprietary pharmaceutical and nutraceutical brands, manufacturer and distributor of healthcare products, and operator of a telehealth platform, announced that it has entered into a definitive agreement, subject to customary closing conditions, with a related party to acquire the license and rights for "DIABIT-IS X", a drug used in the treatment of type-2 diabetes.

Read More

Biocon Biologics partners with Sandoz for distribution of adalimumab BS subcutaneous injection in Japan

Biocon Biologics has signed today a distribution agreement with Sandoz, granting the company the exclusive rights to promote, sell and distribute adalimumab BS for subcutaneous injection [FKB] in Japan. Based on this agreement, Viatris has completed marketing and promotion of the product as of December 15, 2023, but will continue to provide transition support until Sandoz will gradually assume responsibilities for the product starting February 15, 2024. Biocon Biologics has acquired the global biosimilars portfolio of Viatris including adalimumab. Fujifilm Kyowa Kirin Biologics Co. Ltd., the developer of the drug, has concluded an exclusive global marketing license agreement with Biocon Biologics Ltd affiliate.

Read More

Takeda Canada inks contract with Canadian Blood Services for GLASSIA to treat rare form of emphysema

Takeda Canada Inc. (Takeda) has entered into a contract with Canadian Blood Services (CBS) for GLASSIA (alpha-1 proteinase inhibitor) resulting from CBS's request for proposal for hereditary deficiency of Alpha-1 Antitrypsin Deficiency (Alpha-1). Glassia has been approved to be listed on the CBS Plasma Protein and Related Products (PPRP) formulary with specific criteria for reimbursement. This marks Takeda's entry into the Alpha-1 community in Canada, building on the company's commitment to developing innovative treatments for rare diseases.

Read More

Bristol Myers Squibb to buy Boston-based Karuna Therapeutics for $14 billion to bolster neuro portfolio

Bristol Myers Squibb and neuroscience-focused Karuna Therapeutics, Inc jointly announced that they have entered into a definitive merger agreement under which Bristol Myers Squibb has agreed to acquire Karuna for $330.00 per share in cash, for a total equity value of $14.0 billion, or $12.7 billion net of estimated cash acquired. The transaction was unanimously approved by both the Bristol Myers Squibb and Karuna boards of directors. Karuna is a biopharmaceutical company driven to discover, develop and deliver transformative medicines for people living with psychiatric and neurological conditions. Karuna's lead asset, KarXT (xanomeline-trospium), is an antipsychotic with a novel mechanism of action (MoA) and differentiated efficacy and safety.

Read More

veeda clinical research

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

JB Pharma Enters Ophthalmology space, signs RS 1089 crore deal with Novartis for 10 Brands

JB Chemicals & Pharmaceutical Ltd (JB Pharma) has announced that the company has inked a trademark license agreement along with promotion and distribution pact with Novartis for select ophthalmology brands entailing a total sum of Rs 1,089 Crore.

Read More

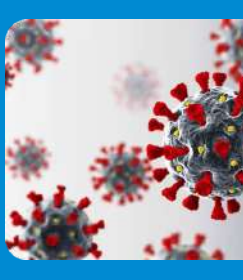
Lupin launches Softovac Liquifibre, a first-of-its-kind liquid fibre

LupinLife, the consumer healthcare business of global pharma major, Lupin Limited (Lupin) announced the launch of Softovac Liquifibre, a 100% ayurvedic liquid laxative. With this, the company enters the Indian liquid laxative market with this innovative product that is a formulation of Isabgol fibre in liquid form and natural actives such as Sonamukhi, Harad, Mulethi, Saunf, Amaltas and Gulab Dal.

Read More

JN-1 a variant of interest, yet India needs to be prepared & proactive for early diagnosis: Dr. Gowri Kulkarni

The coronavirus variant JN.1, which is causing concern among medical experts and the public alike, for now is a variant of interest. It is causing infection, spreading and we need to keep an eye on it. Hence, India needs to be prepared and proactive for its early diagnosis, said Dr. Gowri Kulkarni, Head of Medical Operations, MediBuddy, an integrated healthcare ecosystem platform. The incidence of JN.1 in Kerala reported on December 8, 2023 and its ensuing four fatal cases taking the total number to 1,828 in India as on December 18, 2023, have led to rise in apprehensions. There is need to embark on a stringent surveillance drive, she added.



Read More

Maharashtra FDA unveils Rs. 24.59 crore strategy to overhaul drug regulatory system

In a bid to strengthen its drug regulatory system, the Maharashtra Food and Drug Administration (FDA) has unveiled a comprehensive overhaul strategy, deftly utilizing Rs. 24.59 crore from the Rs. 136 crore Central assistance scheme until March 2024. This Centrally Sponsored Scheme (CSS), with a 60:40 financial partnership between the Central and state governments, aims to strengthen the state's drug regulatory infrastructure. Underscoring the gravity of the situation, the Union health ministry is actively reviewing the scheme every two years, which was set into motion on May 1, 2017. The ambitious initiative, slated to conclude on March 31, 2025, signifies a collaborative effort to elevate Maharashtra's drug regulatory apparatus to international standards.

FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

Read More

AstraZeneca India partners with Roche Diagnostics India to improve diagnostic testing for breast cancer patients

AstraZeneca Pharma India Ltd. signed a memorandum of understanding (MoU) with Roche Diagnostics India to improve diagnostics for breast cancer patients with a key focus to streamlining HER2 diagnostics with newer advancements in the field. Breast cancer, globally the most prevalent cancer among women, takes a critical turn when transitioning to metastatic stages, accounting for 30% of post-diagnosis cases and constituting a primary cause of breast cancer-related fatalities. Vital to patient care is the reassessment of biomarkers, specifically HER2, guiding crucial treatment decisions. The 15% to 20% of cases identified as HER2 positive present opportunities for targeted therapies, with advancements in HER2 testing continually optimizing its clinical application since the 1980s.

Read More

The Veeda Newsletter

DECEMBER 2023: ISSUE 12

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