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The Veeda Newsletter

AUGUST 2023: ISSUE 08

BIOPHARM AMERICA™ September 13–14, 2023
Research Triangle Park, North Carolina

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Meet Veeda Experts at
Biopharm America 2023 for Potential Drug Development Collaborations

Mr. Ajay Tandon
Managing Director

Mr. Rajkumar Agarwal
Chief Business Officer

Book a meeting

Partners in Creating
a healthier tomorrow

Veeda News
News about our two webinars and launch of CRONOS Clinical Module Software

Regulatory
Global regulators confirm good safety profile of COVID-19 vaccines

Financial
Troikaa Pharma's paracetamol intramuscular injection exempted from price control for five years

Clinical Research
JACC-HF reports successful heart failure trial with Daxor BVA-100

Merger and Acquisition
Novartis completes acquisition of Washington-based biopharma company, Chinook Therapeutics

Indian Pharma
Akums launches vildagliptin SR and metformin SR tablets to manage diabetes

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VEEDA NEWS

Register for our latest webinar on SAS Programming for Patient Narratives in Clinical Trials

In this webinar, we will be exploring the role of SAS in producing Regulatory-Compliant Patient Narratives, determine the role of Data Consistency by offering comprehensive insights into study participants and gain insight into Adverse Events, Concomitant Medications, Drug Administration, Laboratory Results, and other related events.

Register Now!

Launch of our customized CRONOS Clinical Module Software

We are pleased to announce the launch of our customized “CRONOS” Clinical Module software, a significant step forward in our ongoing efforts to upgrade clinical conduct and enhance operational effectiveness. “CRONOS” empowers us through its efficient data management capabilities & streamlined paperless processes, reinforcing our commitment to delivering quality outcomes.

Read Now!

Watch our webinar on Lung Cancer Clinical Trials Evaluating Efficacy & Overcoming Resistance

The webinar discusses the shift from non-specific chemotherapy to targeted therapies in lung cancer treatment. These modern therapies focus on specific receptors or genes responsible for rapid cancer cell growth, thereby minimizing damage to healthy cells and reducing side effects.

Watch Now!

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Launch of the WHO Online Repository of Evidence-Informed Decision-Making (EIDM) Tools

The WHO online repository of evidence-informed decision-making (EIDM) tools is the first of its kind to highlight WHO tools and external tools utilized by WHO to facilitate knowledge translation and partner organizations involved in planning, managing, monitoring, and evaluating the process of evidence use and implementation. The Evidence to Policy and Impact Unit of the Research for Health Department in the Science Division, in collaboration with the Evidence-Informed Policy Network (EVIPNet), has developed the repository of tools to support its EIDM capacity-sharing work.

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Gilead announces US FDA places partial clinical hold on initiation of new patients in magrolimab studies to treat AML

Gilead Sciences, Inc. announced that the US Food and Drug Administration (FDA) has placed a partial clinical hold on the initiation of new patients in US studies evaluating magrolimab to treat acute myeloid leukaemia (AML).The FDA action follows the previously announced discontinuation of the phase 3 ENHANCE study of magrolimab in higher-risk myelodysplastic syndromes (HR-MDS).Effective immediately, screening and enrollment of new study participants under the US investigational new drug application (IND 147229) and US Expanded Access Programme will be paused.

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DCGI issues alert on suspected falsified GLP-1-RA products in the market

The Central drug regulator has issued alert on suspected falsified versions of Glucagon-like peptide 1 receptor agonist (GLP-1-RA) products, an anti-diabetes management drug, in the market.The alert follows the World Health Organisation (WHO)'s communication about a safety threat which has been identified with falsified versions of these products being available in the market.GLP-1-RA is a class of pharmaceuticals indicated to manage diabetes type II, which are also sought for weight loss. They are marketed globally under a variety of brands.

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EMA review of data on paternal exposure to valproate

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is reviewing data on the potential risk of neurodevelopmental disorders (NDDs) in children conceived by fathers taking valproate medicines.The review is focussing on data from a retrospective observational study conducted by companies as an obligation following a previous review of valproate use during pregnancy.This retrospective observational study compared the risk of NDDs (including autism spectrum disorder) in children born to men taking valproate with the risk in children born to men taking lamotrigine or levetiracetam (other treatments for epilepsy).

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Global regulators confirm good safety profile of COVID-19 vaccines

EMA has just endorsed a joint statement on the safety of COVID-19 vaccines issued by the International Coalition of Medicines Regulatory Authorities (ICMRA).Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide shows that these vaccines aimed at protecting people from severe outcomes of COVID-19 have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women. The vaccines have saved millions of lives worldwide by significantly reducing the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2.

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DoP notifies PRIP scheme with an outlay of Rs. 5,000 crore to promote research and innovation

The Department of Pharmaceuticals (DoP) has notified the Scheme for Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) with an outlay of Rs. 5,000 crore to support research and development (R&D) and innovation in pharma, medical devices and animal health segments.The scheme has two components comprising strengthening of research infrastructure through establishment of seven National Institutes of Pharmaceutical Education & Research (NIPERs) as Centres of Excellence (CoEs) in specific specialisations at a tentative cost of Rs. 700 crore and promotion of research in Pharma-MedTech sector by providing financial assistance for research in six priority areas - new chemical and biological entities, and natural products; complex generics and biosimilars; precision medicines; medical devices; orphan drugs; and drug development for antimicrobial resistance (AMR).

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Troikaa Pharma's paracetamol intramuscular injection exempted from price control for five years

The National Pharmaceutical Pricing Authority (NPPA) has issued an order exempting paracetamol intramuscular injection formulation of Ahmedabad-based Troikaa Pharmaceuticals from the price control for a period of five years, after taking into account that it is a new drug and has a patent for 20 years from September, 2010.The drug price regulator, while announcing its decision to provide exemption, also said that the company shall inform NPPA, the date of commercial marketing of the formulation paracetamol injection (intramuscular) 250mg/ml in the country and the price to retailer (PTR) and maximum retail price fixed by the company in respect of the formulation by issuing a price list in Form V under DPCO, 2013.

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NPPA modifies guidelines for change in manufacturer to allow existing market entity to produce in its own plant

The National Pharmaceutical Pricing Authority (NPPA) has modified the parameters in its guidelines for allowing change of manufacturers after retail price of formulations are approved, allowing the existing marketing entity to produce the medicine in its own plant.The decision modifying the guidelines finalised in May, 2023, will be a relief to the marketing firms as they will have the flexibility to start manufacturing the products on their own, if required.However, the Authority in its recent meeting which approved the modification, refused to accept the industry's suggestion that the change of manufacturer may be notified by way of filing Form V only, instead of seeking approval.

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NPPA approves 157 intimations for discontinuation of scheduled formulations from April 2020 to July 2023

The National Pharmaceutical Pricing Authority (NPPA) has received a total of 226 intimations under Form IV for discontinuation of scheduled formulations from the market between April 1, 2020 and July 31, 2023 and has approved 157 cases.According to the data from the NPPA, it has approved 27 Form IV intimations in 2022-23 with directions to most of the applications to continue production till certain months of the year 2023, as compared to 48 approved in 2021-22 and 36 in 2020-21. In 2021-22, the 36 Form IV filed included an application for discontinuation of a total of 81 compositions.

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NPPA fixes retail price of 44 formulations

The National Pharmaceutical Pricing Authority (NPPA) has fixed retail price of 44 formulations including anti-diabetic, blood pressure lowering and anti-inflammatory combinations.The Authority meeting held on July 31, 2023 discussed the cases of retail price fixation of the new drugs based on a total of 44 applications filed by the companies and gave its nod to the retail price of all the formulations after considering representations in some of the cases.The formulations that received the price approval include paroxetine controlled release and clonazepam capsules manufactured by Akums Drugs and marketed by Eris Lifesciences, itraconazole capsule (Supra-bioavailable formulation) marketed by Mascot Health Series and marketed by Indchemie Health Specialities, and levetiracetam and sodium chloride infusion manufactured by Akums Drugs and marketed by Mankind Pharma Ltd.

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CLINICAL RESEARCH

Biovica initiates DiviTum TKa clinical trial

Biovica, active in cancer diagnostics, announces the initiation of a prospective clinical trial to study the correlation between DiviTum TKa levels and the effects of medication dose reductions in the care of metastatic breast cancer patients."We are very proud to be partnering with Yale on such an important prospective study. If successful, the trial strengthens DiviTum TKa's clinical evidence which is very valuable in relation to guidelines and reimbursement. Ultimately, the correlation between DiviTum TKa, improved CDK4/6i response and better outcomes is what Biovica is striving for on behalf of patients," said Anders Rylander, CEO of Biovica.

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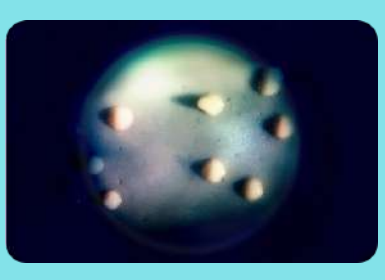
NIH study examines connections between drinking water quality and increased lung infections in people with cystic fibrosis

High levels of some minerals and metals in environmental water supplies may increase the risk of nontuberculous mycobacteria (NTM) pulmonary infections in people with cystic fibrosis, according to a new study from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study, appearing in Environmental Epidemiology, found the presence of the metals molybdenum and vanadium along with sulfate—a collection of mineral salts—in the US municipal water system was associated with an increased incidence of NTM pulmonary infections, the leading cause of drinking-water associated illnesses.



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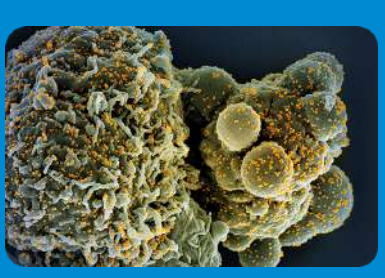
NIH funded study shows severe Covid-19 may lead to long-term innate immune system changes

Severe Covid-19 may cause long-lasting alterations to the innate immune system, the first line of defense against pathogens, according to a small study funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). These changes may help explain why the disease can damage so many different organs and why some people with long Covid have high levels of inflammation throughout the body. The findings were published online in the journal Cell.Researchers led by Steven Z. Josefowicz, Ph.D., of Weill Cornell Medicine in New York City examined immune cells and molecules in blood samples from 38 people recovering from severe Covid-19 and other severe illnesses, as well as from 19 healthy people



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Boehringer Ingelheim to advance survodutide into three global phase III studies in obesity

Boehringer Ingelheim announced it will advance survodutide, its glucagon/GLP-1 receptor dual agonist, into three registrational phase III studies for people living with overweight or obesity. This decision was based on recently presented data from a phase II dose finding study in people living with overweight or obesity. The study demonstrated up to 19 per cent weight loss after 46 weeks of treatment with survodutide."With a strong heritage in cardio-renal-metabolic disease, we are continuing to expand and accelerate our portfolio in this area with the aim of bringing survodutide to patients in need as quickly as possible," said Carinne Brouillon, Head of Human Pharma, Boehringer Ingelheim.

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JACC-HF reports successful heart failure trial with Daxor BVA-100

Daxor Corporation, the global leader in blood volume measurement technology, announces a research letter in the Journal of the American College of Cardiology – Heart Failure reporting on the successful results of a pilot 31 patient randomized control trial (RCT) conducted by the Duke Clinical Research Institute utilizing Daxor's BVA-100 diagnostic to measure clinician assessment accuracy and the impact of optimizing decongestion therapy for heart failure patients with the diagnostic.

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Royalty Pharma, Ferring Pharma ink US$ 500 million royalty agreement for new intravesical gene therapy Adstiladrin

Royalty Pharma plc and Ferring Pharmaceuticals, a research-driven, specialty biopharmaceutical group, announced that Royalty Pharma has acquired a synthetic royalty on US net sales of Ferring's Adstiladrin (nadofaragene firadenovec-vncg) for up to US$ 500 million comprised of an upfront payment of US$ 300 million and a US$ 200 million milestone payment. The milestone payment is contingent on certain manufacturing goals that are expected to be achieved in 2025 for the FDA-approved intravesical gene therapy that Ferring will make available next month through an early experience program for the treatment of adult patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

FERRING PHARMACEUTICALS

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Pyxis Oncology completes acquisition of clinical-stage biopharma company, Apexigen

Pyxis Oncology, Inc., a clinical-stage company focused on developing next-generation therapeutics to target difficult-to-treat cancers, announced the successful completion of its acquisition of Apexigen, Inc. (Apexigen), a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology, in an all-stock transaction valued at approximately $10.7 million.The combined company is positioned at the forefront of ADC innovation with a platform that now includes four key components: novel humanized antibody generation capabilities, an expanded library of linkers with improved stability, site specific conjugation chemistries, and optimized payloads.

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LEO Pharma inks agreement to acquire clinical-stage biopharma company, Timber Pharma

LEO Pharma, a global company dedicated to advancing the standard of care for the benefit of people with skin conditions, announced that it signed an agreement to acquire US-listed clinical-stage biopharmaceutical company, Timber Pharmaceuticals, Inc.Upon closing, this transaction will add an attractive late-stage asset to LEO Pharma's pipeline in medical dermatology. The deal is subject to certain closing conditions including, but not limited to, Timber Pharmaceuticals' shareholder approval.The deal represents a total transaction value of up to $36 million with (i) an initial upfront consideration of $14 million, and (ii) up to an additional $22.0 million in contingent value rights (CVRs) payable upon achievement of certain milestones.

LEO

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Novartis completes acquisition of Washington-based biopharma company, Chinook Therapeutics

Novartis announced that it has completed its acquisition of Chinook Therapeutics, Inc., a Seattle, Washington, based biopharmaceutical company focused on the discovery, development, and commercialization of precision medicines for kidney diseases, in a transaction valued at up to USD 3.5 billion.Chinook's pipeline includes two late-stage assets in clinical development to treat Immunoglobulin A Nephropathy (IgAN), atrasentan and zigakibart (BION-1301), as well as earlier stage research and development programs.

NOVARTIS

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Eli Lilly completes acquisition of DICE Therapeutics

Eli Lilly and Company announced the successful completion of its acquisition of DICE Therapeutics, Inc. The acquisition expands Lilly's immunology portfolio to include DICE's novel oral therapeutic candidates, including oral IL-17 inhibitors currently in clinical development, to treat chronic diseases in immunology."Since our founding nearly 150 years ago, we've strived to make life better for people around the world – but we know that to achieve this goal, we have to bring the brightest minds to Lilly," said Ajay Nirula, Ph.D., senior vice president of immunology at Lilly.

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India's success story in pediatric vaccination program should be further replicated in adult vaccination: Experts

India's success story in pediatric vaccination programme should be further replicated in the form of adult vaccination programme, experts recommended on the occasion of the 2nd edition of the India Vaccine Leaders Conclave (IVLC) held between August 22 and August 23, 2023 under the theme "Building Resilient Vaccine Ecosystems" in Mumbai.Currently approximately 8% of the Indian population is above 65 years of age. It is increasing and estimated to be 19% by 2050.India is doing well in public health intervention in the pediatric vaccination program.

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Akums launches vildagliptin SR and metformin SR tablets to manage diabetes

Akums Drugs and Pharmaceuticals Limited, a leading contract drug manufacturer, has launched vildagliptin SR and metformin SR tablets, a pioneering solution in the fight against diabetes. Designed to cater to patients with type 2 diabetes mellitus who have found inadequate control with metformin monotherapy, this revolutionary combination promises effective glycaemic control and represents a remarkable advancement in diabetes treatment. Vildagliptin SR and metformin SR tablets merge the potent mechanisms of vildagliptin and metformin to offer patients a comprehensive approach to managing their glycaemic levels.

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Agilus Diagnostics launches advanced laboratory in Panjagutta, Hyderabad

Agilus Diagnostics, a subsidiary of Fortis Healthcare Limited., announced the launch of a new laboratory in Panjagutta. The advanced laboratory has the capacity to process 60,000+ samples in a month ranging from simple routine tests to semi-specialized and specialized tests. Recognizing the rising demand for quality diagnostic services, Agilus has expanded its capabilities by launching this laboratory in Hyderabad. The citizens of Hyderabad will now have access to Agilus' extensive test menu comprising of 3,000+ tests and a range of well-curated preventive healthcare packages. The lab will cater to Hyderabad and nearby districts namely Warangal, Karimnagar, Nizambad, Rangareddy etc.

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Mylab introduces a range of dengue tests in the wake of rising dengue cases in India

Mylab Discovery Solutions has introduced two state-of-the-art tests for the detection of dengue infections: the Dengue Rapid Gold Test and the dengue high accuracy Dry Luminescence Assay Test. These rapid point-of-care tests have been developed to meet the critical testing needs for dengue infections in our country.Key features of Mylab's Dengue Rapid Gold Test and Dengue Dry Luminescence Assay Test include differentiation of IgG and IgM antibodies. The tests effectively differentiate between IgM and IgG antibodies, providing valuable insights into the stage and progression of the dengue infection.

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Illumina expands genomics capabilities in India with opening of Solutions Centre

Illumina Inc. a global leader in DNA sequencing and array-based technologies, announced the opening of a new office and state-of-the-art Illumina Solutions Centre in Bengaluru.Illumina's expansion comes after 16 years of working closely with the company's channel partner in India, Premas Life Sciences. Now with its own permanent facility, Illumina will continue to collaborate with Premas to grow the genomics market in India, recognized by the United Nations as the most populous country in the world with more than 1.4 billion people. Expanding access to genomics in this important market will help unlock opportunities for advancing health care and combating the effects of climate change in South Asia.

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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