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The Veeda Newsletter

JANUARY 2023: ISSUE 01

PHARMA SYNERGY

23rd - 24th February 2023, Barcelona

Partners in Creating

a healthier tomorrow

Veeda News
Update on our mini-podcast and an annual conference we attended

Regulatory
EMA Committee for Advanced Therapies elects Ilona Reischl as its new Chair

Financial
NPPA directs Bayer Zydus Pharma to continue selling four scheduled formulations of Urografin

Clinical Research
New research evaluates clinical trials investigating post-acute COVID-19 syndrome treatment

Merger and Acquisition
Sandoz signs agreement to acquire antifungal agent Mycamine from Astellas

Indian Pharma
Pharmexcil to partner with AIBC to facilitate Indian pharma's bilateral trade with Australia

The Veeda Newsletter

JANUARY 2023: ISSUE 01

VEEDA NEWS

Listen to our latest podcast on Identifying the right investigators and patients for your study

Listen to our most recent podcast with Dr. Ashutosh Jani, Head, Clinical Operations Department, to see how Veeda leveraged a strong investigator network to achieve active volunteer involvement in the vaccine research study.

With the aid of Veeda's successful patient enrollment, compliance, and retention techniques, as well as its capability to discover the best locations and investigators, the sponsor was able to complete a vaccine trial volunteer enrollment in just three weeks.

Listen Now!

Glimpse of Veeda representatives at the 13th Annual Conference of the South Asian College of Clinical Pharmacology

We are pleased to share a glimpse of the Veeda representatives at the 13th Annual Conference of the South Asian College of Clinical Pharmacology, an Affiliate of ACCP, "Goal Setting for the Next Decade".

It was our privilege to be an associate sponsor for this event.

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The Veeda Newsletter

JANUARY 2023: ISSUE 01

EMA Committee for Advanced Therapies elects Ilona Reischl as its new Chair

At its January 2023 meeting, EMA's Committee for Advanced Therapies (CAT) elected Ilona Reischl from the Austrian Medicines and Medical Devices Agency (AGES MEA) as its new Chair for a three-year mandate.Before becoming Chair, Dr Reischl served as Vice-Chair of the CAT for the last six years. She replaces Dr Martina Schüssler-Lenz, from the Paul-Ehrlich Institute (PEI) in Germany. "I consider that the CAT's main role is to provide the expertise to ensure that safe and efficacious advanced therapy medicinal products are approved, for the benefit of the patients." said Dr Reischl.

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US FDA clears ImmPACT Bio's IND application for novel bispecific CAR to treat aggressive B-cell lymphoma

ImmPACT Bio USA, Inc., a clinical-stage company developing transformative logic-gate-based CAR T-cell therapies for treating cancer, announced clearance of its first Investigational New Drug (IND) application by the US Food and Drug Administration (FDA) for IMPT-314, a bispecific "OR-Gate" autologous CAR T-cell therapy targeting the B-cell antigens CD19 and CD20. IMPT-314 will be studied in a phase 1/2 clinical trial in patients with aggressive B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL).

IMPACT BIO

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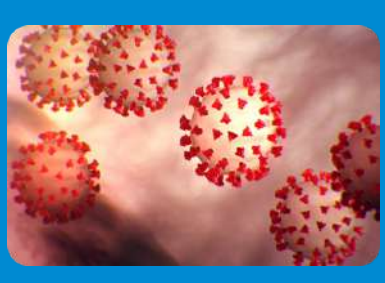
CDC launches website to help consumers find free COVID-19 testing sites

Today CDC launched the COVID-19 Testing Locator website, which will allow consumers to search for free COVID-19 testing sites near them. The locator is part of the CDC Increasing Community Access to Testing (ICATT) program, which provides access to COVID-19 testing, focusing on communities at a greater risk of being impacted by the pandemic, people who do not have health insurance, and surge testing in state and local jurisdiction.



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FDA finalizes guidance on cannabis clinical research

The US Food and Drug Administration has finalized a 2020 draft guidance outlining how sponsors and investigators can conduct clinical trials for certain drugs containing cannabis or cannabis-derived compounds without running afoul of federal law. When Congress passed the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill, it defined hemp as including cannabis and derivatives or extracts of cannabis with "a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis." That means low cannabis-concentration hemp is no longer considered marijuana and is no longer an illegal substance under the Controlled Substances Act (CSA).

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DCGI approves market authorisation for SII's COVID vaccine Covovax as heterologous booster dose

The Drug Controller General of India (DCGI) has approved market authorisation to COVID-19 vaccine Covovax as a heterologous booster dose for adults who have been administered two doses of Covishield or Covaxin, official sources said yesterday.The DCGI's approval came following recommendation by the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO).Prakash Kumar Singh, Director, Government and Regulatory Affairs, Serum Institute of India (SII), had recently written to the DCGI for the approval of Covovax heterologous booster dose for those aged 18 years and above in view of the escalating COVID-19 pandemic situation in some countries, an official source had said.

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The Veeda Newsletter

JANUARY 2023: ISSUE 01

NPPA directs Bayer Zydus Pharma to continue selling four scheduled formulations of Urografin

The National Pharmaceutical Pricing Authority (NPPA) has directed Bayer Zydus Pharma, a joint venture between Bayer (South East Asia) and Cadila Healthcare, to continue production and sales of various strengths and sizes of diagnostic agent Urografin as against the company's application to discontinue the scheduled formulations.The drug price regulator, in the recent Authority meeting held in Delhi, considered the request of the company to discontinue four scheduled formulations - Urografin 76% -20 ml, 50 ml, and 100 ml and Urografin 60%-20 ml under Form IV as per the Schedule II of the Drugs (Prices Control) Order, 2013.

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NPPA revises proposed retail price for Abbott's Nervup Forte Plus upwards following DoP review order

The National Pharmaceutical Pricing Authority (NPPA) has suggested the retail price of Abbott Healthcare's nutritional supplement Nervup Forte Plus at Rs 12.23 per tablet following the Department of Pharmaceuticals' (DoP) order to review the price fixation the drug price regulator has carried out earlier.NPPA, in a revised draft version of price calculation sheet for Alpha Lipoic Acid USP 100mg + Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3mg + Methylcobalamin 1500mcg + Folic Acid IP 1.5mg, stated that there are four companies with a market share of one per cent or above for the product and the average Price to Retailer (PTR) is Rs 10.54.

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NPPA approves ceiling prices of 128 more scheduled formulations from revised Schedule I of DPCO, 2013

The National Pharmaceutical Pricing Authority (NPPA) has revised the ceiling price of 111 scheduled formulations and fixed the ceiling price of 17 new ones in its latest Authority meeting as part of fixing the prices of the formulations listed in the National List of Essential Medicines (NLEM), 2022, which has been amended as the new Schedule I of the Drugs (Prices Control) Order, 2013 recently.The Authority meeting, held on January 11, considered the 134 formulations for which the draft calculation sheet of ceiling prices were uploaded in the NPPA website from December 13 to 23, 2022.

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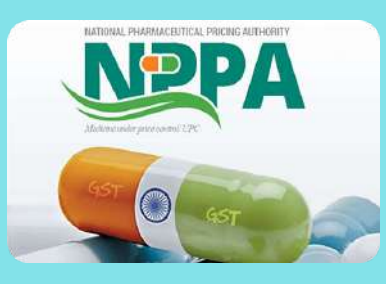
NPPA looks into fixation of retail price of drugs under phase IV clinical trials

The National Pharmaceutical Pricing Authority (NPPA) may fix the retail price of formulations which are under phase IV clinical trials based on the company's application submitted to the central drug regulator for conducting the phase of clinical trials and other documents along with the relevant form. The Authority deliberated the issue of retail price fixation of drugs under phase IV clinical trials after it received applications from the companies. Considering that the matter involves the approval of the drug regulator, the Authority took the view of the representative of Central Drugs Standard Control Organisation (CDSCO) into consideration.



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No need to recall, re-label or re-sticker labels for price revision if manufacturers ensure price compliance

The drug price regulator has clarified that while complying with the prices fixed or revised recently as part of the amended Schedule I of the Drugs (Prices Control) Order, 2013, recalling, re-labelling or re-stickering on the label of the container or pack of released drug stocks in the market prior to the date of notifications is not mandatory, if the manufacturers are able to ensure price compliance at the retailer level through issuance of a revised price list.The clarification comes after the National Pharmaceutical Pricing Authority (NPPA) received some queries from the manufacturers, drug distributors and dealers associations regarding the implementation of notified revised ceiling prices consequent to revision in Schedule I of DPCO, 2013 on the basis of the National List of Essential Medicines (NLEM), 2022.

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veeda clinical research

The Veeda Newsletter

JANUARY 2023: ISSUE 01

Baudax Bio reports positive outcome of interim analysis of phase II randomized trial for BX1000 in patients undergoing elective surgery

Baudax Bio, Inc., a pharmaceutical company focused on innovative products for hospital and related settings, announced the successful outcome of its first interim analysis in a phase II trial of BX1000 for neuromuscular blockade (NMB) in patients undergoing elective surgery."We are encouraged by the results of the first interim analysis of the BX1000 phase II surgery trial," said Gerri Henwood, Baudax Bio's president and chief executive officer. "We believe the use of BX1000, combined with our reversal agent, BX3000, could make for precise control of timing under neuromuscular paralysis for surgical patients, which could result in time and cost savings for patients and hospitals alike. We look forward to completing enrollment in the study in Q1 and sharing topline results for the study in April 2023."

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Elligo Adds AI-Driven Clinical Research Study Technology to Accelerate Trials

Elligo Health Research®, the largest healthcare-enabling research organization, has introduced DataAI Connect, a new data and technology platform that will enable rapid, data-driven clinical research. A scalable, end-to-end data platform, DataAI Connect creates efficiencies across the clinical study workflow — reducing human error and rapidly digesting patient data to accelerate clinical trials.

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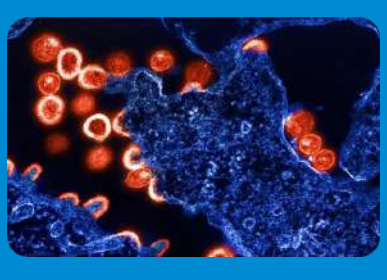
Major Blow as Experimental HIV Vaccine Fails in Late Clinical Trial

The decades-long quest to develop a HIV vaccine has been dealt another major blow, with the 'last true candidate in development' failing to prevent infections any better than a placebo in late-stage clinical trials.The multinational Mosaico study, which began in 2019 and involved more than 3,900 volunteers, was investigating a four-shot HIV vaccine for cisgender men and transgender people who have sex with cisgender men and/or transgender people.As the US National Institute of Allergy and Infectious Diseases (NIAID) reported last week, the trial was stopped after a planned data review by the study's independent data and safety monitoring board found the vaccine was safe, but ineffective.



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New research evaluates clinical trials investigating post-acute COVID-19 syndrome treatment

Over 663 million people contracted COVID-19 globally, of which 10% to 20% suffered from PACS, a complex systemic post-COVID-19 disease with substantial morbidity, per the World Health Organization (WHO) COVID-19 dashboard. Though studies have identified over 100 persistent symptoms associated with COVID-19, most studies have documented fatigue, followed by dyspnea, as the most reported PACS symptom.There is a shortage of medical interventions to treat PACS patients. The data indicate that PACS patients will continue to spike globally in the coming future, increasing the burden on healthcare facilities.

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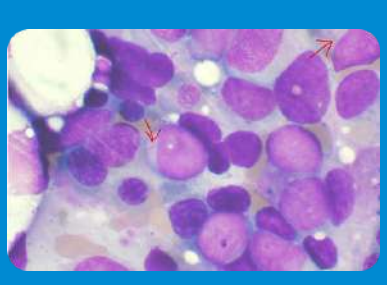
Molecular Partners begins acute myeloid leukemia therapy trial

Molecular Partners has initiated the Phase I first-in-human clinical study of MP0533 for the treatment of acute myeloid leukemia (AML).The Phase I, open-label, dose escalation study has been designed for assessing the efficacy, safety, and tolerability of MP0533 to treat AML.Nearly 20 to 45 patients with relapsed/refractory AML and higher-risk myelodysplastic syndromes (MDS) are planned to be enrolled in the trial across five sites in Switzerland and the Netherlands, along with the selected sites in the HOVON cooperative group.



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The Veeda Newsletter

JANUARY 2023: ISSUE 01

Sandoz signs agreement to acquire antifungal agent Mycamine from Astellas

Sandoz, the global leader in off-patent (generic and biosimilar) medicines, has signed an agreement to acquire worldwide product rights for leading systemic antifungal agent Mycamine (micafungin sodium, Funguard in Japan) from Astellas.Closing is anticipated in the course of H1, 2023, subject to standard conditions and regulatory approvals.Astellas reported Mycamine sales of JPY 18.9 billion (USD 135 million) for the year ending March 31, 2022. The announcement comes after Sandoz successfully completed the acquisition of GSK's global cephalosporins portfolio in October 2021.

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Natus Medical completes acquisition deal with Micromed

Natus Medical Incorporated, a leading provider of medical device solutions focused on the screening, diagnosis and treatment of central nervous and sensory system disorders, has announced the closing of its acquisition of Micromed Holding SAS (Micromed), a global provider of neurophysiology solutions. Micromed products will be added to the Natus Neuro portfolio and developed alongside Natus technologies.

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Sun Pharma To Acquire Concert Pharmaceuticals In $576 Million Deal

Sun Pharmaceutical Industries on Thursday said it has inked a pact to acquire US-based Concert Pharmaceuticals in a $576 million (around Rs 4,688 crore) deal.The companies have executed a definitive agreement under which Sun Pharma will acquire all outstanding shares of Concert through a tender offer for an upfront payment of $8 per share of common stock in cash, or $576 million in equity value, the Mumbai-based drug major said in a regulatory filing.

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Cambrex Acquires Snapdragon Chemistry

Cambrex, a global contract development and manufacturing organization (CDMO) providing drug substance, drug product, and analytical services, announced on Jan. 18 2023 that it has acquired Snapdragon Chemistry, a US-based provider of chemical process development services to a broad range of emerging and established biopharma customers."Today, we welcome our new colleagues from Snapdragon to Cambrex," said Tom Loewald, CEO of Cambrex, in a press release. "With Snapdragon's depth of scientific expertise in API process development, I'm certain our customers will see the benefits of this combination and be delighted to work with Snapdragon's team."

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AstraZeneca to buy US-based clinical-stage biopharma company, CinCor Pharma for $1.8 billion

AstraZeneca has entered into a definitive agreement to acquire CinCor Pharma, Inc. (CinCor), a US-based clinical-stage biopharmaceutical company, focused on developing novel treatments for resistant and uncontrolled hypertension as well as chronic kidney disease.The acquisition will bolster AstraZeneca's cardiorenal pipeline by adding CinCor's candidate drug, baxdrostat (CIN-107), an aldosterone synthase inhibitor (ASI) for blood pressure lowering in treatment-resistant hypertension.Baxdrostat represents a potentially leading next-generation ASI as it is highly selective for aldosterone synthase and spares the cortisol pathway in humans

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The Veeda Newsletter

JANUARY 2023: ISSUE 01

Medical devices industry seeks clarity on misbranded and adulterated medical devices in New Drugs Bill

The medical device industry has sought clarity from the Centre on misbranded and adulterated medical devices with reference to Draft New Drugs, Medical Devices and Cosmetics Bill, 2022.According to industry experts, the draft bill stipulates that medical devices shall be deemed to be misbranded if it “containing colours not expressly permitted in the license or permission issued under this Chapter” with reference to Section 127 (d) misbranded medical devices.Speaking on the sidelines of the recently concluded IPC at Nagpur, Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD) said, “In this regard, we would like to clarify that in medical devices colours are used not only for brand and logo but also for the identification of size/gauge of medical devices.

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Indian pharma makes a strategic shift towards phytopharmaceuticals due to dwindling NCEs

Indian pharma is making a strategic shift towards botanicals or phytopharmaceutical formulations of medicinal plants and herbs. This is because of dwindling new chemical entity (NCE) pipeline.There is an increased interest to go back to nature. This is despite the developments in systems biology and targeted drug development for multi organ therapy with multi target approach, said Dr DB Anantha Narayana, CSO, Ayurvidye Trust .If a well studied lead botanical is selected, it may be possible to develop botanical drugs in much less time to market and at far lower investments than an NCE. For instance, Gugglip tablets is perhaps the first drug approved in India.

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Govt support imp to make Indian pharma $130 bn industry by 2030

The government should take measures to promote innovation and R&D while simplifying regulations for the sector in the upcoming Union Budget, as per pharmaceutical industry bodies.Outlining the wishlist for the sector in the upcoming Union Budget, Indian Pharmaceutical Alliance (IPA) Secretary General Sudarshan Jain said the domestic pharma industry is currently around $50 billion in size and aspires to grow to around $130 billion by 2030 and $450 billion by 2047. "To achieve this vision, the Union Budget 2023-2024 should help fuel innovation and R&D, which will set the pace for propelling the pharmaceutical industry forward," he said.

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No provisions for extension of exemption period for new drugs with indigenous R&D beyond 5 years: NPPA

The National Pharmaceutical Pricing Authority (NPPA) has opined that the provisions for exemption of new drugs developed through indigenous Research and Development (R&D) from the Drugs (Prices Control) Order, 2013 does not provide for extension of exemption period.The opinion was on a request filed by Meril Life Sciences Pvt Ltd for extension of period of exemption from price regulation, granted under Para 32 (ii) of DPCO, 2013 by one year for its Coronary Stent Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100). Interestingly, the price regulator is in the process of refining the Ceiling Price of Coronary Stents after the product was included in the National List of Essential Medicines (NLEM), 2022 through an order recently.

NPPA
AFFORDABLE MEDICINES FOR ALL

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Pharmexcil to partner with AIBC to facilitate Indian pharma’s bilateral trade with Australia

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) will partner with Australia India Business Council (AIBC) to facilitate Indian pharma industry realize its objective of resilient supply chain for active pharmaceutical ingredients (APIs) and faster regulatory approvals in Australia.AIBC is the leading business chamber in Australia responsible for the country’s trade relationship with India.This comes close on the heels of the Indo-Enhanced Cooperation and Trade Agreement (ECTA) signed between India and Australia.

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The Veeda Newsletter

JANUARY 2023: ISSUE 01

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