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The Veeda Newsletter

MAY 2023: ISSUE 05

2023 ASCO ANNUAL MEETING | June 2-6, 2023
McCormick Place, Chicago, Illinois

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Partners in Creating

a healthier tomorrow

Veeda News
News about our events and the launch of our chatbot

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FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults

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Indian Pharma
Indian pharma in aggressive mode to combat bacterial & fungal infections with novel topical formulations: SK Shetty

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Our Latest Podcast on Monoclonal Antibody Study

Hear our latest podcast episode as we explore the complexities of a clinical study on Omalizumab, a biologic drug used to treat severe Asthma and Chronic Idiopathic Urticaria. In this podcast, we'll be delving into the science behind Omalizumab clinical studies and will be covering some key points.

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Veeda Team at 14th Annual Clinical Trial Summit 2023

We are delighted to share a glimpse of Veeda participating as a Gold Sponsor at the 14th Annual Clinical Trial Summit 2023.

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Veeda Bot is Now Live!

With Veeda Bot, you can now quickly and easily navigate through all of our solutions on a single platform. Our chatbot is designed to provide you with the information you need quickly and efficiently, tailoring its responses to your specific needs and preferences.

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FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults

The U.S. Food and Drug Administration approved the oral antiviral Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults.Paxlovid manufactured and packaged under the emergency use authorization (EUA) and distributed by the U.S. Department of Health and Human Services will continue to be available to ensure continued access for adults, as well as treatment of eligible children ages 12-18 who are not covered by today's approval.

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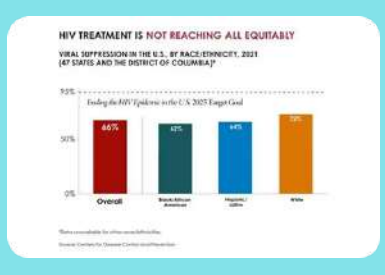
HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections

Estimated annual new HIV infections were 12% lower in 2021 compared to 2017—dropping from about 36,500 infections to about 32,100—according to new CDC data published today. The decline was driven by a 34% decrease in new infections among 13- to 24-year-olds, mostly among gay and bisexual males. HIV prevention efforts must go further and progress must be faster, however, for gains to reach populations equitably and for national goals to end the HIV epidemic to be reached.According to CDC's latest estimates, annual HIV infections dropped from 9,300 in 2017 to 6,100 in 2021 among 13- to 24-year-olds.



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Indonesian FDA clears Novarad's VisAR for intraoperative use in stereotactic spinal surgery

Novarad's VisAR, a surgical navigation system that uses augmented reality, has received clearance from Indonesia's FDA for intraoperative use in stereotactic spinal surgery. VisAR is accurate for both open and minimally invasive surgery (MISS). This cutting-edge technology enables surgeons to transform a patient's imaging data into a 3D hologram, which can be projected onto the patient's body with extreme precision. This allows surgeons to concentrate solely on the surgical objective without requiring them to look away towards a separate monitor, providing accurate surgical guidance.

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EMA and European medicines regulatory network lift COVID-19 business continuity status

EMA and the European medicines regulatory network are lifting their respective COVID-19 business continuity measures after successfully handling the unprecedented operational challenges posed by the pandemic. This was foreseen in PDF icon EMA's workplan for 2023-2025 .'Throughout the pandemic we proved time and again that public health was our priority and ensured that patients in Europe could continue to have access to the newest, highest-quality therapeutics and vaccines,' said Emer Cooke, EMA's Executive Director.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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US FDA accepts Roche's sBLA for Vabysmo to treat retinal vein occlusion

Roche announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Vabysmo (faricimab) for the treatment of macular edema following retinal vein occlusion (RVO).The sBLA is based on results from the phase III BALATON and COMINO studies that demonstrated treatment with Vabysmo provided early and sustained improvement in vision, meeting the primary endpoint of non-inferior visual acuity gains at 24 weeks compared to aflibercept. Vabysmo's safety profile was consistent with previous trials.

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IDMA urges NPPA to delete PTS column from Form V of IPDMS-2 to ensure ease of doing business

The Indian Drug Manufacturers' Association (IDMA) has urged the National Pharmaceutical Pricing Authority (NPPA) to make changes in Form V of IPDMS-2 to ensure ease of doing business.During the recent meeting of industry associations to suggest amendments to the Drug Prices Control Order (DPCO), 2013 and the National Pharmaceutical Pricing Policy (NPPP)- 2012, the IDMA pointed out that in the Form V Price List of DPCO 2013, which is to be mandatorily submitted online through the Integrated Pharmaceutical Database Management System (IPDMS-2), a column for Price to Stockist (PTS) has been included.

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NPPA releases draft calculation sheet for 20 scheduled formulations

The National Pharmaceutical Pricing Authority (NPPA) has released the draft calculation of ceiling price for 20 formulations under the revised Schedule I of Drugs (Prices Control) Order, 2013, with proposed ceiling price revision and fixation of prices for new drugs included under the National List of Essential Medicines (NLEM), 2022.The 16th lot of draft ceiling price calculations released by the NPPA include computation of ceiling prices for various strengths of medicines including tuberculosis drug Isoniazid, oral anticoagulant warfarin, leprosy drug clofazimine, corticosteroid drug fludrocortisone, ultrashort-acting depressant for central nervous system thiopental, among others.

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NPPA refers matter related to special pricing of Cipla's asthma inhaler back to MDC

The National Pharmaceutical Pricing Authority (NPPA) has referred the matter related to Cipla Ltd's application to fix special price for its asthma inhaler medicine back to the Multi Disciplinary Committee (MDC) of Experts to provide clear recommendations for further consideration. Cipla has earlier received a favourable order from the Department of Pharmaceuticals (DoP), which in a review order directed the NPPA to issue fresh orders on merits after analysis of the entire facts.In a latest meeting, the Authority took up the matter for consideration but noted that there was no clear recommendation from the Authority.

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NPPA to fix ceiling prices based on existing methodology and add WPI for rest of the scheduled formulations

The National Pharmaceutical Pricing Authority (NPPA), which has fixed the ceiling price of 651 formulations till the end of March, 2023, has said that for the rest of the scheduled formulations for which prices are to be calculated, it will first compute the prices based on the methodology it has announced earlier and will arrive at a final ceiling price by applying the Wholesale Price Index (WPI) increase of 12.12 per cent on it.The Authority in its latest meeting, has fixed the ceiling prices of 20 scheduled formulations under the revised Schedule I of the Drugs (Prices Control) Order, 2013, based on this decision. It has also fixed the retail price of 15 new drugs based on applications from individual companies.

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NPPA brings in various changes in IPDMS 2.0 version to help industry on online filings

The National Pharmaceutical Pricing Authority (NPPA) has made various changes in its Integrated Public Database Management System 2.0 (IPDMS), the cloud-based application to support the industry in statutory filings with the Authority, including a provision to add specific details of the bulk drug in the online product verification form based on the suggestions by the stakeholders.Many of the suggestions are related to the anomalies related to the existing forms and the Authority has said that they would be addressed once the forms are amended.The Authority said that several requests were received for the addition of the new bulk drug/formulation & strengths in the IPDMS 2.0.

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UK MHRA launches public consultation on ICH Good Clinical Practice Guideline which encourages innovation in clinical trials

The UK Medicines and Healthcare products Regulatory Agency (MHRA) is seeking views from the public and other stakeholders in a 3-month long consultation on the Good Clinical Practice (GCP) guideline revised by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The MHRA became a regulatory member of the ICH in May 2022.The ICH E6(R3) GCP guideline supports the MHRA's ambition to maintain patient safety, alongside enabling and encouraging innovation and risk-proportionate regulation of clinical trials within the UK.

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DUO-E phase III trial shows Imfinzi plus Lynparza & Imfinzi alone both significantly improved PFS in advanced endometrial cancer when added to chemotherapy

Positive high-level results from the DUO-E phase III trial showed Imfinzi (durvalumab) in combination with platinum-based chemotherapy followed by either Imfinzi plus Lynparza (olaparib) or Imfinzi alone as maintenance therapy both demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) compared to standard-of-care chemotherapy alone in patients with newly diagnosed advanced or recurrent endometrial cancer. There was a greater clinical benefit observed with the combination of Imfinzi and Lynparza as maintenance treatment.Overall survival (OS) data were immature at the time of this analysis however, a favourable trend was observed for both treatment regimens.

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Daiichi Sankyo begins phase 3 trial of mutant strain Covid-19 vaccine, DS-5670 in Japan

Daiichi Sankyo announced that it has administered an mRNA vaccine (DS-5670) against the novel coronavirus infectious disease (Covid-19), which is being developed by Daiichi Sankyo in Japan, to the first subject in a phase 3 clinical trial of a booster vaccination with an Omicron-adapted bivalent vaccine (booster vaccination trial).This booster vaccination trial is a phase 3 clinical trial that enrolls approximately 1,400 healthy individuals who have completed the primary and booster series of vaccination with a Covid-19 vaccine approved in Japan and evaluates the efficacy and safety of DS-5670 (Omicron-adapted bivalent vaccine) using a Covid19 vaccine (Omicron-adapted bivalent vaccine) approved in Japan as the control.

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Sony, Astellas enter collaborative research pact to discover a novel ADC platform for oncology field

Sony Corporation and Astellas Pharma Inc. announced that they have entered into a collaborative research agreement to discover a novel antibody-drug conjugate (ADC) platform in oncology based on Sony's unique polymeric material, "KIRAVIA Backbone." ADC is expected to selectively deliver anti-cancer drugs to target cells, thereby increasing efficacy and reducing side effects caused by anti-cancer drugs attacking normal cells. The technology to create linkers which conjugates antibodies and drugs, is considered to be a key to development of a better-performing ADC.

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Hummingbird Bioscience, Merck collaborate to evaluate HMBD-001 in combo with cetuximab in squamous NSCLC

Hummingbird Bioscience, a data-driven precision biotherapeutics company discovering and developing transformative biologic medicines for hard-to-treat diseases, announced it has entered into a clinical trial collaboration and supply agreement with Merck to evaluate HMBD-001 in combination with cetuximab in squamous non-small cell lung carcinoma (sqNSCLC).Under this collaboration, Hummingbird Bioscience will evaluate the safety, tolerability, and anti-tumour activity of its potentially best-in-class HER3-targeting antibody,

Hummingbird Bioscience

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Sun Pharma plans to acquire 100 per cent stake in Israel's Taro in all-cash deal

India's largest pharmaceutical company Sun Pharma on Saturday proposed to fully acquire Israel-based Taro Pharmaceutical Industries through a reverse triangular merger. The Mumbai-based drug major, which currently owns a 78.48% stake in Taro, will purchase the shares in the all-cash deal for $38 per ordinary share that will be paid in full at the completion of the proposed transaction."We believe that the proposed transaction provides a compelling liquidity opportunity for the company's shareholders and will benefit the company and all of its stakeholders," the company said in its filing to the Bombay Stock Exchange.

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Evercare Group, Indus Health Plus enter year-long partnership

Evercare Group and Indus Health Plus have announced a new 12-month exclusive partnership to provide extended care to beneficiaries of Indus Health Plus at Evercare facilities. Evercare, a healthcare service provider with facilities in India, Bangladesh, Pakistan, Kenya, and Nigeria, and Indus Health Plus, a healthcare organisation providing services to their customers, will collaborate on a project that will allow Indus Health Plus to refer their beneficiaries to Evercare Facilities. Under the MoU, Evercare Facilities will provide medical services to Indus Health Plus' beneficiaries on a direct billing basis. Medical services covered under this collaboration include physician services, nursing care, diagnostic tests, medical procedures, and more.

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Pyxis Oncology to acquire clinical-stage biopharma company, Apexigen for $16 million

Pyxis Oncology, Inc., a clinical-stage company focused on developing next-generation therapeutics to target difficult-to-treat cancers, and Apexigen, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology, announced a definitive agreement by which Pyxis Oncology will acquire Apexigen in an all-stock transaction for an implied value of $0.64 per Apexigen share. For each share of Apexigen, Pyxis Oncology will issue 0.1725 shares of its common stock, par value $0.001 per share, for a total enterprise value of approximately $16 million.

PYXIS ONCOLOGY Apexigen

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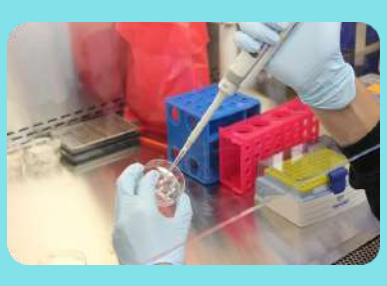
CohBar, Morphogenesis ink merger agreement to advance an innovative late-stage clinical immuno-oncology pipeline of therapies to overcome resistance to cancer immunotherapy

CohBar, Inc., a clinical-stage biotechnology company, and Morphogenesis, Inc., a privately-held phase 2/3 clinical-stage biotechnology company, announced that they have entered into a definitive agreement for an all-stock transaction forming a company combining expertise and resources to advance a late-stage oncology pipeline. The combined company will focus on advancing Morphogenesis' two technologies that seek to overcome the major obstacles that limit the effectiveness of current immunotherapies in treating cancer. The combined company is expected to operate under the name "TuHURA Biosciences, Inc." and to trade on The Nasdaq Capital Market ("Nasdaq"). The transaction is expected to close in the third quarter of 2023.



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Worldwide enters rare disease partnership with Every Cure

Full-service contract research organisation (CRO) Worldwide Clinical Trials has partnered with Every Cure to expedite the discovery of treatments for patients with rare diseases.Worldwide will serve as a drug development and clinical trial partner to Every Cure, a non-profit organisation that aims to 'unlock the full potential of existing medicines to treat every disease possible'.The company will make use of its clinical development and rare disease expertise to identify links between rare diseases and generic drugs.

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Indian pharma in aggressive mode to combat bacterial & fungal infections with novel topical formulations: SK Shetty

Indian pharma industry is in an aggressive mode to combat bacterial and fungal infections with novel topical formulations. This is going by the fall in immunity, increasing environmental conditions, climate change, pollution, rise in stress across age-groups and growing number of bed ridden patientsin the geriatric segment specifically in dermatology, said Sridhar Kumar Shetty, managing director, Nemus Pharmaceuticals.The global topical drug delivery market in terms of revenue is estimated to be worth $207.4 billion as of 2022 and is poised to reach $317.8 billion by 2027, growing at a CAGR of 8.9% from 2022 to 2027.

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India makes cough syrup testing mandatory for exports

The Indian government has made it compulsory for cough syrup makers to get samples tested before exporting their products.Starting 1 June, these companies will have to get a certificate of analysis from a government-approved laboratory.The rule change comes after some Indian-made cough syrups were linked to deaths in The Gambia and Uzbekistan.The controversies had cast a pall over India's pharmaceutical industry, which makes a third of the world's medicines.

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Public health initiatives by Takeda to strengthen health system for rare diseases in India

Takeda Biopharmaceuticals India Private Limited (formerly known as Baxalta Bioscience India Private Limited), a global values-based, R&D-driven biopharmaceutical leader conducted dissemination of its public health initiatives in strengthening the health system for rare diseases (RD) in India. These initiatives aim to improve access to healthcare for rare disease patients who otherwise face significant outcomes like childhood disabilities and life-long morbidity, early mortality, and progressively poor Quality of Life. The meeting was witnessed by Takeda's partners including APCO Worldwide, MAMTA Health Institute for Mother and Child, US-India Strategic Partnership Forum, and DakshamA Health and Education.

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Gujarat FDCA in collaboration with NIC soon to issue NCC and PC of pharma cos online towards ease of doing business

The Gujarat Food and Drugs Control Administration (FDCA) in collaboration with the National Informatics Centre (NIC) will soon be issuing Non Conviction Certificates (NCC) and Performance Certificates (PC) of pharma companies online towards Ease of Doing Business (EoDB).NCC provides a declaration in the prescribed proforma, stating that the licensee has not been convicted for the violations of provisions of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 for sales units.NCC is required to be produced by the manufacturers to the procurement agency as part of the tender condition for government medicines supply. Mostly MSMEs take part in the tender process to fulfill the state government supply.

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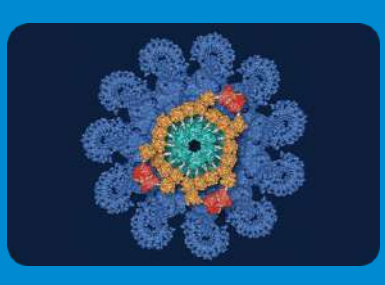
Novartis gets Indian patent for NLRP3 Inflammasome inhibitors

Swiss pharma major Novartis AG has received an Indian patent for its NOD like receptor protein 3 (NLRP3) inflammasome inhibitors which could be used to treat a large number of inflammatory diseases which are caused by a faulty NLRP3 pathway. Companies including Novartis have been pursuing the potential for NLRP3 inflammasome inhibitors to find new ways to treat chronic diseases from Alzheimer's disease, cancer, to osteoarthritis among others. Novartis filed the application for patent for the invention NLRP3 inflammasome inhibitors with the Indian Patent Office on May 15, 2020 and it was published on November 20, 2020. The patent has been granted by the Deputy Controller of Patents & Designs, on May 2, 2023, for the term of 20 years from May 15, 2020 in accordance with the provisions of the Patents Act.



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