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# The Veeda Newsletter

APRIL 2023: ISSUE 04

BIO KOREA International Convention

May 10-12, 2023
COEX, Seoul

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Meet Veeda Group Experts at

# BIO Korea 2023

**Mr. Rajkumar Agarwal**
Head, Business Development

**Mr. Sanjib Banerjee**
Chief Operating Officer

**Mr. Gamlendra Mishra**
Business Development Manager

Book a meeting

Partners in Creating

## a healthier tomorrow

### Veeda News
Introducing our Chatbot- "Veeda Bot" & glimpse of Veeda Experts at CPHI North America 2023

### Regulatory
Takeda gets FDA expansion of HyQvia to treat kids with primary immunodeficiency

### Financial
Sapphiros awarded $11 million from NIH RADx Tech to develop a next-generation molecular OTC test

### Clinical Research
India turns out to be a responsive market for clinical data management for clinical trials engagement

### Merger and Acquisition
Merck acquires Prometheus Biosciences for approximately $10.8 billion

### Indian Pharma
EIZO Corporation expands its global footprint with launch of Indian subsidiary

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## Introducing our Chatbot - "Veeda Bot"

With Veeda Bot, you can now quickly and easily navigate through all of our solutions on a single platform. Veeda Bot will walk you through the process, making sure you have a simple and hassle-free experience, whether you're looking to learn more about our services, visit our scientific resource hub or want to submit a business enquiry and much more.


**Know More!**

## Veeda Experts were at CPHI North America 2023

We are excited to share a glimpse of our team who attended CPHI North America 2023. Our team had a great opportunity to discuss the drug-development needs of Generics, Complex Generics, and Innovator drug molecules with various global pharma and biopharma companies.


**Know More!**

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## CDC's Disease Detectives Give First-Hand Accounts from the Front Lines of Public Health

Global pharma major Lupin Limited (Lupin) announced that its alliance partner Caplin Steriles Limited (Caplin) has received final approval from the United States Food and Drug Administration (FDA) for its Abbreviated new Drug Application (ANDA) rocuronium bromide injection, 10mg/mL in 5 mL and 10 mL multi-dose vials, to market a generic version of Zemuron bromide injection, 50 mg/5 mL and 100 mg/10 mL of Organon USA Inc. Rocuronium bromide injection (Zemuron) had an annual sale of approximately USD 53 million in the US (IQVIA MAT December 2022).


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## Single-arm trials as pivotal evidence for the authorisation of medicines in the EU

EMA has opened a public consultation on a PDF icon reflection paper that discusses key concepts for single-arm clinical trials that are submitted as pivotal evidence in support of marketing authorisation applications for medicines in the European Union (EU). This is the first guidance document by an international medicine regulator articulating the considerations and challenges associated with this type of clinical trials. Stakeholders are invited to send their comments via an online form by midnight (CET) on 30 September 2023.

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## CDC simplifies COVID-19 vaccine recommendations, allows older adults and immunocompromised adults to get second dose of the updated vaccine

Following FDA regulatory action, CDC has taken steps to simplify COVID-19 vaccine recommendations and allow more flexibility for people at higher risk who want the option of added protection from additional COVID-19 vaccine doses.CDC's Advisory Committee on Immunization Practices (ACIP) met today to discuss these COVID-19 vaccine recommendation changes, and the associated implications and implementation. Although there was no vote at this meeting, ACIP members expressed their support for these recommendations.

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## Takeda gets FDA expansion of HyQvia to treat kids with primary immunodeficiency

Takeda revealed it was building a new manufacturing facility in Japan which would increase the company's capacity for plasma production nearly fivefold in that country.Three weeks later, it has become apparent why Takeda wanted to be able to make more of the blood-derived therapies. The FDA has signed off on an expansion for HyQvia to treat children with primary immunodeficiency (PI).The subcutaneous immune globulin therapy, which is the lone PI treatment administered once a month, is now available to patients 2 years and older.


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## FDA updates generic transdermal and topical delivery systems guidances

The US Food and Drug Administration (FDA) on Wednesday issued two revised draft guidances for generic drug submissions that use transdermal and topical delivery systems (TDS). The revised guidances make numerous technical clarifications that abbreviated new drug application (ANDA) sponsors should consider when filing their premarket application. The revised documents update previous draft versions issued in 2018 and shed light on the agency's evolved thinking on how generic drug TDS products should be evaluated. (RELATED: Latest Batch of FDA Product Specific Guidances Focus on Topical, Transdermal Drugs, Regulatory Focus, 9 October 2018)

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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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## Mankind Pharma sets IPO price band at Rs 1,026-1,080 per share

Drug maker Mankind Pharma on Wednesday said it has fixed a price band of Rs 1,026-1,080 a share for its Rs 4,326-crore initial public offering (IPO).The three-day initial public offering (IPO) will open for subscription during April 25-27, and the bidding for anchor investors will open on April 24, the company announced. The company's IPO is entirely an offer for sale (OFS) of 40,058,844 equity shares by promoters and other existing shareholders.


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## Sapphiros awarded $11 million from NIH RADx Tech to develop a next-generation molecular OTC test

Sapphiros, a platform company dedicated to building the next generation of consumer diagnostic technologies, announced that the it has been selected by the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Tech programme to develop a high performance, over-the-counter (OTC), molecular multiplex respiratory diagnostic test that can rapidly detect RSV, influenza A, influenza B and Covid-19 in a single test.Sapphiros has been awarded $11.1 million to deliver the initial programme of work, which combines proprietary isothermal molecular chemistries and proprietary high-volume, reel-to-reel conductive ink, printed electronics, and sensing technologies.

SAPPHIROS

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## NPPA asks industry to submit price details of 139 formulations as part of revising ceiling price

The National Pharmaceutical Pricing Authority (NPPA) has sought the industry to furnish the Price To Retailer (PTR) and Moving Annual Turnover (MAT) of a total of 139 formulations as part of fixing the ceiling prices of these scheduled formulations under the revised Schedule I of the Drugs (Prices Control) Order (DPCO), 2013.The formulations for which the details were sought include abacavir tablet 60 mg, combination of abacavir 60 mg and lamivudine 30 mg, various strengths of acetylsalicylic acid, amikacin injection, activated charcoal, amoxicillin, combinations of artesunate and sulfadoxine pyrimethamine, barium sulphate, bendamustine hydrochloride, benzylpenicillin powder for injection, budesonide nasal spray, calcium foliage injection, cefadroxil tablet, cefazolin powder for injection, chlorhexidine solution 5%, clarithromycin tablet and capsules, among others.


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## NPPA refers industry representation on 50% price cut on patented components to MDC

The National Pharmaceutical Pricing Authority (NPPA) has deferred fixing price of various anti-diabetic drug formulations with components which went off-patent of late, in a recent meeting, and referred the matter back to the Multi Disciplinary Committee (MDC) of Experts for examination in the light of industry representations.The development is in connection with the NPPA's methodology to calculate the price of drugs which have recently gone off-patent, under which it reduces the price of the patent component by 50 per cent while fixing the retail price.

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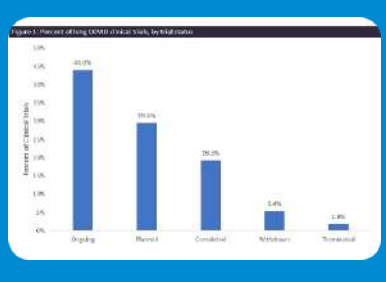
## The lasting effects of the Covid-19 pandemic

As the Covid-19 pandemic becomes endemic, it continues to have lasting effects, especially with lingering symptoms in those who were diagnosed with the infectious disease. The National Institute of Health (NIH) named these lasting symptoms post-acute sequelae of SARS-CoV-2 infection (PASC), also known as long Covid. Long Covid consists of a wide range of conditions that can last for weeks, months, or even years after infection. The most common symptoms include tiredness and fatigue, shortness of breath, and change in smell or taste. Certain people or groups are at a higher risk of developing these conditions, including individuals who experienced a more severe Covid-19 illness, those who had underlying health conditions prior to having Covid-19, and those who did not get a Covid-19 vaccine.



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## MaaT Pharma announces US FDA lifts clinical hold on phase 3 IND application for MaaT013 in patients with acute graft-versus-host disease

MaaT Pharma, a clinical-stage biotechnology company, reported that the US Food and Drug Administration has lifted the clinical hold and cleared the Investigational New Drug (IND) application to initiate in the US an open-label, single arm phase 3 pivotal clinical trial evaluating the safety and efficacy of MaaT013 to treat gastrointestinal acute Graft-versus-Host Disease (aGvHD) as a third line of treatment. "We are grateful for the FDA's continued engagement and are very pleased with the lift of the hold on MaaT013's IND application. This is the first time the Agency has authorized the phase 3 clinical evaluation in the US of a microbiota-based live biotherapeutic based on a pooling technology, which provides greater bacterial diversity, in a standardized and scalable approach, with the goal of safely improving patients' outcomes.

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## MIT researchers develop wearable patch for painlessly deliver drugs through the skin

The skin is an appealing route for drug delivery because it allows drugs to go directly to the site where they're needed, which could be useful for wound healing, pain relief, or other medical and cosmetic applications. However, delivering drugs through the skin is difficult because the tough outer layer of the skin prevents most small molecules from passing through it. In hopes of making it easier to deliver drugs through the skin, MIT researchers have developed a wearable patch that applies painless ultrasonic waves to the skin, creating tiny channels that drugs can pass through. This approach could lend itself to delivery of treatments for a variety of skin conditions, and could also be adapted to deliver hormones, muscle relaxants, and other drugs, the researchers say.

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## Human centred clinical trials driving increased participation

At UCB, patients are at the center of everything we do. With that comes an understanding that patients are not only patients but are first and foremost human beings. That is why innovation, to me, means human centric health, and delivering human centred clinical trials as part of people's health journey.When it comes to clinical trials our vision is to educate, empower and enable all patients to actively participate. Traditionally, clinical trials were conducted in a clinical setting in 100% of cases. That is all changing, with a move towards hybrid clinical trials split between the clinic and the home, where possible, and putting human needs at the center of our clinical trials.

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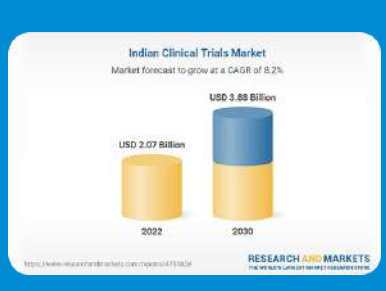
## India turns out to be a responsive market for clinical data management for clinical trials engagement

India has turned out to be a responsive market for clinical data management for clinical trials engagement. In the past, clinical data was often collected using paper-based systems, making it difficult to manage and analyze large amounts of data. This led to errors, delays, and increased costs.According to Krutikesh Age, co-founder, DPHS, a clinical research, development, diagnostics and data management solutions company, with the advent of electronic data capture (EDC) systems, clinical data management became more efficient and reliable. EDC systems allowed for faster data collection, real-time data monitoring, and improved data quality.

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## RetinAI partners with Boehringer Ingelheim to advance novel treatments for patients with geographic atrophy using AI

RetinAI Medical AG (RetinAI), a leader in clinical and imaging data management software and advanced analytics using AI for ophthalmology, announced a new partnership with Boehringer Ingelheim. The companies aim to improve patient outcomes in geographic atrophy (GA) by combining RetinAI's Discovery platform and AI tools with Boehringer Ingelheim's research in retinal diseases. GA is a progressive, advanced form of age-related macular degeneration and a leading cause of complete loss of sight, estimated to affect around 5 million people worldwide1. The number of people affected by GA increases exponentially with age. As the population ages, the prevalence of the disease is expected to rise. The loss of vision is traumatic and permanently impacts many aspects of life.


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## Everest Medicines partners with Shanghai Pharma subsidiary to accelerate the commercialization of Xerava in Mainland China

Everest Medicines, a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative medicines and vaccines, announced that it has signed a Memorandum of Understanding (MoU) for a strategic partnership with a subsidiary of Shanghai Pharma, SPH Keyuan Xinhua Pharmaceutical Co., Ltd. (SPH Kyuan).According to the MoU, Everest and SPH Kyuan will work closely to promote import and channel distribution of Xerava (eravacycline) in China. SPH Kyuan's leading position in drug import, nationwide distribution network, and modern logistics system will help expand the scale and speed of commercialization of Xerava to benefit patients and address urgent unmet needs in the country.

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## Headlands acquires clinical research site in Massachusetts

Headlands Research has acquired a Massachusetts–based clinical research site specialised in neurodegenerative diseases such as Alzheimer's and Parkinson's.The Headlands Research Eastern Massachusetts site is set to deepen the neurology research capabilities of the expanding network of multinational trial sites.With a focus on diversity, quality, and advanced technology, the site aims to improve the lives of people through new medical therapies.

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## GSK to acquire Canada-based late-stage biopharma company, BELLUS Health for US$ 2.0 billion

GSK plc and BELLUS Health Inc. announced that they have entered into an agreement under which GSK will acquire BELLUS, a Canada-based, late-stage biopharmaceutical company working to better the lives of patients suffering from refractory chronic cough (RCC) for US$ 14.75 per share of common stock in cash representing an approximate total equity value of US$ 2.0 billion (£1.6 billion).The acquisition provides GSK access to camlipixant, a potential best-in-class and highly selective P2X3 antagonist currently in phase III development for the first-line treatment of adult patients with RCC.


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## Merck acquires Prometheus Biosciences for approximately $10.8 billion

Merck, known as MSD outside the United States and Canada, and Prometheus Biosciences, Inc. (Prometheus) announced that the companies have entered into a definitive agreement under which Merck, through a subsidiary, has agreed to acquire Prometheus for $200.00 per share in cash for a total equity value of approximately $10.8 billion. "At Merck, we are committed to delivering on our purpose to save and improve lives and continue to identify and secure opportunities where compelling science and value creation align," said Robert M. Davis, chairman and chief executive officer, Merck.

MERCK

Prometheus Biosciences

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## Indian pharma firm responds after WHO issues alert against another cough syrup

After World Health Organization (WHO) issued an alert against India-manufactured cough syrup being sold in the Marshall Islands and Micronesia, the company manufacturing the syrup has responded. Based in the northern Indian state of Punjab, QP Pharmachem Limited manufactured the affected product but has alleged that someone duplicated the syrup to defame the Government of India. "Food And Drug Administration (FDA) of Punjab doubt that someone has duplicated the product (cough syrup) sent to Cambodia and then sold it in the Marshall Islands and Micronesia to defame the Government of India," said QP Pharma MD Sudhir Pathak.

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## Sun Pharma introduces Cequa, a novel therapy for dry eye disease in India

Sun Pharmaceutical Industries Limited announced that one of its wholly-owned subsidiaries has launched a novel ophthalmology treatment, Cequa, in India for patients who have dry eye disease (DED) with inflammation, a commonly occurring condition. Cequa is the first dry eye treatment available in India that is delivered with nanomicellar (Ncell) technology. Kirti Ganorkar, CEO – India Business, Sun Pharma, said, “Current treatment options for dry eye disease have limitations and hence a strong unmet need exists in this space. We are excited to introduce Cequa as a new treatment option for dry eye disease in India. This is an important milestone for Sun Pharma as we bring one of our key global specialty products to India."

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## Gujarat FDCA approves layout designs of 1,130 drug manufacturing units from April 1, 2020 till March 31, 2023

The Gujarat Food and Drug Control Administration (FDCA) has approved layout designs of total 1,130 companies from April 1, 2020 till March 31, 2023. In 2020-21, the layout designs of 649 companies were approved, in 2021-22, the layout designs of 214 companies were approved, in 2022- 23, the layout designs of 267 companies were approved. “These companies represent all allopathic, ayurvedic and homoeopathic manufacturing units in the state. These units will be set up in Ahmedabad, Baroda, Bharuch, Gandhinagar, Vapi, Valsad, Rajkot, Morbi and Mehsana. Post approval, the companies do the basic construction work and get manufacturing licenses over a period of 1 to 2 years time,” informed Gujarat FDCA Commissioner Dr HG Koshia.

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## Lupin Diagnostics launches Regional Reference Laboratory in Bengaluru

Global pharma major Lupin Limited (Lupin) announced the launch of its new state-of-the-art Regional Reference Laboratory in Bengaluru, Karnataka, as part of the expansion of its diagnostics network. The new laboratory marks a significant step forward in Lupin Diagnostics' mission to provide accessible and affordable diagnostics and preventive healthcare services across India. The Regional Reference Laboratory complements the company's existing network of 25 laboratories and 410+ collection centres across India.

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## EIZO Corporation expands its global footprint with launch of Indian subsidiary

Japan based EIZO Corporation, a global leader in visual technology, has announced the launch of its new subsidiary, EIZO Private Limited in Mumbai. The establishment of this wholly-owned subsidiary marks EIZO's 11th overseas sales office and solidifies its position as a leading global provider of high-end visual solutions.EIZO offers total imaging solutions with a range of monitors, software, video capture, processing, and distribution solutions, cameras, and advanced integrated technologies, to meet the specialized needs of customers in business, creative fields, healthcare, air traffic control, maritime, security & surveillance.

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