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The Veeda Newsletter

AUGUST 2024: ISSUE 08

Veeda Group CEO and MD, Dr Mahesh Bhalgat delivers keynote address at the 3rd Indian Vaccine Leaders Conclave

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a healthier tomorrow

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Veeda Group Celebrates Independence Day across all Sites in India

All Veeda site locations in India, including those in Gujarat (Ahmedabad and Mehsana) and Karnataka (Bengaluru), were decorated with tricolor ribbons and balloons. Employees from all locations gathered to pay respect and honor the enduring legacy of the heroes who fought for India's freedom.

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Veeda Group Organizes a CRA Workshop for its Clinical Operations Team

The team of 40 clinical research associates underwent training on important topics related to clinical monitoring, uniformity in monitoring visit reports, remote source data verification, eTMF, training on patient eligibility assessment, and other relevant topics.

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Cutting Edge Instruments in Discovery Biology – Veeda Biopharma Division

With a wide array of assays, assay formats, industry-standard technologies and capabilities, Veeda Biopharma is uniquely positioned to provide critical data to accelerate your drug discovery and development.

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Waiver of local clinical trial requirements by CSDSO a well-deliberated move: Shweta Rai

Waiver of local clinical trial requirements is a well-deliberated move by the Central Drugs Standard Control Organization (CDSCO). This being for drugs already approved in well-regulated markets, will help bring medicines to patients with high unmet needs much quicker than before, noted Shweta Rai, managing director India and country division head South Asia, Bayer Pharmaceuticals

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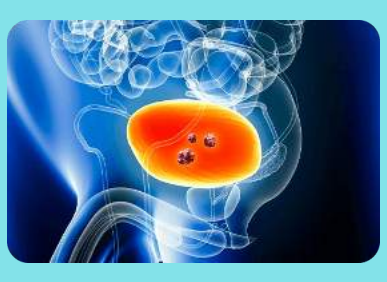
Janssen-Cilag's Balversa receives European approval for adult patients with unresectable or metastatic urothelial carcinoma

Janssen-Cilag International NV, a Johnson & Johnson company, announced that the European Commission (EC) has approved Balversa (erdafitinib) as a once-daily oral monotherapy for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (mUC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting.



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Alembic Pharma gets USFDA nod for generic drug

Alembic Pharmaceuticals on Monday said it has received approval from the US health regulator to market a generic medication used to treat moderate-to-severe psoriasis of the scalp. The company has received final approval from the US Food & Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Betamethasone Valerate Foam, the drug firm said in a statement.

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CDSCO declares 70 drugs tested in July as NSQs

The Central Drugs Standard Control Organisation (CDSCO) has released a list of 70 drug samples declared as Not of Standard Quality (NSQ), with samples of drugs labelled as manufactured by some of the major companies failing the quality test.

The State drug regulators have reported 13 NSQs to the CDSCO in the prescribed format, while CDSCO released the list of 57 NSQs during the month. During July also a large number of States and Union Territories did not submit any data related to NSQ alert to the CDSCO, it reported

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CDSCO must maintain a registry of all brand names of drugs to avoid LASA during dispensing: Dr BR Jagashetty

The Central Drugs Standard Control Organisation (CDSCO) should maintain a registry of all branded drugs in a time-bound manner as it will avoid confusion in medicine dispensing across pharmacy outlets in the country thereby avoiding Look Alike & Sound Alike (LASA) medicines in the market. To this end, Union Health Ministry's plans to crack down on LASA brand names of medicines is laudable as it could pose serious risk to patient safety, said Dr BR Jagashetty, former National Adviser (Drugs Control) to MoHFW & CDSCO and former Karnataka state drugs controller

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Zydus Lifesciences net profit grows 30.6% in Q1FY25

Pharma major Zydus Lifesciences Ltd has posted a growth of 30.6 per cent in net profit during the first quarter of the current fiscal, at Rs. 1,419.9 crore as compared to Rs. 1,086.9 crore during the same period of previous fiscal year. The revenue from operations for the quarter ended June, 2024 stood at Rs. 6,207.5 crore, as compared to Rs. 5,139.6 crore during the same period of previous fiscal year

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Biocon in Q1FY25 registers consolidated revenues of Rs. 4,567 crore, growth up 30%, net profit at Rs. 660 crore

Biocon in Q1FY25 registers consolidated revenues of Rs. 4,567 crore, growth up 30 per cent. The company said that its Q1FY25 consolidated revenue includes proceeds of Rs. 1,057 crore, on account of the strategic collaboration between Biocon Biologics & Eris Lifesciences. Net profit at Rs. 660 crore and net profit margin is 14 per cent. The EBITDA stood at Rs. 1,1755 crore with a 38 per cent growth. The new R&D investment is Rs. 228 crore with an increase of 9 per cent.

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Pharma sector grew 8% in FY24: Report

New product launches by the pharma sector have shrunk by 54% in Q4FY24 as compared to the year-ago period, said a recent report by IQVIA. The report also highlights that the chronic segment grew faster (10%) than the acute segment (3%) in the March quarter.

As per the report, the Indian pharma sector registered a growth of 8% in revenue terms in FY24. However, there was a marginal drop of 3.6% in the last quarter of FY24 compared to the preceding quart

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Medical Devices Parks under DoP scheme report committed investment of over Rs. 13,700 crore

The four medical devices parks being developed under the scheme for Promotion of Medical Devices Parks of the Department of Pharmaceuticals (DoPs) have seen commitments for investment to the tune of over Rs. 13,776 crore till the end of July, 2024. The total committed investment is except for the Park coming in Himachal Pradesh, since the committed investment for this project is not available, according to the ministry of chemicals and fertilisers. While the scheme had a financial outlay of Rs. 400 crore to be implemented within the tenure from 2020-21 to 2024-25, the Centre has released a meagre Rs. 30 crore each for the four projects.

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Eli Lilly rolls out direct patient access to weight loss star Zepbound - at a deep discount

Eli Lilly has come up with a new way of supplying its popular weight-loss drug Zepbound that the company hopes could expand access while addressing other issues such as high prices and off-label cosmetic usage.

Single-dose Zepbound vials in 2.5mg and 5mg dosage strengths are now available for self-pay through the company's online LillyDirect pharmacy at a discount of 50% or more compared to the list price of other GLP-1 medicines for obesity, the company announced.

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SciSparc submits IND application to US FDA for SCI-110 phase IIb trial to treat Tourette syndrome

SciSparc Ltd., a specialty clinical-stage pharmaceutical company, announced the submission of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for its phase IIb clinical trial for its proprietary SCI-110 for the treatment of Tourette syndrome (TS). The phase IIb clinical trial will be conducted at three global leading centers of excellence: the Yale Child Study Center at the Yale School of Medicine in Connecticut, United States, the Hannover Medical School in Hannover, Germany, and at the Tel Aviv Sourasky Medical Center in Israel (Sourasky).

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Qure.ai launches FDA-cleared AI solution for advanced lung nodule quantification on CT scans at AABIP 2024

Qure.ai, a global innovator in medical imaging AI, has announced a pivotal 510(k) FDA clearance for its AI-powered chest CT solution: qCT LN Quant. The new AI solution is now available to support radiologists and pulmonologists in analyzing lung nodules on non-contrast chest CT scans and tracking volumetric growth as part of progression monitoring.

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Bayer is advancing in studies on heart failure management showcasing late-breaking heart failure data from phase III study FINEARTS-HF with finerenone

Bayer will present late-breaking Phase III data on finerenone (Kerendia) in patients with heart failure (HF) and a left ventricular ejection fraction (LVEF) of greater than or equal to 40%, as well as insights on the efficacy and safety of finerenone among patients included in the three completed pivotal trials (FINEARTS-HF, FIDELIO-DKD, and FIGARO-DKD) with overlapping cardio-kidney-metabolic conditions within a Hot Line session at ESC Congress 2024.

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AiViva Biopharma completes patient enrollment in phase 1 trial of AIV007 for age-related macular degeneration and diabetic macular edema

AiViva Biopharma Inc., a clinical-stage biotechnology company, announced that it has fully enrolled and completed dosing the last patient in a phase 1 trial with wet age-related macular degeneration (wAMD), and/or diabetic macular edema (DME). “We have achieved a major milestone, full enrollment in our phase 1, safety trial in the US” said Diane Tang-Liu, PhD, CEO, president & co-founder of AiViva Biopharma. “AIV007 (lenvatinib) is a broad-spectrum tyrosine kinase inhibitor, targeting the convergence of fibrosis, angiogenesis, and inflammation. We believe AIV007, formulated with our proprietary JEL technology and administered periocularly, has the potential to address the root causes of wet AMD, DME and many other ocular diseases. We are on target to have the study completed, and full results Q1 2025.

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Shilpa Medicare successfully completes phase-3 clinical studies of NorUDCA

Shilpa Medicare has successfully completed phase-3 clinical studies of its novel product SMLNUD07 - Nor Ursodeoxycholic Acid (NorUDCA) tablets that is expected to revolutionise the treatment of patients suffering from Nonalcoholic Fatty Liver Disease (NAFLD). This trial was a multicentric, placebo controlled double blinded study conducted on total 165 Nonalcoholic fatty liver disease (NAFLD) patients across India - a significant statistically powered number of patients leading to better reliability of data and results.

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Medi Assist TPA to acquire 100% stake in Paramount TPA from Fairfax Asia and Dr Nayan Shah & family

Medi Assist Insurance TPA, a wholly owned subsidiary of Medi Assist Healthcare Services has signed a definitive documents for 100% acquisition of Paramount Health Services & Insurance TPA, a player in the TPA space, owned by Fairfax Asia and the Shah family. This acquisition marks a milestone in the TPA sector consolidating Medi Assist's position as a market leader. The transaction is subject to customary closing conditions and regulatory approvals from the Insurance Regulator (IRDAI), said the communication note.

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Fischer Medical collaboration with Tech Avant-Garde to enhance health programmes in Indian educational institutions

Fischer Medical Ventures (Fischer MV) has announced significant progress made on it collaboration with Tech Avant-Garde (TAG), a nation-wide innovative educational solutions provider, to co-implement comprehensive health programmes in institutions across India. This strategic partnership that aims to drive holistic healthcare to the Indian student population and their connected communities will enable healthier and more conducive learning environment.

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Tonix Pharma and Bilthoven Biologicals collaborate on advancing development of Tonix's mpox vaccine, TNX-801

Tonix Pharmaceuticals Holding Corp. (Tonix), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, and Bilthoven Biologicals (BBio), part of the world's largest vaccine manufacturer the Cyrus Poonawalla Group, which includes the Serum Institute of India, announced a collaboration to advance TNX-801, Tonix's mpox vaccine candidate. TNX-801 (recombinant horsepox virus) is a live replicating, attenuated virus vaccine based on horsepox in preclinical development to prevent mpox and smallpox.

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McKesson to buy controlling stake in Florida Cancer Specialists' unit for about $2.5 billion

Drug distributor McKesson (MCK.N), opens new tab said on Monday it would buy a controlling stake in community cancer center Florida Cancer Specialists & Research Institute's (FCS) business and administrative services unit for $2.49 billion in cash. McKesson would own roughly a 70% stake in the unit, Core Ventures, which manages non-clinical administrative functions such as providing operational and advisory support services to FCS clinics across Florida.

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Fairfax, Bain look to buy Gujarat API company Farmson

Canadian billionaire Prem Watsa's Fairfax Group and Bain Capital are vying for a buyout of Vadodara-based active pharmaceuticals ingredient (API) maker Farmson Basic Drugs in a deal valuing the company at ₹4,000 crore. "Due diligence has been done by both the private equity firms. The final bids are expected shortly," said a person close to the development. Farmson, founded in 1969 by KK Vithani, is among the largest makers of API paracetamol globally. The company is estimated to make a revenue of ₹2,000 crore in FY25. In FY24, the company made a revenue of ₹1,750 crore and posted a pre-tax profit (Ebitda) of ₹400 crore.

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India set to launch pilot e-commerce export hubs to boost cross-border pharma trade

The Directorate General of Foreign Trade (DGFT) has issued a new trade notice signaling the pilot launch of E-Commerce Export Hubs (ECEH). This initiative, referenced under Section B of Chapter 9 of the Foreign Trade Policy (FTP) - 2023, aims to revolutionize cross-border e-commerce by establishing designated areas equipped with favorable business infrastructure and facilities.

According to the trade notice (Trade Notice No. 14/2024-25), the ECEH concept is centered around several critical objectives like predictability and efficiency. By reducing turnaround time for e-commerce exports, ECEHs will ensure more predictable and faster processing, benefiting exporters

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India needs a more developed API industry-friendly policy for growth of pharma industry: Dr Subhash Mandal

India needs a more developed API industry-friendly policy for the development of the pharma sector and to become self-sufficient in active pharmaceutical ingredients. The industry sector has to match with its counterparts in other countries, especially in the area of drug discovery and development, comments Dr. Subhash C Mandal, chairman of the Regulatory Affairs Division of the IPA and the general secretary candidate for the IPA election.

“Being the oldest and apex pharmacy professional organisation in the country, the Indian Pharmaceutical Association (IPA) has some kind of distinct perspectives about the development of pharma industry and the pharmacy profession, hence as a candidate I presume that the new team of office-bearers who are going to be elected soon will coordinate with the state branches to take the issues with the central and the state governments,” he added.

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US Biosecure Act: Impact on Indian pharma companies

The Biosecure Act has led larger multinational corporations to cautiously explore ways to diversify their supplier base. This has increased the interest from big pharma in Indian companies.

Laurus Labs, for example, has observed the beginning of vendor diversification and an uptick in late-phase project requests.

However, this shift is expected to unfold gradually over time, rather than within a few months or quarters, according to Dr Chava of Laurus Labs who anticipates that companies will start by handing over small projects with collaborations expanding progressively.

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Pharmarack and IPA jointly launch report on evolving Indian pharma supply chain.

Pharmarack Technologies Pvt. Ltd., in collaboration with the Indian Pharmaceutical Alliance (IPA), has released a report titled "Changing Dynamics of Indian Pharma Supply Chain," offering insights into the rapidly evolving landscape of India's pharmaceutical supply chains. Based on data from over 200,000 chemists and 12,000 distributors trading products from more than 6,000 manufacturers across India, the report includes delves into the impact of recent regulations such as Good Manufacturing Practices (Revised Schedule M) and Good Marketing Practices (UCPMP).

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Indian pharma exporters feel pain on Bangladesh crisis

The political unrest and violence in Bangladesh are posing significant challenges for Indian pharmaceutical exporters, leading to stranded funds and concerns over financial stability. This situation threatens to impact medicine availability and healthcare services in Bangladesh. Despite the market's growth potential, many Indian companies are now hesitant to supply without advance payments, emphasising the importance of risk management in this unpredictable scenario.

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