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The Veeda Newsletter

FEB 2021: ISSUE 02

TOUCHING NEW HORIZONS TOGETHER!

Veeda News
Glimpse of our inaugural event for Ingenuity BioSciences

Regulatory
FDA Approves First in the World, First-of-Its-Kind Implant for the Treatment of Rare Bone Disease as a Humanitarian Use Device

Financial
Indian pharma grows for 5th straight month; sales rise 4.5% in January

Clinical Research
Can new ethical guidelines re-shape HIV prevention trials?

Merger and Acquisition
Somru Bioscience and Veeda Clinical Research Announce Joint Venture Global Biotherapeutic Contract Research Organization

Indian Pharma
Covid Vaccine can be a game changer for Indian Pharma Industry on a global platform

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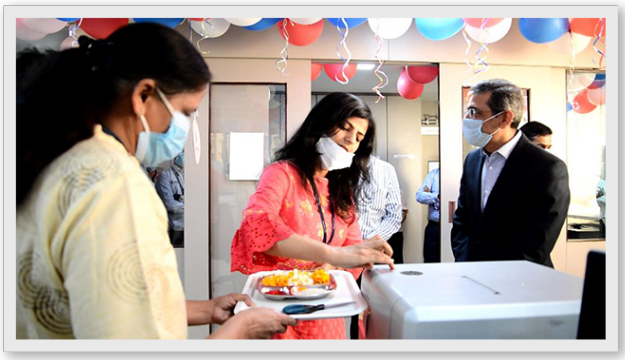
Veeda and Somru announced the launch of their premier global center of excellence lab under the flagship of Ingenutiy BioSciences Pvt. Ltd.



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WHO announces updates on new molecular assays for the diagnosis of tuberculosis (TB) and drug resistance.

Significant advances to the diagnosis of tuberculosis (TB) and drug resistance in adults, adolescents and children are expected, following key updates on new molecular assays, announced by the World Health Organization (WHO) in a Rapid Communication released today.

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FDA Approves First in the World, First-of-Its-Kind Implant for the Treatment of Rare Bone Disease as a Humanitarian Use Device

Today, the U.S. Food and Drug Administration approved the Patient Specific Talus Spacer 3D-printed talus implant for humanitarian use. The Patient Specific Talus Spacer is the first in the world and first-of-its-kind implant to replace the talus—the bone in the ankle joint that connects the leg and the foot—for the treatment of avascular necrosis (AVN) of the ankle joint.

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WHO launches consolidated guidelines for malaria.

The WHO Guidelines for malaria, launched today, bring together the Organization's most up-to-date recommendations for malaria in one user-friendly and easy-to-navigate online platform. They are designed to support malaria-affected countries in their efforts to reduce and, ultimately, eliminate a disease that continues to claim more than 400 000 lives each year.

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EMA preparing guidance to tackle COVID-19 variants

EMA is developing guidance for manufacturers planning changes to the existing COVID-19 vaccines to tackle the new virus variants. In order to consider options for additional testing and development of vaccines that are effective against new virus mutations, the Agency has requested all vaccine developers to investigate if their vaccine can offer protection against any new variants.

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First new chemical entity discovered by Indian scientist's gets USFDA approval

Umbralisib, a novel cancer drug discovered and out-licensed by India's Alembic Pharmaceuticals and its associate drug discovery company Rhizen Pharmaceuticals, has received the drug regulatory approval for sales in the US market. The drug is touted to be the first new chemical entity (NCE) discovered by Indian scientists to secure a US Food and Drug Administration (FDA) approval.

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Pharma's 3Q profitability improvement starts to taper off: Ind-Ra

India Ratings and Research (Ind-Ra) does not expect Indian pharmaceutical companies to sustain the healthy operating margins reported during 3Q FY21 and 9M FY21. The India formulations business grew year-on-year (yoy) during 3Q FY21 and 9M FY21 while growth across other segments was lower both on quarter-on-quarter (qoq) and yoy basis, it said on Wednesday.

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NPPA asks medical devices cos to submit price related info within 21 days for price monitoring exercise

The National Pharmaceutical Pricing Authority (NPPA) in exercise of powers of para 29 of Drugs Prices Control Order (DPCO)-2013 has directed manufacturers and importers of all non-scheduled medical devices to submit price related information in the prescribed format duly certified by practicing chartered accountant (CA) within 21 days of issue of this office memorandum (OM) price monitoring exercise.

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Indian pharma grows for 5th straight month; sales rise 4.5% in January

The Indian pharmaceutical market's (IPM) maintained its growth trajectory for the fifth consecutive month by expanding 4.5 per cent in January. After growing 8.5 per cent in December, it grew 4.5 per cent last month, signalling that the post-Covid recovery is in full swing, pointed an Anand Rathi report.

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NPPA reviews functioning of PMRU in Gujarat to assess compliance to DPCO

The National Pharmaceutical Pricing Authority (NPPA) officials visited Price Monitoring and Research Unit (PMRU) at the Gujarat Food and Drug Control Administration (FDCA) headquarters in Gandhinagar to review its progress and assess compliance to Drug Price Control Order (DPCO) -2013 and share experiences on the same for effective drug price ceiling regime in the country. This comes close on the heels of Gujarat FDCA having referred 519 cases of ceiling price violations to NPPA from January 1 to December 31, 2020.

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Glenmark launches kidney cancer treatment drug in India priced 96% lower than innovator brand

Glenmark Pharma NSE -2.02 % on Tuesday launched a generic kidney cancer treatment drug 'Sunitinib oral capsules' in India priced 96 per cent lower compared to the innovator brand. In a regulatory filing, Glenmark Pharma said it launched "SUTIB, the generic version of Sunitinib oral capsules to treat kidney cancer in India.

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China approves clinical trials for 16 indigenous COVID-19 vaccines

China has approved clinical trials for 16 indigenous COVID-19 vaccines, of which six are in the third stage, according to a state-run media report. The latest vaccines for clinical trials are based on recombinant protein, adenovirus vector, and nucleic acid and attenuated influenza-viruses technologies, state-run Xinhua news agency reported, citing data from the National Medical Products Administration.

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First-in-Human Clinical Trial to Assess Gene Therapy for Alzheimer's disease

Researchers at University of California San Diego School of Medicine have launched a first-in-human Phase I clinical trial to assess the safety and efficacy of a gene therapy to deliver a key protein into the brains of persons with Alzheimer's disease (AD) or Mild Cognitive Impairment (MCI), a condition that often precedes full-blown dementia.

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COVID-19 Has Presented Plenty of Obstacles for Neurology Clinical Trials, but Also Some Creative Opportunities

Researchers leading clinical trials related to stroke, amyotrophic lateral sclerosis, and dementia discuss the logistical and ethical challenges of conducting research during the pandemic. While some trials have been halted, others have carried on, applying innovative workarounds and study protocols.

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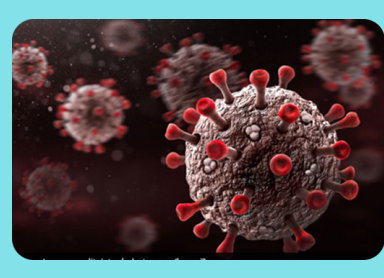
UK to begin world-first human trials to study COVID-19

The UK is to begin the world's first COVID-19 human trials to study the impact of the deadly virus on a healthy body's immune system, after receiving the approval of the country's clinical trials ethics body on Wednesday. The initial study is intended to help scientists understand how the immune system reacts to the virus that causes COVID-19.



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Can new ethical guidelines reshape HIV prevention trials?

In a bid to include ethical considerations in the HIV prevention trial process UNAIDS and the World Health Organisation recently launched a new guidance document for ethical consideration for HIV prevention trials. The guidance among other things, calls for the inclusion of communities that live in settings where trials are taking place as equal partners.

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Somru Bioscience and Veeda Clinical Research Announce Joint Venture Global Biotherapeutic Contract Research Organization (CRO) in India

Ingenuity Bioscience Pvt. Ltd – Veeda Clinical Research, one of India's leading and largest independent CRO companies, and Somru BioScience Inc., a leading Canadian-based biotechnology company based in Charlottetown, Prince Edward Island, are proud to announce the establishment of an innovation-centric bioanalytical laboratory in Ahmedabad, India. Veeda and Somru announced the launch of their premier global centre of excellence lab under the flagship of Ingenuity BioSciences Pvt. Ltd.

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Centrient Pharmaceuticals to Acquire Astral SteriTech

Centrient Pharmaceuticals has signed an agreement for the acquisition of Astral SteriTech Private Limited, an international manufacturer specialized in sterile antibiotic injectable finished dosage forms. With the acquisition of Astral SteriTech, Centrient strengthens its position in beta-lactam antibiotics.

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Novartis Buys Antibiotics Business from GSK in Generics Push

Swiss drugmaker Novartis' generics division is buying a GlaxoSmithKline antibiotics business that includes the brands Zinnat, Zinacef and Fortum for up to $500 million, the drugmakers said on Thursday. Novartis' Sandoz unit will pay GSK $350 million for the cephalosporin antibiotics business at the closing of the deal, which is expected in the second half of this year, plus a further $150 million upon hitting set milestones.

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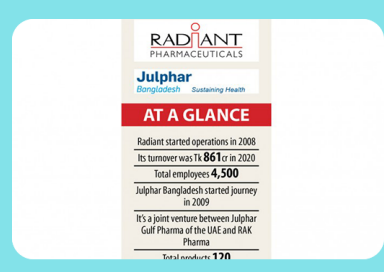
Karo Pharma acquires European OTC brand portfolio from Teva Pharmaceuticals

Karo Pharma Aktiebolag ("Karo") today announces the acquisition of an OTC brand portfolio containing Flux®, Decubal®, Lactocare®, Apobase®, Dailycare® and Fludent® from Teva Pharmaceuticals (Teva) for a total consideration of EUR 84m. The transaction transfers ownership of the brand portfolio, comprised of Flux®, Decubal®, Lactocare®, Apobase®, Dailycare® and Fludent® from Teva to Karo.



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Horizon Therapeutics to acquire Viela Bio for $3bn

Through the acquisition, Dublin-headquartered Horizon Therapeutics will grow its rare disease medicine portfolio, gaining Uplizna (inebilizumab-cdon), the first and only FDA-approved B-cell-depleting humanized monoclonal antibody for the treatment of eye disease neuromyelitis optica spectrum disorder (NMOSD)

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DoP issues revised guidelines for implementing PPP order for procurement of indigenous medical devices

The Department of Pharmaceuticals (DoP) has issued revised guidelines for implementing the provisions of public procurement (preference to Make in India) Order (PPO)-2017 DPITT guidelines for procurement of Make in India medical devices. The Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153 (iii) of the General Financial Rules 2017, had earlier issued PPO - 2017 dated June 15, 2017 which was partially modified on May 28, 2018, May 29, 2019 and September 16, 2020 respectively.

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Covid Vaccine can be a game changer for Indian Pharma Industry on a global platform

We may contemplate that Covid 19 came from Wuhan labs or their wet market; but what is more important is it came from PRC or China. It travelled to 192 countries and infected millions, left a million dead and billions of livelihoods impacted across the world. Global economy (GDP), which was valued at 90 trillion USD (approx.) took a big hit, as all the cogs stopped working and operators went running for cover.

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India to become 2nd biggest coronavirus vaccine producer in the world

India is projected to become the second largest producer of Covid-19 vaccines in the world, providing them not only for its own population, but for other developing nations, analysts say. The South Asian nation was producing around 60 percent of the world's vaccines even before the Covid-19 pandemic, and the production capacities of Indian pharma manufacturers allow vaccines to be made at relatively low cost.

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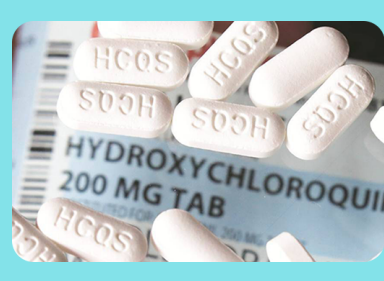
Gujarat FDCA approves 161 & 181 pharma plants based on MoUs signed in VGS-2017 and VGS-2019

The Gujarat Food and Drug Control Administration (FDCA) has approved and commissioned 161 pharmaceutical plants based on 249 MoUs signed with pharma companies in Vibrant Gujarat Global Summit (VGGS)-2017 and commissioned 181 pharmaceutical plants based on 273 MoUs signed with pharma companies in VGGS-2019.



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IRDAI issues guidelines on standard vector borne disease health policy

The Insurance Regulatory and Development Authority of India (IRDAI) has issued guidelines on standard vector borne disease health policy. "In order to make available vector borne disease specific health insurance product addressing the needs of insuring public for getting health insurance coverage to specified vector borne disease, the authority encourages all general and health insurers to offer standard vector borne disease health policy," the draft said.

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