The Veeda Newsletter

MAY 2022: ISSUE 05

Our team recently concluded a Hybrid Symposium on 'Immuno-centric Approach to Biosimilar and Vaccine Development - Scientific & Regulatory Considerations'

Partners in Creating

a healthier tomorrow

Veeda News

Update about our latest Symposium and participation in upcoming BIO International Convention

Regulatory

FDA Urges Drug Manufacturers to Develop Risk Management Plans to Promote a Stronger, Resilient Drug Supply Chain

Financial

NPPA fixes retail price of Emcure's HIV drug combination following review order from DoP

Clinical Research

eConsent—The First Step to Enable Clinical Trial Access to Anyone, Anytime, Anyplace

Merger and Acquisition

These were the biggest pharmaceutical deals in early 2022

Indian Pharma

Glenmark launches "Hello Skin" -Whatsapp based chatbot to help patients suffering from fungal infections

The Veeda Newsletter

MAY 2022: ISSUE 05

Meet Veeda Group Experts at Booth No. 1256 to discuss your drug development requirements at BIO International Convention

Glimpse of Veeda's participation at the 13th Annual Clinical Trials Summit 2022

veeda clinical research

The Veeda Newsletter

MAY 2022: ISSUE 05

FDA Urges Drug Manufacturers to Develop Risk Management Plans to Promote a Stronger, Resilient Drug Supply Chain

Drug shortages pose a significant public health threat as they can delay, and in some cases, even deny critically needed care for patients. Over the past decade, the FDA's efforts have contributed to fewer new drug shortages and reduced the time to resolve existing drug shortages. This is due, in part, to authorities the agency now has, including those added by the Food and Drug Administration Safety and Innovation Act.

Read More

Incentivizing collaboration towards the health-related Sustainable Development Goals

Ahead of the 75th World Health Assembly, the 13 signatory agencies of the Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP) have released their third progress report, Stronger collaboration for an equitable and resilient recovery towards the health-related SDGs, incentivizing collaboration. The report notes that, more than two years into the COVID-19 pandemic, compounded by overlapping global crises, progress on the health-related SDGs is further off track. Countries have achieved about one-fourth of what is needed to achieve the SDG health targets by 2030

Read More

US FDA and Gujarat FDCA to have regulatory forum for 3 days

The US FDA-Gujarat FDCA regulatory forum is going on 17th, 18th & 19th May 2022. In this meeting, first time 12 officials from US FDA, senior officers from Gujarat FDCA and 4 nominated officers from the CDSCO are participating. In this meeting, US FDA will provide an overview of recent initiatives including OGPS reorganization, and GMP inspectional trends in India. US FDA officials and Gujarat FDCA officials will discuss on Drug Inspection Lifecycle: site selection, planning, execution, reporting, evaluation and regulatory action, case study and discuss elements of observed inspection SOP for future participation as an observer in the US FDA led inspection followed by panel discussion.

Read More

US FDA's draft guidance on benefit-risk considerations to speed up approvals

Indian life sciences industry sees that the recent for product quality assessment will put in place system for the companies for faster approvals to access the export markets. US is a notable market for Indian pharma and biotechnology. It is a country where every third prescription is seen to be a medicine developed in India. In order to further strengthen the quality standards the guidance is seen to be a valuable document. The guidance describes the benefit-risk principles applied by FDA when conducting product quality-related assessments of chemistry, manufacturing, and controls information submitted for FDA assessment as part of original new drug applications (NDAs) for original biologics license applications (BLAs)

Read More

CDSCO Panel Directs SII To Submit Safety And Immunogenicity Data For TB Vaccine

Rejecting the vaccine major Serum Inst. of India's proposal for emergency use authorization of rBCG vaccine for prevention of Tuberculosis in ≥6 years of age, the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) has recommended the firm to submit safety and immunogenicity data in proposed indication & age group for consideration of its proposal. This came in line with the proposal presented by vaccine major Serum Inst. of India for grant of emergency use authorization for rBCG vaccine (VPM1002) for prevention of Tuberculosis in ≥6 years of age before the committee.enicity Data For TB Vaccine

Read More

veeda clinical research

The Veeda Newsletter

MAY 2022: ISSUE 05

NPPA fixes retail price of Emcure's HIV drug combination following review order from DoP

Bringing a two and a half year old dispute by the Pune-based Emcure Pharmaceuticals related to the price fixation of its HIV drug combination to a closure, the National Pharmaceutical Pricing Authority (NPPA) has revised the retail price of the same on par with the price it has fixed earlier for another manufacturer. The drug price regulator has also fixed the retail price of 84 drug formulations including anti-diabetic combinations of sitagliptin, linagliptin and others. According to the latest notification of NPPA, the price of each darunavir ethanolate equivalent to Darunavir 800 mg and Ritonavir IP 100 mg tablet manufactured by Hetero Labs Ltd and marketed by Emcure Pharmaceuticals, will be Rs. 212.91.

Read More

Pfizer to sell all its patented drugs at nonprofit price in low-income countries

Pfizer Inc will make all of its patented medicines including COVID-19 treatment Paxlovid and big-selling breast cancer drug Ibrance available at a not-for-profit price to 45 of the world's poorest countries, the drugmaker said on Wednesday. These countries lack good access to innovative treatments. It can take four to seven years longer for new treatments to become available in low-income countries, according to the Bill & Melinda Gates Foundation, if they become available at all. Pfizer said its plan includes 23 wholly-owned, patented medicines and vaccines that treat infectious diseases, certain cancers, and rare and inflammatory diseases. In addition to Paxlovid and Ibrance, the list includes pneumonia vaccine Prevnar 13, rheumatoid arthritis drug Xeljanz and cancer treatments Xalkori and Inlyta.

Read More

Dr Reddy's sees sharpest intra-day rally since Sept 2020; stock surges 8%

Shares of Dr Reddy's Laboratories moved higher by 8 per cent to Rs 4,259 on the BSE in Friday's trade. The stock gained 9 per cent in two days after the pharma company reported better-than-expected revenue growth in March quarter (Q4FY22). The board also recommended a final dividend of Rs 30 (600 per cent) per equity share of Rs 5 each for the financial year 2021-22. The stock witnessed its sharpest rally in intra-day since September 2020. Earlier, on September 18, 2020, it zoomed 14 per cent in intra-day, and ended 10 per cent higher on the BSE. The company's revenue was up 15 per cent to Rs 5,437 crore for Q4FY22, primarily driven by market share gains, strong launches, productivity improvement and divestment of brand.

Read More

Sun Pharma jumps 4% on receiving USFDA nod for Mesalamine capsule

Sun Pharmaceutical Industries Sun Pharma 904.304.35 (0.48%) TOP INSIGHT Board Meeting on 30 May, 2022 Meeting Agenda: Audited Results & Final Dividend. Please add to watchlist to track closely.... See More NSE 0.56 % jumped 4.3 per cent in early trade on Friday after the drugmaker said that it received final approval from the US health regulator for Mesalamine extended release capsules, used to treat bowel disease, in the American market. The company has received approval from the US Food and Drug Administration (USFDA) for the product, a generic version of Pentasa extended release capsules (500 mg), the Mumbai-based drug major said in a statement.

Read More

AIOCD seeks 10% trade margin for wholesalers & 20% for retailers

The All India Organisation of Chemists and Druggists (AIOCD), a representative body of 9.4 lakh chemists across the country, has urged the National Pharmaceutical Pricing Authority (NPPA) to allow 10 per cent trade margin for wholesalers on price to retailer (PTR) and 20 per cent for retailers on maximum retail price (MRP) of drugs. AIOCD made the appeal following a virtual meeting of stakeholders on Rational Trade Margin (RTM) held by NPPA last week to slash the drug price. At the meet, stakeholders were asked to submit their suggestions.

Read More

veeda clinical research

The Veeda Newsletter

MAY 2022: ISSUE 05

A Faster, Broader Pipeline for Phase I Clinical Trials Investigating Immunotherapies, Targeted Therapies

Six years after the Phase I Clinical Trial Infusion Center opened its doors at Smilow Cancer Hospital, Director Patricia LoRusso, DO, still gets a thrill reporting to her clinic every day. The state-of-the-art facility serves as the dynamic hub of Yale Cancer Center's cutting-edge Phase I Clinical Trial Program. The program advances promising cancer therapies, such as immunotherapies, through the FDA approval pipeline and provides hope for patients with advanced-stage cancers in need of another option beyond the standard treatment.

Read More

How Technology Helps With Multinational Clinical Research

The Covid-19 vaccine studies showed that clinical trials must find more participants, especially diverse participants, and one way that might help is by going multinational. Technology made it possible for research sponsors to communicate and share documents and data with multiple sites around the world, even when travel was restricted. Holding trials across multiple countries doesn't just help vaccine trials—it can also help clinical trials that have strict enrollment requirements, like biomarker-driven oncology trials.

Read More

How smartphones and wearables are advancing clinical research and treatment

Often, it requires periodic visits to an academic medical center or clinic. Participants may need to take time off from work, find childcare, and travel — sometimes many miles from their homes. Many have health issues that make these tasks even more difficult. What's more, the data collected by researchers only provide a snapshot in time that may not represent the totality of the person's condition. "It's odd that we ask sick patients to come see us on our terms," says Ray Dorsey, MD, a professor in the Department of Neurology at the University of Rochester Medical Center in New York. "Most people want to participate in research, but we make it so inconvenient."

Read More

DoP preparing roadmap for strengthening testing infrastructure for medical devices

The Department of Pharmaceuticals (DoP) is in the process of preparing a roadmap to strengthen the testing infrastructure for medical devices to enable smoother transition to the upcoming licensing regime. A task force formed in this regard with representatives of the department and industry is expected to submit its recommendations this month. According to an official document, a meeting was held on April 11, 2022 on the measures to be taken towards strengthening of testing infrastructure to enable smoother transition to licensing for medical devices under the leadership of S Aparna, secretary, DoP

Read More

eConsent—The First Step to Enable Clinical Trial Access to Anyone, Anytime, Anyplace

Diversity, inclusivity, and accessibility are the new buzz words in clinical trials. An equitable access to easily understandable, unbiased, and consistent communication of any study for informed decision making is the first and foremost fundamental step for any clinical trial participant. Consenting is the process of information sharing, discussion, and agreement between an investigator and participant. It is one of the most critical steps in a clinical trial since without an agreement, there won't be any participation. And it is widely expected that a better-informed trial participant will demonstrate a lower probability of dropping out at a later stage.

Read More

veeda clinical research

The Veeda Newsletter

MAY 2022: ISSUE 05

Mirum Pharmaceuticals, Inc. (MIRM) Acquires Satiogen Pharmaceuticals

Mirum Pharmaceuticals, Inc. (Nasdaq: MIRM) today announced that it has acquired Satiogen Pharmaceuticals, Inc., a San Diego-based company. Satiogen, now a wholly-owned Mirum subsidiary, was an existing licensing partner for LIVMARLI® (maralixibat) oral solution and volixibat. Through the transaction, Mirum obtained all Satiogen licensing payments and Satiogen-owned intellectual property relating to LIVMARLI and volixibat. “The acquisition of Satiogen is a strategic step that consolidates the economics of our commercial and pipeline programs,” said Chris Peetz, president and chief executive officer of Mirum. “The Satiogen team laid some of the foundational groundwork for the potential for IBAT inhibitors in liver disease that is now translating to substantial benefits for patients and a successful launch of LIVMARLI in Alagille syndrome. We thank the Satiogen team as we build on their work to continue to advance important therapies for rare disease.”

Read More

M3 Global Research Acquires Pharma-Insight

The acquisition further strengthens m3’s european presence, with pharma-insight’s dedicated german call centre, plus coverage in germany, the uk, france, denmark, netherlands, norway, austria, italy, poland, switzerland, spain and the czech republic, alongside capabilities in the us, canada, brazil, china, japan and south korea. founded in 2003 by the baus family, and headquartered in hilden, germany, pharma-insight has a portfolio of market research services covering the life sciences industry. this includes a dedicated healthcare panel, the addition of which further strengthens m3’s provider panel.

Read More

Aprea Therapeutics Acquires Atrin Pharmaceuticals

Aprea completed the acquisition of Atrin, a privately held biotechnology company focused on the discovery and development of novel therapeutics targeting proteins in the DNA damage response, or DDR, pathway in oncology through synthetic lethality. The Company believes its cash and cash equivalents as of March 31, 2022 will be sufficient to meet its current projected operating requirements through the second half of 2023.

Read More

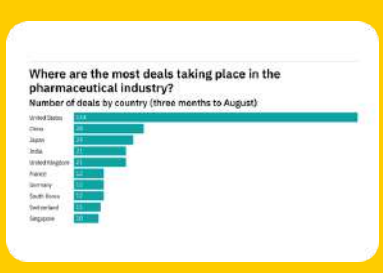
Regional REIT completes three acquisitions in deals totalling £48m

Regional REIT, the property firm which has offices in Old Trafford overseeing properties throughout the North West, has completed three separate office investments in Derby, Milton Keynes and Crawley for a total sum of £48.2m. The acquisitions are £19.8m, £15.9m, and £12.5m, respectively, reflecting net initial yields of 8.6%, 8.9% and 8.4%, with an overall blended net initial yield of 8.7%.

Read More

These were the biggest pharmaceutical deals in early 2022

There were 256 deals recorded involving top pharmaceutical companies in the three months to April with a number of high profile contract service agreement, licensing agreement, partnership, merger, venture financing, equity offering, asset transaction, debt offering, acquisition and private equity deals. That’s according to GlobalData’s Financial Deals database, which tracks market activity across a variety of sectors and deal types. The deals below only include those that have been completed – so excludes rumours or those that have been agreed but not yet executed.



Read More

veeda clinical research

The Veeda Newsletter

MAY 2022: ISSUE 05

Cadila Pharma launches cholesterol drug Belmore

Ahmedabad-based Cadila Pharmaceuticals has launched a novel drug for the treatment of high LDL cholesterol for the first time in India. To be sold under the brand name Belmore, Bempedoic acid is a one-of-its-kind drug for the treatment of high LDL (low-density lipoprotein) cholesterol, also known as bad cholesterol. “Belmore (bempedoic acid) provides additional benefits to patients, and all pre-launch studies have established this advantage. Belmore is one more addition to our fast-growing portfolio of indigenous innovations. We are committed to continuing our journey of making affordable drugs available to everyone,” said Jawed Zia, CEO , Domestic Prescription Business, Cadila Pharmaceuticals.

Read More

Glenmark launches “Hello Skin” -Whatsapp based chatbot to help patients suffering from fungal infections

Glenmark Pharmaceuticals Ltd. (Glenmark), an innovation-led global pharmaceutical company, has developed an digital patient education tool , “Hello Skin” in collaboration with the IADVL (Indian Association of Dermatologists, Venereologists and Leprologists), to help patients suffering from dermatophytosis (ringworm or tinea) in India, to adhere to the recommended treatment duration. “Hello skin” is the first Whatsapp based chatbot, which helps patients in not only improving adherence to topical/systemic recommended therapy with daily pill reminders, but also in creating disease awareness and provides skincare tips to patients suffering from ringworm. This platform is patient friendly and will be available in 6 different regional languages including Hindi and English, enabling better patient compliance to the technology.

Read More

Department Of Pharmaceuticals Releases Guidelines On Pharmaceutical Innovation And Entrepreneurship-2022

With an aim to reach the mark of becoming a five trillion-dollar economy by 2024, the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers has recently unveiled common guidelines on pharmaceutical innovation & entrepreneurship-2022.The Policy Guidelines on Pharmaceutical Innovation & Entrepreneurship target to encourage innovation, entrepreneurship, and creation of, or participation in, spin-offs & start-ups by faculty members/scientists/staff members/trainees/alumni of academic pharmaceutical institutions based on innovative ideas and research output of the former with impactful commercialization of these innovations.

Read More

Pharma clocks best export performance ever in FY22: Government

The government on Monday said the pharma sector has registered the best export performance ever in 2021-22 as shipments rose 18 percent year on year. According to the ministry of commerce and industry, the sector more than doubled to Rs 1,83,422 crore in 2021-22 from 2013-14 . Exports in 2021-22 sustained positive growth despite global trade disruptions and drop in demand for COVID medicines. Trade balance continues to be in India’s favour, with a surplus of $15175.81 million, the ministry said.

Read More

IPC releases Indian Pharmacopoeia 2022

In a bid to promote the highest standards of drugs for use in humans and animals, the Indian Pharmacopoeia Commission (IPC) has released Indian Pharmacopoeia 2022 containing 92 new monographs, 21 vitamins, minerals, amino acids, fatty acids and 27 active pharmaceutical ingredients (APIs). The Indian Pharmacopoeia which is likely to be effective from December 1, 2022, also includes 3 new biotechnology derived therapeutic products, 2 herbs & herbal products, 2 blood & blood related products, 33 dosage forms (chemicals), 4 vaccines and immunosera for human use. Besides this, the IP also contains 12 new general chapters.

Read More

For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

Corporate Office

VEEDA CLINICAL RESEARCH LIMITED
Block 6, Magnet Corporate Park,
100 ft. Thaltej - Hebatpur Road,
Nr.Sola Bridge, Off. S.G.Highway,
Thaltej, Ahmedabad 380 054

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

OTHER ADDRESS:

- Sarkhej - Gandhinagar Highway
  Vedant Complex, S. G. Highway, nr. YMCA club,
  Ahmedabad, Gujarat 380051

- Insignia, Besides Auda Garden, Opp. Zenobia
  Residency, Sindhu Bhavan Road, Off. S. G. Highway,
  Bodakdev, Ahmedabad- 380059, Gujarat, India

- Radhe Palladium
  Panchot Cir, Kunal, Mehsana, Gujarat 384002