veeda clinical research®

The Veeda Newsletter

JUNE 2022: ISSUE 06

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

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

“We are privileged to partner with Ahammune Biosciences in the clinical development of a novel solution for the management of Vitiligo as compared to currently available therapies. Veeda Clinical Research, along with its subsidiary Bioneeds India Private Limited and Joint Venture company Ingenuity Biosciences, will continue to invest in our preclinical and early and late phase clinical research capabilities to be able to partner with innovative biotech companies in developing novel therapies for unmet healthcare needs.”

- Ajay Tandon

Managing Director, Veeda Clinical Research

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

Joint drugs controller nabbed taking bribe to clear Biocon Biologics' diabetes injection

The CBI on Monday apprehended Joint Drugs Controller S Eswara Reddy for allegedly receiving a Rs 4-lakh bribe to waive phase-three clinical trial of Insulin Aspart injection, an underdevelopment product of Biocon Biologics, officials said. After getting inputs about an exchange of bribe, the CBI registered a case of criminal conspiracy and corruption against Reddy, posted at CDSCO headquarters, and Dinesh Dua, Director at Synergy Network India Private Limited, among others. The CBI, which was working on the input for over a month, carried out a raid and Dua was caught giving Rs 4-lakh bribe to Reddy of the total promised amount of Rs 9 lakh on behalf of Biocon Biologics, a subsidiary of Kiran Mazumdar Shaw-led Biocon, officials said.

Read More

FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

the U.S. Food and Drug Administration authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age. For the Moderna COVID-19 Vaccine, the FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had been authorized for use in adults 18 years of age and older.

Read More

FDA Approves First Systemic Treatment for Alopecia Areata

The U.S. Food and Drug Administration approved Olumiant (baricitinib) oral tablets to treat adult patients with severe alopecia areata, a disorder that often appears as patchy baldness and affects more than 300,000 people in the U.S. each year. Today's action marks the first FDA approval of a systemic treatment (i.e. treats the entire body rather than a specific location) for alopecia areata. "Access to safe and effective treatment options is crucial for the significant number of Americans affected by severe alopecia," said Kendall Marcus, M.D., director of the Division of Dermatology and Dentistry in the FDA's Center for Drug Evaluation and Research. "Today's approval will help fulfill a significant unmet need for patients with severe alopecia areata."

Read More

CDSCO classifies 214 medical devices in various segments under Medical Devices Rule, 2017

The Central Drugs Standard Control Organisation (CDSCO) has announced classification of around 214 medical devices in various therapeutic segments, as part of its efforts to bring in the medical devices under the prescribed rules in the country. The medical devices pertaining to dental, and obstetrical and gynaecological treatment have been classified under the provisions of Medical Devices Rules 2017, through different notifications. It may be noted that this is in continuation with classifying devices in these segments last year. This includes 123 devices for obstetrical and gynaecological treatments, including abdominal decompression chamber I, birthing bed/table powered, cervical anesthesia kit, reusable or single use syringe used for cervical anaesthasia, endocervical aspirator, laparoscope system, among others.

Read More

CDSCO directs all licensed blood centres to register on e-Rakt Kosh in a week

In an effort to manage the blood stock and blood banking system in the country better, the Central Drug Standard Control Organisation (CDSCO) has asked all licensed blood centres to register themselves on the e-Rakt Kosh portal within a week's time. According to a directive by the ministry of health and family welfare, all licensed blood centres are required to register on the portal to enter their data regarding blood stock availability and update the same on a daily basis, in addition to the data related to blood donors and monthly reports, among others. "This will benefit existing blood centres in the long run by increasing the numbers of available voluntary blood donors," said Dr V G Somani, Drugs Controller General (India) in a notice of advisory.

Read More

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

Pharma exports register growth of 10.3% in May

Exports of pharmaceuticals from the country has continued to register a growth of around 10 per cent during the month of May, 2022, in line with the exports trend reported in the first month of the fiscal 2022-23, according to the quick estimates for selected major commodities for the month released by the ministry of commerce and industry. Exports of drugs and pharmaceuticals during May crossed $2.07 billion as compared to $1.87 billion during the same month of last year. The growth registered was 10.28 per cent, said the Ministry. Exports for the two months including April and May, 2022, have witnessed a growth to $4.13 billion, as compared to $3.77 billion reported during the corresponding two months of last fiscal year.

Read More

NPPA's expert panel recommends fixing retail price of sitagliptin FDCs on 34 applications by generic cos

In continuation with its efforts to fix and regulate the retail price of fixed dose combinations (FDCs) of anti-diabetes drug sitagliptin , which is on the verge of becoming off-patent, the expert committee of the drug price regulator has recommended fixing prices of 10 FDC products based on 34 applications by generic drug makers. The Multidisciplinary Committee of Experts (MCE) of National Pharmaceutical Pricing Authority (NPPA) in a meeting held in early June, received 34 applications based on 10 FDCs of sitagliptin and metformin tablets, including sitagliptin 50mg+metformin 500 mg tablet, sitagliptin 50 mg+metformin 1000 mg, among others. The Committee noted that the formulation 'sitagliptin' is on the verge of becoming off-patent in July 2022.

Read More

NPPA floats fresh EoI for the proposed project to track availability of essential drugs

The National Pharmaceutical Pricing Authority's (NPPA) has restarted its efforts to track the availability of essential drugs across the country with an Expression of Interest (EoI) with schedule to open the bids from eligible agencies on July 4, 2022. The authority had earlier cancelled an EoI it floated to shortlist an agency to implement the project as there were no eligible bidders. The open tender for the fresh round of bidding was published in the eProcurement system on June 9 with the bid submitting timeline from June 13 to June 30. The bids are expected to be opened on July 4, 2022. Earlier, the drug price regulator issued a notice on April 18, 2022, seeking EOI for short listing an organisation for tracking the availability of specified medicines in the supply chain across the country.

Read More

NPPA extends price regulation on oxygen concentrators till June 30

The National Pharmaceutical Pricing Authority (NPPA) has further extended the capping on the trade margin of oxygen concentrators for one more month, till the end of June, 2022. The trade margin rationalisation (TMR) was announced in June, 2021, in the backdrop of increased use of oxygen concentrators during the Covid-19 pandemic, since the virus mainly affects the respiratory system of a patient, especially those with co-morbidity such as diabetes, cardiac problems, among others. In an order on May 30, regarding capping the trade margin of oxygen concentrators at first point of sale or price to distributor, for fixation of maximum retail price of the product.

Read More

Sun Pharma to expand field force in India by 10 pc this fiscal

Drug major Sun Pharma NSE 1.34 % plans to increase its field force in the domestic market by 10 per cent in the current fiscal in order to drive twin objectives of brand focus and geographical expansion, according to a senior company official. The Mumbai-based drug major, which is the fourth largest specialty generic drug maker in the world, currently employs around 11,000 Medical Representatives (MRs) and related staff in the country."The field force expansion done in FY21 has met with good success and considering the current market conditions, we will be undertaking a further expansion of about 10 per cent for our field force in FY23, driven by the twin objectives of brand focus and geographical expansion," Sun Pharmaceutical Industries NSE 1.34 % CEO (India Business) Kirti Ganorkar said in an analyst call.

Read More

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

Novartis commits $17.7M to set up clinical trial centers in historically Black medical schools

Novartis has invested another $17.7 million as part of a 10-year plan to address racial inequalities in clinical trials. The Swiss pharma and its U.S. foundation set up the Beacon of Hope initiative in July 2021 in collaboration with 26 historically Black colleges, universities and medical schools. The aim is to address health disparities through holistic community-based collective action. The latest move sees the company commit $17.7 million in grants over 10 years as part of a collaboration with Howard University College of Medicine, Meharry Medical College and Charles R. Drew University of Medicine and Science.

Read More

How to Overcome the Disruption of Clinical Trials

Sponsors and clinical research organizations (CROs) are continuing to deal with entirely new processes and a world with ever-evolving travel restrictions, fearful patients, and data collection. There are also a unique set of challenges that have come along with hospitals at capacity, for example, the cutbacks in elective surgeries and other hospital services have affected the tumor banks that store cancer samples for use in additional research. While some concerns have waned over time, there is a consensus that the COVID-19 virus is here to stay, and disruptions to clinical trial processes are still possible for the long term.

Read More

Walgreens Launches Clinical Trial Business to Address Industrywide Access and Diversity Challenges and Redefine Patient Experience

The introduction of Walgreens clinical trial offerings coincides with recent steps taken by the U.S. Food and Drug Administration to increase racial and ethnic diversity in clinical trials given 20 percent of drugs have a variation in responses across ethnic groups1, yet 75 percent of clinical trial participants are white, while only 11 percent are Hispanic and fewer than 10 percent are Black and Asian2. “Walgreens trusted community presence across the nation, combined with our enterprise-wide data and health capabilities, enables us to pioneer a comprehensive solution that makes health options, including clinical trials, more accessible, convenient and equitable,” said Ramita Tandon, chief clinical trials officer, Walgreens.

Read More

Life Science sector gearing up digitization strategies to cover clinical trials

Digital technology has more to offer life science companies than making their manufacturing more efficient, it can have benefits far earlier in a drug’s development. Clinical trials are crying out for their own digital transformation, if the results of a new survey by industry association the Ethical Medicines Industry Group (EMIG) and data archive provider Arkivum are anything to go by. They examined how digital technologies are changing the industry by quizzing 305 executives, including representatives of 171 drug companies and 15 clinical research organizations (CROs).

Read More

Abu Dhabi primed to be major clinical trial capital, officials say

The UAE's capital is well placed to become the leading destination for clinical trials, officials from Department of Health — Abu Dhabi say. With its population of people from all parts of the world and its strategic position on the map, Abu Dhabi is suited to attract international life sciences corporations, they said during a visit to the US. A delegation from Abu Dhabi visited the US Chamber of Commerce in Washington, the US capital, and toured biomedicine research and development in the city of Boston, a centre for life sciences. The state of Massachusetts is viewed as a template for how to develop economic growth from the sector. For every life sciences job created there, five more in wider health and sciences open up.

Read More

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

DRL acquires injectable portfolio from US-based Eton Pharma for $50 million

Dr. Reddy's on Friday announced that it has acquired a portfolio of branded and generic injectable products from Deer Park, Illinois, based Eton Pharmaceuticals. Under the terms of the agreement, Dr. Reddy's will pay $5 million upfront in cash, plus contingent payments of up to $45 million. The acquisition supports Dr. Reddy's efforts to accelerate and expand affordable medications for patients, the company said in a statement.

Read More

invoX Pharma to acquire F-star Therapeutics

invoX Pharma, a wholly-owned subsidiary of Sino Biopharmaceutical (HKEX: 1177) that is focused on research and development (R&D) and business development activities outside of China, today announced that it has entered into a definitive agreement to acquire all of the issued and outstanding shares of F-star Therapeutics' (Nasdaq: FSTX) common stock for $7.12 per share. The proposed acquisition values F-star, a UK and USA-based clinical-stage biopharmaceutical company, at approximately $161 million. The transaction has been unanimously approved by the invoX and F-star boards of directors and is expected to close in the second half of 2022.

Read More

Integrated research organisation Centricity merges with Aventiv

Integrated research organisation (IRO) Centricity Research has announced the merger with Aventiv Research to expand its footprint and expertise across the US and Canada. With the latest deal, Aventiv became the fourth clinical research firm to join Centricity. The company has study sites in Ohio and Arizona and focuses on Phase I-IV pharmaceutical, device and diagnostic clinical trials in various therapeutic regions. Established in 2007, Aventiv has carried out over 475 clinical trials with more than 55 pharmaceutical sponsors, facilitating Food and Drug Administration (FDA) approval and availability for use of 26 drugs.

Read More

Revelation Pharma Completes Eighth Acquisition

Osceola Capital ("Osceola"), a lower middle-market private-equity firm, announced today the eighth addition to the Revelation Pharma Corporation ("Revelation") platform by purchasing Wedgewood Pharmacy's human-health book of business. Wedgewood Pharmacy operates compounding pharmacies that offers sterile and non-sterile compounded medications for animal patients in 50 states. Terms of the transaction were not disclosed. The acquisition of Wedgewood Pharmacy's book of business represents Revelation's continued desire to acquire and grow a national partnership of 503A and 503B compounding pharmacies and Wedgewood Pharmacy's strategy to focus on compounding exclusively for animal health in its compounding pharmacies.

Read More

Eagle Pharmaceuticals Completes Acquisition of Acacia Pharma Group plc, Expanding Acute Care Footprint

Eagle Pharmaceuticals, Inc. today announced it has completed the acquisition of the entire issued share capital of Acacia Pharma Group plc ("Acacia Pharma") (EURONEXT: ACPH) by way of a scheme of arrangement under Part 26 of the United Kingdom's Companies Act 2006 (the "Transaction"). "The closing of this transaction is a great achievement for Eagle both strategically and financially. The addition of the two products expands our presence in the acute care space, and we believe that our highly capable hospital-based salesforce will have great success commercializing these assets. We believe BARHEMSYS and BYFAVO represent two compelling opportunities, as both address significant unmet clinical needs," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals

Read More

veeda clinical research

The Veeda Newsletter

JUNE 2022: ISSUE 06

Digitization & automation are immediate needs to bolster manufacturing & packaging operations: Kaushik Desai

The Indian pharma industry must adopt technology and automation without delay. New tools and processes are enabling smart decentralized production with intelligent factories, integrated platform technologies and flexible manufacturing systems, said Kaushik Desai, advisor, Indian Pharma Machinery Manufacturers Association (IPMMA). The 5 digital technology trends in life sciences sector are artificial intelligence (AI) and analytics, Internet of Things (IoT), data integration platforms, cloud content management and information security. Pharma 4.0 is evolving slowly and steadily.

Read More

Parliamentary panel calls for rules and guidelines for e-Pharmacy Sector

Expressing its displeasure on the delay in finalising the e-Pharmacy Rules to control the online pharmacies in the country, the Department related Parliamentary Standing Committee on Commerce has recommended the draft of the e-pharmacy rules the Centre has published almost four years back to be finalised and implemented at the earliest. The Committee, headed by Member of Parliament V Vijayasai Reddy, in a report on the promotion and regulation of e-commerce in India presented to the Chairman of Rajya Sabha on June 15, added that a comprehensive guideline for the e-pharmacy or e-health platforms should be released by the government, among others.

Read More

Centre integrates eSanjeevani telemedicine service with NHA's Ayushman Bharat Digital Mission

The National Health Authority (NHA) announced successful integration of eSanjeevani with its flagship scheme – Ayushman Bharat Digital Mission (ABDM). With the integration, eSanjeevani telemedicine platform joins other 40 digital health applications that have completed their ABDM integration. Together, these health tech services are building a robust, inter-operable and inclusive digital health ecosystem for the country, said NHA. The integration allows the existing users of eSanjeevani, the telemedicine service of ministry of health and family welfare (MoHFW) to easily create their Ayushman Bharat Health Account (ABHA) and use it to link and manage their existing health records like prescriptions, lab reports, etc

Read More

Trivitron to launch made-in-India CT-Scan and MRI in FY2022-23

Trivitron Healthcare is planning to launch made-in-India CT-Scan and MRI in the financial year 2022-23. It will be for both Indian as well as international market and it will be used for serving the purpose of better diagnosis in remote areas too, because of their smart features, cost, and portability. The company also plans to set up its second ultrasound manufacturing facility in India at Patalganga Industrial Area, Mumbai. Chandra Ganjoo, Group Chief Executive Officer, Trivitron Healthcare, while talking to Pharmabiz said that the company has partnered with Illumina to expand NGS-based technology to help diagnose patients quickly and more accurately. "We are working to develop and distribute a suite of standardized, commercial IVD assays to deliver an effective and non-invasive way of diagnosing cancers, determining infectious pathogens, and identifying prenatal diseases", he said.

Read More

ICMR releases SOP for diagnosing and managing anthrax

The Indian Council of Medical Research (ICMR), the country's apex body for promotion of biomedical research, has come out with standard operating procedure (SOP) for anthrax. The SOP will be of tremendous use as a national guideline for handling suspected human, animal and environmental specimens towards diagnosing and managing anthrax. It will also add fillip to the existing biosafety measures in the country and facilitate responsible handling of agents of biothreat potential. Anthrax is a serious infectious disease caused by gram-positive, rod-shaped bacteria known as Bacillus anthracis. It occurs naturally in soil and commonly affects domestic and wild animals around the world. People can get sick with anthrax if they come in contact with infected animals or contaminated animal products. Symptoms depend on the route of infection.

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