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The Veeda Newsletter

ISSUE 08: AUG 2020

KEEPING CLINICAL TRIALS
MOVING BEYOND THE PANDEMIC

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FDA Updates Analysis of Medical Device Reports of Breast Implant Illness and Breast Implant-Associated Lymphoma

Today, the U.S. Food and Drug Administration is providing an update on adverse events reported to the Agency related to breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and systemic signs and symptoms referred to by patients as breast implant illness (BII).

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FDA releases NARMS Strategic Plan: 2021-2025

The U.S. Food and Drug Administration, in cooperation with the U.S. Centers for Disease Control and Prevention, and the USDA's Food Safety and Inspection Service, its partners in the National Antimicrobial Resistance Monitoring System, is releasing the NARMS Strategic Plan: 2021-2025.

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FDA Approves Treatment for Rare Disease Affecting Optic Nerves, Spinal Cord

The U.S. Food and Drug Administration has approved Enspryng (satralizumab-mwge) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults with a particular antibody – patients who are anti-aquaporin-4 or AQP4 antibody-positive. NMOSD is a rare autoimmune disease of the central nervous system that mainly affects the optic nerves and spinal cord. Enspryng is the third approved treatment for the disorder.

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ANDA consolidation process updated in new MAPP

The US Food and Drug Administration (FDA) has updated its manual of policies and procedures (MAPP) for the review of requests to consolidate previously approved generic drug applications.

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The Canadian application process and alternate pathway for COVID-19–related clinical trials

This article offers an overview of the clinical trial application process and guidance on the regulatory obligations pursuant to Part C, Division 5, of the Food and Drug Regulations “Drugs for Clinical Trials Involving Human Subjects” in Canada. The authors focus on clinical trial applications only for biologics (schedule D) and pharmaceuticals (schedule F).

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Dr Reddy's launches generic Favipiravir in India at ₹99 it is one of the more expensive versions

Dr Reddy's Laboratories, on August 19, joined the list of companies which launched their own generic version of favipiravir in India. The company has priced 'Avigan' at ₹99 — a premium price when compared to other versions of the same drug. The whole course of the tablet is expected to cost over ₹12,000.

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India's incentives for domestic API production could cut supply risk

India's government last month announced incentives to boost domestic manufacturing of active pharmaceutical ingredients (API) and key starting materials (KSM), which could improve backward integration over the next few years and curtail supply-chain disruption risk for Indian drug makers, says Fitch Ratings.

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Minimal impact of Covid-19 on Indian pharma industry: ICRA

The domestic pharma industry is expected to grow at a 4-6 per cent in FY-2021 owing to Covid impact, though FY 2020-2023, CAGR is expected to be in the range of 8-11 per cent on the back of healthy demand from the domestic market given increasing spend on healthcare along with improving access, rating agency ICRA has said.

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NPPA fixes retail prices of 30 formulations, rejects four applications

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail prices of 30 formulations under the provision of the Drugs (Prices Control) Order (DPCO) 2013. Although the authority received applications for 34 new drug pricing, it approved only 30 new drugs.

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NPPA issues final guidelines to discontinue making medicines under price control

The National Pharmaceutical Pricing Authority (NPPA) has issued the final guidelines for discontinuation of manufacturing medicines, which are under price control regime. The issued guidelines are also applicable to scheduled medical devices which have been notified as a drug.

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ICMR helping Serum Institute in conducting clinical trials for two vaccines

The Indian Council of Medical Research (ICMR) is supporting Serum Institute of India (SII) in conducting the phase 2 and 3 clinical trials for two vaccines for covid-19, one developed by University of Oxford and the other by US-based Novavax.

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China to expand clinical trials of African swine fever vaccine

China's domestically developed vaccine against the African swine fever is in progress and clinical trials of the vaccine will be expanded soon, according to the Ministry of Agriculture and Rural Affairs. The vaccine, developed by Harbin Veterinary Research Institute under the Chinese Academy of Agricultural Sciences (CAAS), has completed environmental release tests, which showed no clinical abnormal symptoms and no pathological changes among vaccinated pigs, according to the institute.

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How we accelerated clinical trials in the age of coronavirus

In March, as the tsunami of COVID-19 hit Europe, it became obvious that the virus could overwhelm the United Kingdom's National Health Service (NHS). To address this issue, colleagues and I repurposed infrastructure so that clinical trials could safely get data about more treatments from more patients more quickly.

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Diversity Will Broaden Clinical Trial Workforce

Welcoming more people of color into the clinical trial workforce will have a number of benefits, says Laurie Halloran, BSN, MS, CCRA, president and CEO of Halloran Consulting Group, not the least of which will be to "bring a legitimacy to clinical research it doesn't currently have [when] the patient population we're studying needs to be [more] diverse."

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Modernizing Clinical Research: Keeping Pace with Medical Device & Diagnostics Innovation

Clinical studies are the foundation of successful development of device and diagnostic products. Studies are also complex, from site selection and subject enrollment, to study monitoring, and data management. This year, on top of the usual challenges, COVID-19 brought many clinical studies to a halt. With the reduction of traditional face-to-face interactions at the site level, the pandemic has been a significant roadblock for the clinical research community and the medtech industry overall.

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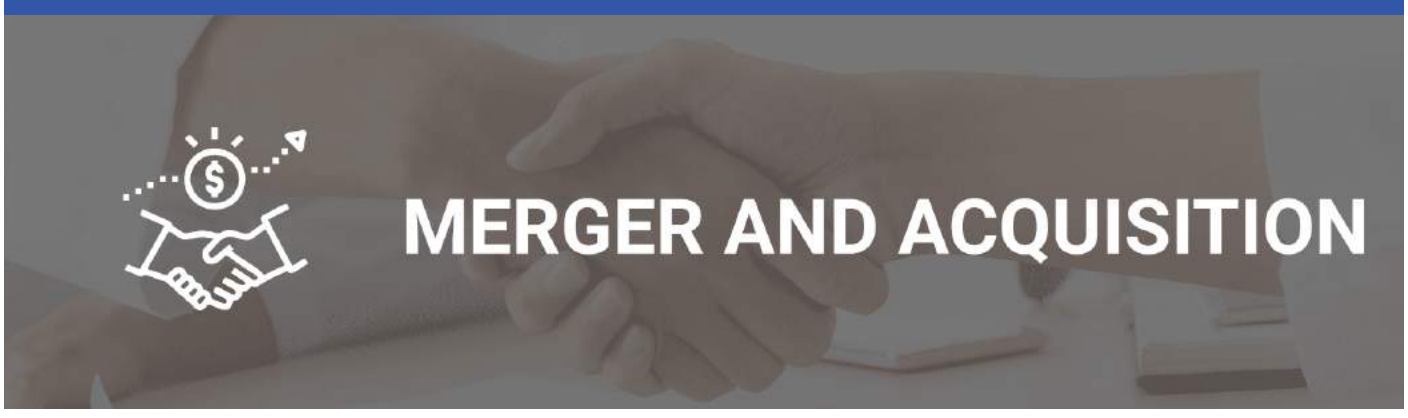

J&J to acquire Momenta Pharma for $6.5B

Johnson & Johnson will buy Cambridge, Mass.-based Momenta Pharmaceuticals for $6.5 billion, a move to strengthen the drugmaker's portfolio of autoimmune disease treatments. The acquisition, announced Aug. 19, will give J&J's Janssen unit access to nipocalimab, Momenta's experimental drug being tested to treat autoimmune diseases.

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Top 5 pharmaceutical M&A deals this year

While the number of pharmaceutical acquisitions is only slightly down in the first half of 2020, the combined value of merger and acquisition deals has gone down significantly, according to EvaluatePharma's "Pharma, Biotech & Medtech Half-Year Review 2020."

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Sanofi to acquire Principia Biopharma

Sanofi and Principia Biopharma, a late-stage biopharma company focused on developing treatments for immune-mediated diseases, entered into a definitive agreement under which Sanofi will acquire all of the outstanding shares of Principia for $100 per share in cash, which represents an aggregate equity value of approximately $3.68 billion (on a fully diluted basis).

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MSD Pharma acquires Takeda Pharma's Dunboyne manufacturing facility

MSD Pharmaceuticals, a renowned global healthcare firm that provides innovative healthcare solutions, has reportedly announced that it has agreed to acquire the cutting-edge biologics plant of Takeda Pharmaceuticals, located in Dunboyne, Co Meath. This acquisition agreement would bring the total MSD site numbers within Ireland to six.

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Bayer expands women's health pipeline with KaNDy acquisition

Bayer has announced plans to acquire UK-based biotech company KaNDy Therapeutics, in a move to expand its drug development pipeline in women's healthcare. This includes KaNDy's investigational compound NT-814, which recently completed a Phase IIb study which showed positive findings for the treatment of moderate-to-severe vasomotor symptoms due to the menopause.

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India's pharma market to grow by 12 to 14 per cent in three years: KPMG

India's domestic pharmaceuticals market is expected to grow by 12 to 14 per cent in the next three years while the export market may grow by 8 to 14 per cent, according to a new report by professional services firm KPMG. Backed by a 41 billion dollar pharma industry, the country ranks as the third-largest market globally by volume and 13 largest by value.

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INDIAN PHARMA & COVID-19

With the spread of COVID-19 and the ongoing race for a vaccine or effective treatment against the new coronavirus, attentions have been drawn to one of the only pharmaceuticals hubs in the world which has the capacity to mass produce billions of units of such a pharmaceutical product: India. Since the mid-1960s, India has made a name for itself as a manufacturing center for pharmaceuticals.

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India’s CMO market emerges as hotbed for global private equity investment

India’s contract manufacturing organization (CMO) and pharma market has strongly attracted investment from global private equity firms in recent times, driven by favorable government policies and a thriving generic drugs market, says Global Data, a leading data and analytics company.

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Govt to strengthen vaccine intelligence network to monitor vaccine stocks and cold chain for mass immunization of COVID-19 vaccine

As part of the government’s roadmap for procuring, financing and distributing a potential COVID-19 vaccine for mass immunization, the Union health ministry is planning to strengthen Electronic Vaccine Intelligence Network (eVIN) to digitize vaccine stocks and monitor cold chain centres through an online smart application platform.

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DTI lures India pharma firm to Philippines

The Department of Trade and Industry (DTI) is encouraging Indian pharmaceutical firms to invest and make the Philippines its manufacturing hub in Southeast Asia. In a statement, DTI-Export Marketing Bureau director Senen Perlada said the Philippines is an ideal gateway to Southeast Asia for Indian pharmaceutical firms. “Maybe India’s hesitation is the scale. But think of the ASEAN market, not just the Philippine market.

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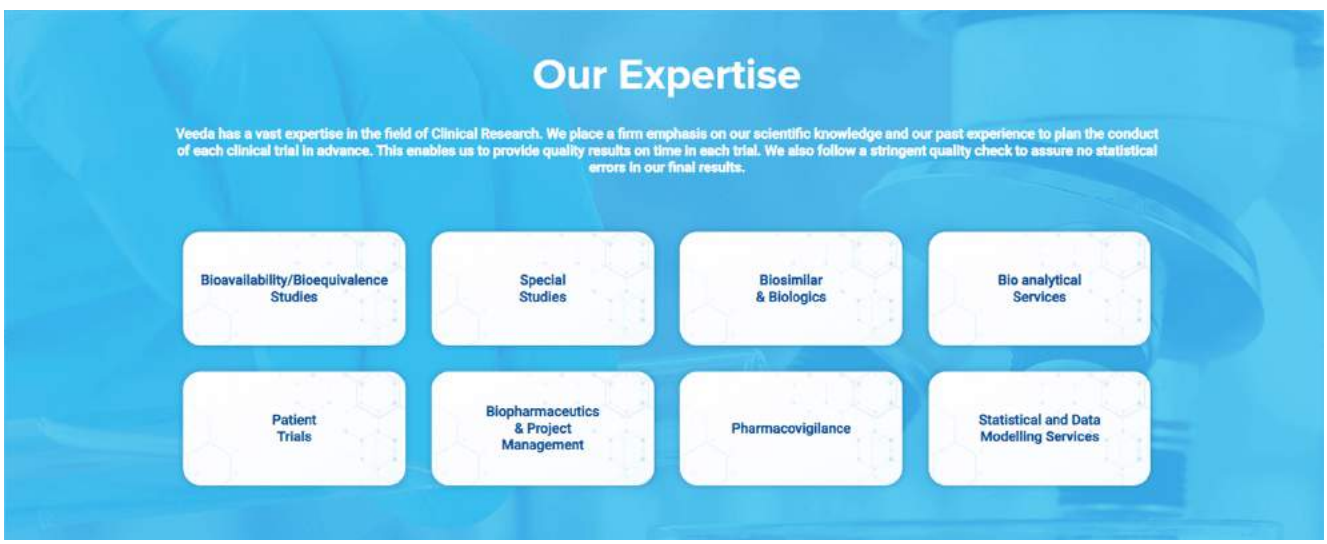

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