The Veeda Newsletter

FEBRUARY 2024: ISSUE 02

Veeda Biopharma

Webinar on

Immunogenicity Risk Assessment for Innate Immune Response Modulating Impurities (IIRMI)

Chandrasekhar Koduru
Head, Discovery Biology

Watch Now!

Partners in Creating

a healthier tomorrow

Veeda News
Latest news on our recent event participations

Regulatory
US FDA grants priority review to Merck's sBLA for Keytruda plus chemotherapy to treat primary advanced or recurrent endometrial carcinoma

Financial
Indian pharma companies to facilitate supply of 27 high quality vaccines to Russian market

Clinical Research
AstraZeneca's Tagrisso demonstrated overwhelming efficacy benefit for patients with unresectable, stage III EGFR-mutated lung cancer in LAURA phase III trial

Merger and Acquisition
AstraZeneca completes acquisition of clinical-stage biopharma company, Gracell Biotechnologies

Indian Pharma
Lupin introduces Ganirelix acetate injection in US market

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VEEDA NEWS

A glimpse of our team's participation at Bio Asia 2024

We are excited to share a glimpse of our team who attended Bio Aisa 2024 to discuss drug development of generics, complex generics, and innovator drug molecules with various global pharma and biopharma companies.

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Veeda Expert at PharmaSynergy 2024

Glimpse of our team who attended PharmaSynergy 2024 to discuss drug development requirements with various global pharma and biopharma companies.

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REGULATORY

US FDA accepts for priority review Bristol Myers' sNDA for Krazati in combo with cetuximab for patients with previously treated KRAS G12C-mutated locally advanced or metastatic CRC

Bristol Myers Squibb announced that the US Food and Drug Administration (FDA) has accepted for priority review the supplemental new drug application (sNDA) for Krazati (adagrasib) in combination with cetuximab for the treatment of patients with previously treated KRASG12C-mutated locally advanced or metastatic colorectal cancer (CRC). The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 21, 2024.

Read More

UK MHRA announces codeine linctus, an oral solution or syrup to treat dry cough, to be reclassified to prescription-only medicine due to risk of abuse and addiction

The UK Medicines and Healthcare products Regulatory Agency (MHRA) announced that codeine linctus, an oral solution or syrup licensed to treat dry cough in adults, is to be reclassified to a prescription-only medicine due to the risk of abuse, dependency and overdose. Codeine linctus is an opioid medicine which has previously been available to buy in pharmacies under the supervision of a pharmacist but will now only be available on prescription following an assessment by a healthcare professional.

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US FDA grants priority review to Merck's sBLA for Keytruda plus chemotherapy to treat primary advanced or recurrent endometrial carcinoma

Merck, known as MSD outside of the United States and Canada, announced the US Food and Drug Administration (FDA) has accepted for priority review a new supplemental Biologics License Application (sBLA) seeking approval for Keytruda, Merck's anti-PD-1 therapy, in combination with standard of care chemotherapy (carboplatin and paclitaxel), followed by Keytruda as a single agent for the treatment of patients with primary advanced or recurrent endometrial carcinoma. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action, date of June 21, 2024.

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US FDA approves Xolair as first and only medicine for children and adults with one or more food allergies

Roche announced that the US Food and Drug Administration (FDA) has approved Xolair (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and paediatric patients aged 1 year and older with IgE-mediated food allergy. People taking Xolair for food allergies should continue to avoid all foods they are allergic to (commonly referred to as "food allergen avoidance"). Xolair should not be used for the emergency treatment of any allergic reactions, including anaphylaxis.

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US FDA approves Iovance Biotherapeutics' Amtagvi for advanced melanoma

Iovance Biotherapeutics, Inc., a biotechnology company focused on innovating, developing and delivering novel polyclonal tumour infiltrating lymphocyte (TIL) cell therapies for patients with cancer, announced that the US Food and Drug Administration (FDA) has approved Amtagvi (lifileucel) suspension for intravenous infusion. Amtagvi is a tumour-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

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Apollo Health & Lifestyle keeps its financial operations healthy with Oracle Fusion Cloud ERP

Apollo Health & Lifestyle Limited, one of India's largest retail healthcare companies, has selected Oracle Fusion Cloud Enterprise Resource Planning (ERP) to optimize its financial operations and increase productivity. With Oracle Cloud ERP, Apollo Health & Lifestyle will be able to eliminate manual processes and embrace continuous innovation to improve speed and accuracy in reporting, align financial and operational planning, and gain insights to drive better decisions.

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JB Pharma reports net profit growth of 26% to Rs. 134 crore in Q3 FY24

JB Chemicals & Pharmaceuticals ltd (JB Pharma), one of the fastest growing pharmaceutical companies in India, announced its financial results for the quarter ended 31st December, 2023.JB Pharma recorded revenue of Rs. 845 crore in third quarter of FY24 registering growth of 7% from Rs. 793 crore in Q3 FY23. Operating EBITDA (earnings before interest depreciation and taxes) improved by 22% to Rs. 235 crore in Q3 FY24 as compared to Rs. 193 crore in Q3 FY23. Profit after taxes registered strong growth of 26% to Rs. 134 crore in Q3 FY24 vs Rs. 106 crore in Q3 FY23.

GOOD PEOPLE for GOOD HEALTH

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CDSCO declares around 5% of drug samples tested in January as NSQs

The CDSCO, in its monthly drug alert, said that during the month of January, it has tested a total of 932 samples out of which 46 were declared as NSQ, while no samples were declared as spurious or misbranded. The Organisation also said that a sample of Alkem Health Science's Pan 40 (pantaprazole gastro-resistant tablet) declared as NSQ during the month of December, 2023 is purported to be spurious.

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Pharmaceuticals export grows 6.8% in January

Exports of drugs and pharmaceuticals during the month of January posted a growth of 6.84 per cent as compared to the same month of previous year. For the first 10 months of the current fiscal year pharma exports grew 8.07 per cent, according to the Central government.The provisional data released by the government shows that in January this year, the drugs and pharmaceuticals exports reported a growth to $2.13 billion, as compared to $1.99 billion exports during the same month of last year.

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Indian pharma companies to facilitate supply of 27 high quality vaccines to Russian market

A Russian-based company has recently approached the Embassy of India in Moscow seeking 27 high-quality vaccines akin to those produced by Western pharmaceutical powerhouses. The Pharmaceutical Export Promotion Council of India (Pharmexcil) has facilitated this connection, providing a unique opportunity for Indian pharmaceutical companies to open business avenues in the Russian market.

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CLINICAL RESEARCH

LATITUDE phase III interim trial data indicates ViiV's long-acting injectable HIV treatment Cabenuva has superior efficacy compared to daily therapy in individuals living with HIV who have adherence challenges

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, announced results from an interim analysis of the LATITUDE phase III trial, indicating their long-acting injectable antiretroviral treatment (ART) for HIV, Cabenuva (cabotegravir + rilpivirine), demonstrated superior efficacy in maintaining viral load suppression compared to daily oral therapy in individuals with a history of ART adherence challenges.

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Polpharma Biologics' investigational biosimilar shows PK/PD comparability to inflammatory bowel disease blockbuster Entyvio

Polpharma Biologics, an international biotech company dedicated to the development and manufacturing of biosimilars, announced topline results demonstrating the pharmacokinetic (PK) and pharmacodynamic (PD) comparability of its biosimilar candidate PB016 to its reference drug, Entyvio (vedolizumab). Results came from a single-dose, randomized, double-blind, 3-arm parallel-group study assessing the PK/PD and immunogenicity for PB016 compared to Entyvio after intravenous administration in 120 healthy subjects. PB016 was found to show comparability to Entyvio in all investigated PK and PD parameters, with no immunogenicity or safety imbalances to the reference drug.

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AstraZeneca's Tagrisso demonstrated overwhelming efficacy benefit for patients with unresectable, stage III EGFR-mutated lung cancer in LAURA phase III trial

Positive high-level results from the LAURA phase III trial showed AstraZeneca's Tagrisso (osimertinib) demonstrated a statistically significant and highly clinically meaningful improvement in progression-free survival (PFS) for patients with unresectable, Stage III epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after chemoradiotherapy (CRT) compared to placebo after CRT.

Overall survival (OS) data showed a favourable trend for Tagrisso, although data were not mature at the time of this analysis. The trial will continue to assess OS as a secondary endpoint.

AstraZeneca

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Jacobio Pharma gets China CDE approval to begin phase III trial of SHP2 inhibitor plus KRAS G12C inhibitor

Jacobio Pharma, a clinical-stage oncology company drugging the undruggable targets, announced it received approval of registrational phase III clinical trial of the combination therapy between its novel KRAS G12C inhibitor glecirasib and novel SHP2 inhibitor JAB-3312. JAB-3312 is the first SHP2 inhibitor entered into phase III study globally in combination with KRAS G12C inhibitor.

加科思 Jacobio

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Neurophth completes patient enrollment in phase I/II trial of Opvika to treat Leber hereditary optic neuropathy

Neurophth Therapeutics, Inc. (Neurophth), China's leading in-vivo gene therapy company for ophthalmic diseases, announced that the last patient has been enrolled in phase I/II clinical trial of Opvika (Esonadogene Imvoparvovec) for the treatment of Leber hereditary optic neuropathy caused by ND4 mutation (ND4-LHON).

Neurophth 纽福斯

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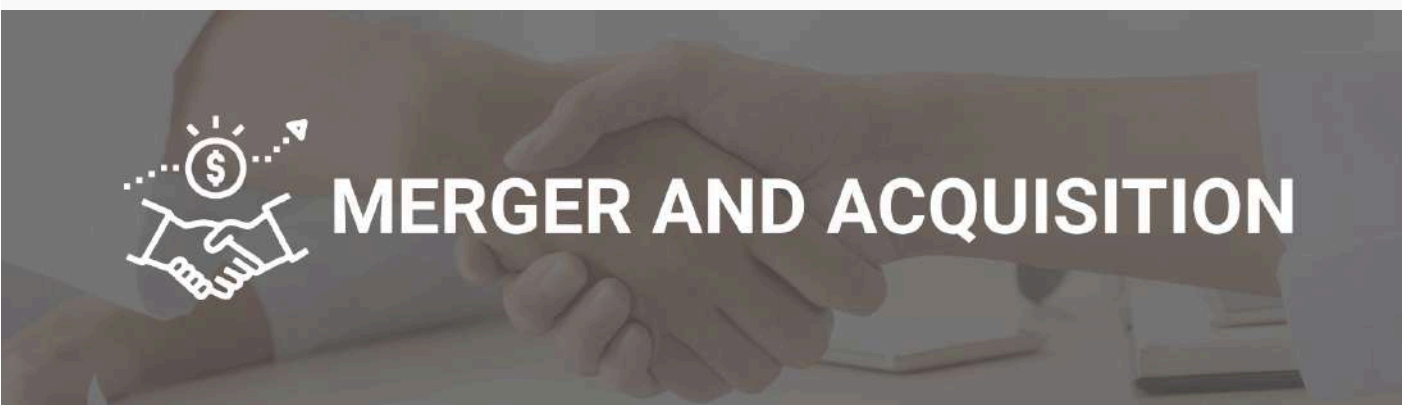

AstraZeneca completes acquisition of clinical-stage biopharma company, Gracell Biotechnologies

The acquisition enriches AstraZeneca's growing pipeline of cell therapies with GC012F, a novel, clinical-stage FasTCAR-enabled BCMA and CD19 dual-targeting autologous chimeric antigen receptor T-cell (CAR-T) therapy. GC012F is a potential new treatment for multiple myeloma, as well as other haematologic malignancies and autoimmune diseases including systemic lupus erythematosus (SLE).

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Teva, Jiangsu Nhwa form partnership to market & distribute Austedo in China

Teva Pharmaceutical Investments Singapore Pte Ltd (TPIS), a subsidiary of Teva Pharmaceutical Industries Ltd. and Jiangsu Nhwa Pharmaceutical Co., Ltd (Nhwa) announced it formed a partnership for the marketing and distribution of Teva's Austedo (deutetrabenazine) for the treatment of neurodegenerative and movement disorders - chorea associated with Huntington's disease (HD) and tardive dyskinesia (TD) in adults. The partnership intends to increase patients' access to Teva's Austedo, leveraging Nhwa's leadership in China's neuro-psychiatric health sector.

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Takeda inks partnership with Biological E for 'Make in India' manufacturing for its dengue vaccine

Takeda inks strategic partnership with Biological E. Limited, the former's dengue vaccine, TAK-003. The partnership marks a crucial step in the fight against the global public health threat of dengue fever, aligning with the disease-specific target set by the World Health Organization (WHO) to achieve zero case-fatality rate due to dengue by 2030.

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Telix to expand US footprint with acquisition of Texas-based bioconjugation firm, IsoTherapeutics

Telix has entered into an agreement to acquire IsoTherapeutics Group, LLC (IsoTherapeutics), a specialty radiopharmaceutical development and bioconjugation firm, based in Angleton, Texas. Founded in 2005, IsoTherapeutics is a privately held, commercial-stage company, which provides radiochemistry and bioconjugation development and contract manufacturing services to many companies in the radiopharmaceutical industry, including Telix.

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DarioHealth acquires Twill to create digital health platform across most prevalent chronic conditions

DarioHealth Corp, a leading digital health company revolutionizing how people with chronic conditions manage their health through a user-centric, multi-chronic condition digital therapeutics platform, announced that it has acquired Twill, Inc. (Twill), a leader in digital-led care. The combination enables Dario to create one of the most comprehensive digital offerings in the market for chronic conditions, spanning a wide spectrum of health and well-being needs from emotional health to the costliest chronic conditions. The transaction creates immediate scale, with three of the top eight national health plans, multiple Fortune 100 employers and several major pharmaceutical companies as customers.

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Viatris certified as a great place to work in India for the third consecutive year

Mylan Laboratories, a Viatris Company, has been recognized with the great place to work certification in India for the third consecutive time. This recognition is a testament to Viatris' commitment to fostering a positive, engaging, and inclusive workplace culture that values the well-being and professional development of its employees. The certification reaffirms Viatris' commitment to making its employees feel valued, supported, and heard.

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Lupin receives US FDA approval to market generic Minzoya and Balcoltra tablets

Global pharma major Lupin Limited (Lupin) announced that it has received approval from the United States Food and Drug Administration (FDA) for its Abbreviated New Drug Application for Minzoya (levonorgestrel and ethinyl estradiol tablets, USP and ferrous bisglycinate tablets), 0.1 mg/0.02 mg and 36.5 mg, to market a generic equivalent of Balcoltra (levonorgestrel and ethinyl estradiol tablets, USP and ferrous bisglycinate tablets) 0.1 mg/0.02 mg and 36.5 mg, of Avion Pharmaceuticals LLC. The product will be manufactured at Lupin's Pithampur facility in India.

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Lupin introduces Ganirelix acetate injection in US market

Global pharma major Lupin Limited (Lupin) announced the launch of the United States Food and Drug Administration (FDA) approved Ganirelix acetate injection, 250 mcg/0.5 mL, single-dose prefilled syringe.

Ganirelix acetate injection, 250 mcg/0.5 mL, single-dose prefilled syringe is a generic equivalent to the reference listed drug (RLD), Ganirelix acetate injection, 250 mcg/0.5 mL of Organon USA LLC.

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CDSCO approves Boehringer Ingelheim's Jardiance for treatment of adults with chronic kidney disease

The Central Drugs Standard Control Organisation (CDSCO) has approved Boehringer Ingelheim's Jardiance (empagliflozin) 10mg tablets to treat kidney failure. The drug was approved by the central drug regulator earlier for the treatment of heart failure with preserved ejection fraction (HFpEF) and heart failure with reduced ejection fraction (HFrEF).

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Life-threatening brain condition being missed by majority of emergency department health professionals: Survey

A recent survey revealed that many are at risk due to misdiagnosis of encephalitis, a deadly brain inflammation. Over half of the surveyed Indian emergency medical professionals missed encephalitis as a potential diagnosis even when presented with common symptoms.

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