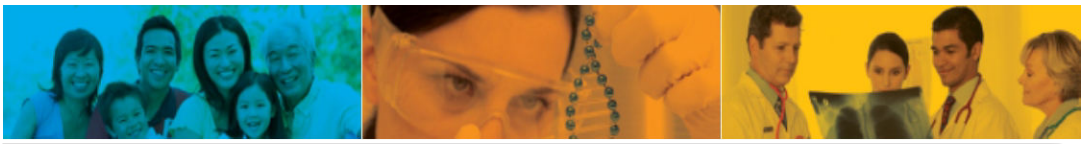

Clinical Research Newsletter Volume - 5, May 2016

LAMBDA

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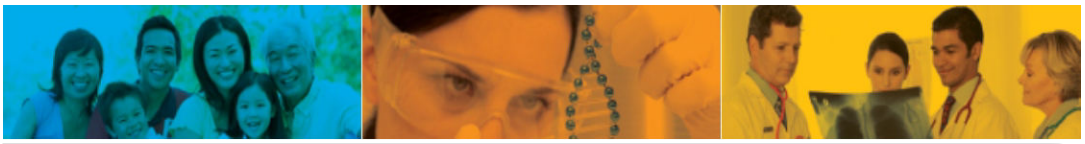


LAMBDA

GLOBAL NEWS

1.1. Novel Vaccine Strategy Protects Against Chikungunya Virus — April 01, 2016

- New research from The Wistar Institute has demonstrated how a novel vaccine strategy that boosts the immune system by rapidly producing antibodies against CHIKV, combined with a traditional DNA-based vaccine approach, can provide both short term and long term protection against the virus.
- The vaccination regimen in this study provided stable, persistent responses against a virus with rapidly increasing global incidence. Study results are published in the Journal of Infectious Diseases.

1.2. EMA Begins Pharmacovigilance Training Courses — April 08, 2016

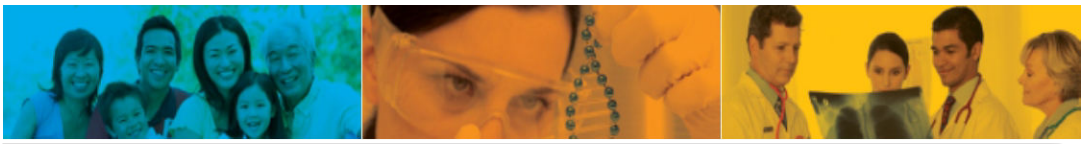
- The European Medicines Agency (EMA) this week began running a series of pharmacovigilance training sessions to help companies and regulators meet their obligations when using EudraVigilance, a centralized European database of suspected adverse reactions to medicines in the European Economic Area (EEA).
- At least one user from each national competent authority, marketing-authorization holder or sponsor of clinical trials in the EEA should complete the training to ensure the information collected in EudraVigilance is of the highest quality and integrity, EMA said

1.3. Access Campaign - New Threat Against Affordable Medicines in Trade Negotiations With India and Asean — Apr. 22, 2016

- Access to affordable medicines could be severely restricted for millions of people around the world under the current proposals in the Regional Comprehensive Economic Partnership (RCEP) trade agreement, Medecins Sans Frontieres (MSF) warned today.
- MSF sounded the alarm regarding the potential harmful consequences of the trade deal ahead of the next round of RCEP negotiations starting in Perth, Australia this Sunday. Text from the negotiations' leaked chapter on intellectual property shows that Japan and South Korea have made proposals that go beyond what international trade rules require undermining access to affordable generic medicines.

1.4. Hematological Cancers Market to Hit $70.1 Billion by 2022 Despite Key Patent Expirations, Says GBI Research — April 28, 2016

- A new report from business intelligence provider GBI Research states that the market for hematological cancers, which covers leukemia, lymphoma and myeloma, is expected to more than double from $30.7 billion in 2015 to $70.1 billion in 2022, representing a compound annual growth rate of 12.5%.
- This strong growth will occur in spite of a number of key patent expirations for drugs including Rituxan, Gleevec and Velcade, as new drugs hit the market and the prevalence of hematological cancers increases.A number of drugs currently not marketed will also develop into blockbuster drugs, including selinexor, venetoclax, KTEC-19, and polatuzumab vedotin.
- As the use of targeted therapies continues to generate revenue above that of non-specific chemotherapy classes of treatment, key companies investing in the hematological cancers pipeline and targeted therapies will drive the market substantially



DOMESTIC NEWS

2.1. Indian Pharma cos registers 29 % growth in ANDA approvals from US FDA in 2015

April 12, 2016

- The year 2015 marked by a significant higher US FDA approvals for ANDAs as compared to steady decline in approvals during the last couple of years.
- The US FDA approved total 564 ANDAs in 2015 as compared to 385 ANDAs in 2014 and 400 ANDAs in 2013. The ANDA approvals went up sharply by 46.5 per cent during 2015 as compared to declined of 3.8 per cent in 2014 and 16 per cent in 2013.

2.2. FIND, Cipla collaborate to improve hepatitis C diagnosis and treatment in India

April 21, 2016

- In order to build diagnostic capacity and an enabling environment for hepatitis C treatment, Foundation for Innovative New Diagnostics (FIND), a global non-profit organisation dedicated towards development of affordable diagnostic tests, and Cipla have signed a collaborative agreement to improve the sensitivity of new hepatitis C diagnostic tests, develop and demonstrate programmes that combine hepatitis C virus (HCV) testing and treatment for high-risk populations, including those with HIV co-infection.

2.3. Exemption of DCGI nod for academic research to boost innovation: Experts

April 26, 2016

- Experts in the field of clinical research have hailed the Union health ministry's recent decision providing exemption from the mandatory prior permission from Drug Controller General of India (DCGI) for clinical trials, approved by the ethics committees, which are undertaken in the medical institutions or hospitals for academic research.
- This according to experts is poised to boost institutional research conducted in India as it will give the institutional ethics committee power to govern the number of studies an investigator can undertake based on requirement of a particular study.

REGULATORY NEWS

3.1. Some Type 2 Diabetes Drugs May Increase Risk of Heart Failure

April 05, 2016

- The US Food and Drug Administration (FDA) updated its safety communication for Type 2 diabetes medicines containing saxagliptin and alogliptin as they may increase the risk of heart failure, particularly in patients who already have heart or kidney disease.
- FDA has added new warnings to the following drug labels about this safety issue: Onglyza (saxagliptin) and Kombiglyze XR (saxagliptin and metformin extended release) From AstraZeneca; Nesina (alogliptin), Kazano (alogliptin and metformin) and Oseni (alogliptin and pioglitazone) from Takeda.

3.2. FDA Offers Final Proprietary Naming Guidance to Minimize Medication Errors April 05, 2016

- The final guidance from the US FDA is part of a host of proprietary name evaluation measures from the reauthorization of the Prescription Drug User Fee Act and aims to help reduce medication errors.
- Product names that look or sound alike can lead to medication errors and potential harm to patients. In its finalized guidance, FDA offers recommendations on what sponsors or applicants should include in their submissions to ensure that the agency can review the proprietary name appropriately.

3.3. FDCs of cos with no data submitted to DCGI to prove safety, efficacy banned April 05, 2016

- Even as interim stay has been granted to 20 odd pharma companies including Abbott, Pfizer and Macleods, the Union health ministry may ban another 739 drugs based on the Kokate committee report.
- The Kokate committee reviewed 6214 drugs, out of which 1083 were found irrational and 344 FDCs were recently banned which comprised of over 1600 brands.

3.4. Data Integrity in cGMP Drug Manufacturing: FDA Offers New Draft Guidance April 14, 2016

- The recent influx of concerns over data manipulation and other data integrity questions in India, China and elsewhere has pushed the US FDA to put out new draft guidance to help the pharmaceutical industry ensure data is consistent and accurate.
- The guidance includes 18 questions and answers on data integrity, alongside well-defined terms on data as they relate to current good manufacturing practice (cGMP) records, as well as recommendations on when workflows on computer systems need to be validated, and how to ensure electronic master production and control records (MPCR) are monitored and can only be used by authorized personnel.

DRUG APPROVALS AND LAUNCHES

4.1. FDA Approves Second Biosimilar, First mAb Biosimilar for US Market April 05, 2016

- The US Food and Drug Administration (FDA) on Tuesday approved the second biosimilar in the US, known as Inflectra (infliximab-dyyb), which is biosimilar to Janssen Biotech's Remicade (infliximab).
- Celltrion and Pfizer's Inflectra has been approved as biosimilar, not as an interchangeable product, meaning in a number of states, pharmacists will not be able to automatically switch patients from Remicade to Inflectra

4.2. FDA approves new drug for chronic lymphocytic leukemia in patients with a specific chromosomal abnormality April 11, 2016

- The U.S. FDA approved Venclexta (venetoclax) for the treatment of patients with chronic lymphocytic leukemia (CLL) who have a chromosomal abnormality called 17p deletion and who have been treated with at least one prior therapy.
- Venclexta is the first FDA-approved treatment that targets the B-cell lymphoma 2 (BCL-2) protein, which supports cancer cell growth and is overexpressed in many patients with CLL. Venclexta is marketed by AbbVie and Genentech USA Inc. of South San Francisco, California.

4.3. FDA approves expanded indication for Gilotrif April 18, 2016

- Boehringer Ingelheim has won US licensing for the expanded use of its EGFR-directed non-small cell lung cancer (NSCLC) drug Gilotrif.
- The authorisation by the US regulator means that Gilotrif (afatinib) can now be provided as a second-line treatment for patients with squamous cell carcinoma (SqCC) of the lung whose disease has progressed despite chemotherapy.

4.4. Elexis announces FDA Approval of CABOMETYX™ (Cabozantinib) for Patients with Advanced Renal Cell Carcinoma April 25, 2016

- Exelixis, Inc. announced that the U.S. FDA has approved CABOMETYX™ (cabozantinib) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.
- CABOMETYX, which was granted Fast Track and Breakthrough therapy designations by the FDA, is the first therapy to demonstrate in a phase 3 trial for patients with advanced RCC, robust and clinically meaningful improvements in all three key efficacy parameters overall survival, progression-free survival and objective response rate.

DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Amgen (AMGN), UCB Phase 3 Data Comparing Romosozumab With Teriparatide Presented at ENDO April 01, 2016

- Amgen and UCB announced detailed Phase 3 results showing the investigational agent romosozumab demonstrated a statistically significant increase in hip bone mineral density (BMD) and strength compared with teriparatide in postmenopausal women with osteoporosis transitioning from bisphosphonate treatment.
- The data, from the randomized, open-label, international, multi-center STRUCTURE study were presented during an oral session at ENDO 2016, the Endocrine Society's 98th Annual Meeting & Expo in Boston.

5.2. Positive topline results from two Phase III dupilumab studies April 01, 2016

- Sanofi and Regeneron have announced positive topline results from two placebo-controlled Phase III studies evaluating investigational dupilumab in adult patients with inadequately controlled moderate-to-severe atopic dermatitis (AD).
- In the studies known as LIBERTY AD SOLO 1 and SOLO 2, treatment with dupilumab as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, quality of life, and mental health.

5.3. Amgen's high cholesterol drug yields positive clinical trial results April 04, 2016

- Amgen has announced positive results from the Phase III GAUSS-3 clinical trial evaluating Repatha (evolucumab) in patients with high cholesterol who cannot tolerate statins.
- The clinical trial showed that the use of Repatha in patients with reproducible statin intolerance due to muscle-related side effects resulted in a significantly greater reduction in low-density lipoprotein cholesterol (LDL-C) after 24 weeks, compared to ezetimibe.

5.4. Phase 3 trial shows rheumatoid arthritis symptoms significantly improved with baricitinib April 11, 2016

- Eli Lilly and Incyte Corporation recently announced novel data from the pivotal Phase 3 RA-BEACON global trial of baricitinib, a once-daily oral drug presently under regulatory review for moderate-to-severe rheumatoid arthritis (RA).
- The results, "Baricitinib in Patients with Refractory Rheumatoid Arthritis" published in the New England Journal of Medicine, revealed the study met its primary endpoint of improved American College of Rheumatology 20 percent (ACR 20) response for baricitinib versus placebo at week 12.

5.5. Opdivo shows biggest survival increase for head and neck cancer in 20 years in Phase III trials April 20, 2016

- Opdivo (nivolumab) showed the biggest increase in survival for patients with head and neck cancer for 20 years, according to new Phase III clinical trial data presented by Bristol-Myers Squibb at the American Association for Cancer Research congress.
- In the CHECKMATE Phase III clinical trial, in patients with current or metastatic platinum-refractory squamous cell carcinoma of the head and neck, more than double the number of patients treated with Opdivo were still alive at one year vs. the comparator arm (36% vs. 16%).

5.6. Lemtrada shows clinical efficacy in multiple sclerosis in 10-year follow-up data April 20, 2016

- Sanofi Genzyme has presented 10-year follow-up data on Lemtrada (alemtuzumab) which points to its efficacy in patients with relapsing-remitting multiple sclerosis (RRMS).
- The ongoing Phase II CAMMS223 study showed that, over 10 years of follow-up, 76% of patients were shown to be free from 6-month confirmed disability worsening. .

MERGER/ACQUISITIONS/COLLABORATION

6.1. Takeda and Teva establish joint company for generics in Japan April 01 , 2016

- Takeda and Teva announce the establishment of Teva Takeda Yakuhin Ltd. Teva will have a 51% stake in the company and Takeda will own 49%.
- The joint company will meet the wide-ranging needs of patients and growing importance of generics in Japan through the provision of off-patent drugs.

6.2. Cutis pharma, Dr. Reddy's Laboratories Announce Partnership April 06, 2016

- CutisPharma, a specialty pharmaceutical company that has historically developed and distributed kits used by pharmacists to safely create compounded medications, announced that it is entering into Active Pharmaceutical Ingredient (API) supply and joint development agreements with Dr. Reddy's Laboratories Ltd.
- The partnership is to to advance several programs in Cutis Pharma's R&D portfolio, including RM-02, RM-03, and RM-06, toward FDA approval.

6.3. Allergan Partners with Heptares for Neurological Disorder Treatments April 07, 2016

- Allergan and Heptares Therapeutics, the wholly-owned subsidiary of Sosei Group Corporation, announced that Allergan's wholly-owned subsidiary, Allergan Pharmaceuticals International Limited, and Heptares have entered into a definitive agreement under which Allergan will license exclusive global rights to a broad portfolio of novel subtype-selective muscarinic receptor agonists in development for the treatment of major neurological disorders, including Alzheimer's disease.

6.4. Pfizer & IBM's Parkinson's Disease Research Collaboration April 07, 2016

- Pfizer Inc. and IBM announced a first-of-its-kind research collaboration to develop innovative remote monitoring solutions aimed at transforming how clinicians deliver care to patients suffering from Parkinson's disease.
- The experimental approach will rely on a system of sensors, mobile devices, and machine learning to provide real-time, around-the-clock disease symptom information to clinicians and researchers.

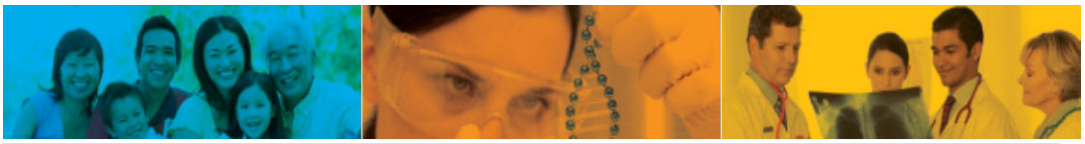
PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. 950bn Drugs will Go Off Patent in Japan in the Next three Years April 04, 2016

- In the next 3 years, ¥950b drugs will go off patent in Japan- and as happened in 2015, substantial volume growth due to new patent expiry opportunities will help Japanese generic companies to withstand NHI pricing pressure.
- ·Consolidation activities like Teva-Takeda JV -will make this growing domestic generic market more competitive and companies with direct sales model may fetch upper hand due to less dependence on wholesale distribution channel.

7.2. NIST Technique creates nanocontainers for drug delivery. April 08, 2016

- Researchers at NIST (National Institute of Standards and Technology) received patent for microfluidics-based method of creating precisely sized, nanometer-scale capsules. Said method can produce liposomes with 100400 nm dia typ, which is useful for attaching to 110 μm cells.
- Continuing research will focus on more applications using different types of nanoparticles.



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TECHNOLOGY/NDDS NEWS

8.1. Researchers Redesign Epilepsy Drug: Increasing Potency & Reducing Side Effects

April 01, 2016

- Researchers at the University of Pittsburgh School of Medicine and Arts & Sciences have designed a more effective version of an FDA-approved epilepsy drug with the potential for fewer side effects, according to a study published in Molecular Pharmacology.
- The experimental agent also could prove to be a treatment for tinnitus and other disorders caused by volatile neural signaling.

8.2. FDA approves first wire-free pacemaker

April 07, 2016

- The first leadless, wire-free heart pacemaker has been approved by the U.S. Food and Drug Administration. Medtronic's Micra Transcatheter Pacing System works like other pacemakers to regulate heart rate in people with heart rhythm disorders, but does not use wired leads to make the electrical connection between the device and the heart.
- The new inch-long Micra device is implanted directly into the right ventricle chamber of the heart, with no wire lead needed.

8.3. Breakthrough Parkinson's disease blood test

April 20, 2016

- A blood test developed by researchers at Melbourne's La Trobe University will enable doctors to detect the abnormal metabolism of blood cells in people with Parkinson's, allowing them to provide treatment options much earlier.
- Currently there is no definitive test to diagnose Parkinson's disease and patients have to rely on a neurological exam, which can be problematic because results are often open to interpretation.