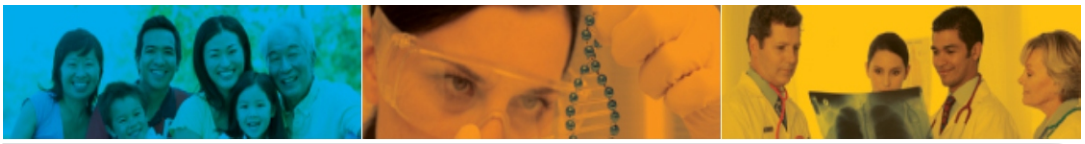

Clinical Research Newsletter Volume - 6, June 2016

LAMBDA

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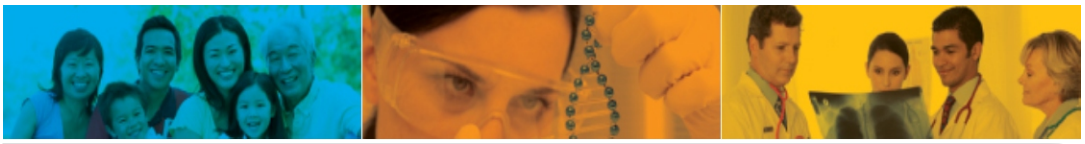


GLOBAL NEWS

1.1. Rheumatoid arthritis can cause hearing loss due to multiple factors, new study

May 03, 2016

- Rheumatoid arthritis can cause hearing loss due to multiple factors, according to a new study.
- The most common type of hearing loss in rheumatoid arthritis is sensorineural hearing loss, which includes synovial destruction of incudostapedial and incudomalleolar joints, rheumatoid nodules, auditory neuropathy, destruction of the cochlear hair cells, and drug-induced ototoxicity

1.2. Asia-Pacific Non-Small Cell Lung Cancer Market to Reach Almost $5 Billion by 2022, says GBI Research

May 05, 2016

- A new report from business intelligence provider GBI Research states that the Non-Small Cell Lung Cancer (NSCLC) market in Asia-Pacific (APAC) countries, including India, China, Australia, South Korea, and Japan, will experience strong growth from $2.7 billion in 2015 to $4.9 billion by 2022, representing a compound annual growth rate of 8.7%.
- Immune-checkpoint inhibitors, such as Opdivo and Keytruda, will be particularly important drivers of growth, with the former recently gaining approval in Japan, Australia and South Korea and the latter currently undergoing Phase III trials in Australia, Japan and South Korea.

1.3. ICH Looks to Global Expansion

May 06, 2016

- The newly renamed International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is looking to bring more pharmaceutical and medical device regulators into its ranks as members and observers.
- The council is now set on becoming an even more international organization, with an interest in adding regulators from other jurisdictions, particularly in China, and other regulatory member groups

1.4. New immune drugs show long-term survival for deadly cancers

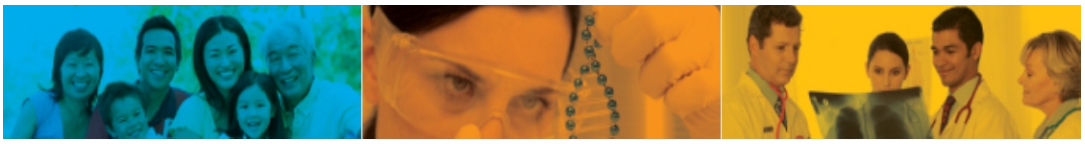
May 20, 2016

- According to new study data, Merck & Co.'s Keytruda and Bristol-Myers Squibb's Opdivo could help patients live years longer than those receiving older treatments
- Specifically, Keytruda helped about 40 percent of patients with advanced melanoma survive at least three years
- 23 percent of patients with advanced lung cancer who received Opdivo were alive two years after beginning therapy, 15 percent higher than those treated with the standard chemotherapy.

1.5. CDISC Unveils New Standard for Clinical Trial Registries

May 24, 2016

- The new standard from the Clinical Data Interchange Standards Consortium (CDISC) will help industry generate submissions for multiple, global clinical trial registries, particularly those from the World Health Organization (WHO), European Medicines Agency (EMA) and ClinicalTrials.gov from a single file.
- The standard, known as the Clinical Trial Registry (CTR) XML, is inspired by the International Committee of Medical Journal Editors (ICMJE), and is based upon the 20-item WHO Trial Registration Data Set as well as EudraCT specific extensions



LAMBDA

DOMESTIC NEWS

2.1.Roll-out of HPV vaccine campaigns in Indian schools

May 02, 2016

- New Delhi has become the first state in the country to launch the Human Papillomavirus (HPV) vaccine as a public health programme for school children. This will be completed in the current academic year over two phases.
- The HPV vaccine protects people against the group of 150-odd HPVs, some of which can cause cervical cancer.
- Children will be given two doses of the vaccine. The first and the second doses will be administered within 30 days of each other. A third booster dose will be given within 240 days of the first vaccine, which will be covered in the next phase, said officials.

2.2. Delhi HC questions government's decision; drug ban saga continues

May 06, 2016

- The Delhi High Court asked the government how it banned some combination drugs without taking into consideration data from manufacturers that had the Centre's approval and using data from manufacturers without approvals instead.
- Pfizer's cough syrup Corex, which had received a 'No Objection Certificate' (NOC) from DCGI in 1995, was brought up as an example during the proceedings.
- The court has extended by another week the stay granted to over 60 pharmaceutical companies that have petitioned the ban on 344 fixed dose combination (FDC) drugs as it continues to hear the government defend its decision.

2.3. Tata Memorial Hospital tests Rs 2,000 per month chemotherapy for ovarian cancer

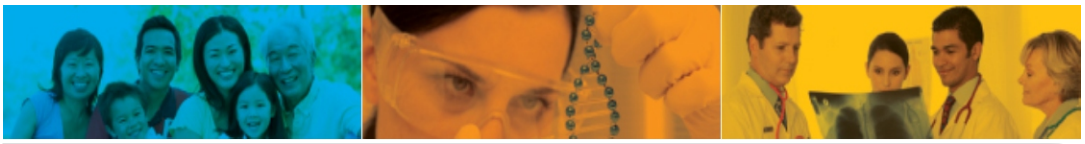
May 09, 2016

- Tata Memorial Hospital are testing a low-cost, low-dose daily chemotherapy for patients whose ovarian cancer has recurred more than twice.
- As cancer medicines are expensive, the idea was not only reduce costs substantially, but to reduce toxicity and side-effects usually associated with cancer treatment. "If one considers that the cost of conventional chemotherapy is Rs 50,000 a cycle, the low-dose alternative would work out to barely Rs 2,000 a month. It is also 1/20th the dosage of conventional drugs," said Dr Gautam Goyal from the hospital.

2.4. Sanofi Recalls Painkiller in India

May 21, 2016

- Sanofi recalled four batches of its painkiller, Combiflam (a combination of paracetamol and ibuprofen), in India after the country's drug regulatory body (CDSCO) found the lots were substandard.
- The Central Drugs Standard Control Organization (CDSCO), India's regulatory body, said on its website in February and April that some of the Combiflam batches weren't of "standard quality," having failed disintegration tests.



REGULATORY NEWS

3.1. NICE recommends combined drug therapy proven to extend life for skin cancer May 01, 2016

- NICE has published final draft guidance recommending trametinib (Mekinist, Novartis Pharmaceuticals) in combination with dabrafenib (Tafinlar, Novartis Pharmaceuticals) to treat a type of skin cancer that has spread and can't be surgically removed.
- Patients with BRAF V600 mutation positive melanoma receiving the new treatment in two clinical trials survived an average of 6 months longer than those on other drugs.

3.2. FDA Considers New User Fee Program for OTC Drugs May 03, 2016

- The US FDA announced that it will gather information on creating a new user fee program for nonprescription, over-the-counter (OTC) drugs.
- User fee programs (such as PDUFA, GDUFA, BsUFA and MDUFA, all of which are now being re-negotiated for 2017) are the life blood of FDA and provide much-needed financial resources from industry, in addition to Congressional appropriations, that support the timely and efficient review of the efficacy and safety of drugs, biologics and devices.

3.3. FDA Calls for Head-to-Head Trials in Revised Draft Guidance on Hepatitis C Drugs

May 07, 2016

- The US FDA released a revised version of its draft guidance on direct-acting antiviral (DAA) Hepatitis C virus (HCV) drugs, which calls on sponsors to conduct head-to-head Phase III studies for drugs in development.
- FDA says the draft guidance only applies to drugs with a mechanism that interferes with HCV replication "through a direct interaction with the HCV genome, polyprotein, or its polyprotein cleavage products," and does not cover new immune-based drugs or those that work to prevent or reverse outcomes of chronic HCV.

3.4. FDA Warning: Antipsychotic Drug May Lead to Urges to Gamble, Binge Eat, Shop, & Have Sex

May 15, 2016

- The FDA is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics).
- These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced.

3.5. Fluoroquinolone Risks Outweigh Benefits in Some Cases May 18, 2016

- The US FDA advised that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis and uncomplicated urinary tract infections (UTIs) who have other treatment options.
- When used systemically (i.e. tablets, capsules and injectable), an FDA safety review found that fluoroquinolones are associated with disabling and potentially permanent serious side effects involving the tendons, muscles, joints, nerves and central nervous system.

3.6. European Commission publishes new harmonized standards for devices, implants, IVDs

May 16, 2016

- In the Official Journal of the European Union, the European Commission on Friday published a new list of the harmonized standards that manufacturers of medical devices, implantable devices and in vitro diagnostic devices can use to demonstrate their products comply with EU law.
- The standards were published as part of the implementation of the European Council's Directive 93/42/EEC from 1993, which deals with medical devices and their regulation.

3.7. Olanzapine: Drug Safety Communication - FDA Warns About Rare But Serious Skin Reactions

May 24, 2016

- FDA is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- A search of the FDA Adverse Event Reporting System (FAERS) database identified 23 cases of DRESS reported with olanzapine worldwide since 1996, when the first olanzapine-containing product was approved.

DRUG APPROVALS AND LAUNCHES

4.1. EMA Approves Antimicrobial Resistance Drug

May 01, 2016

- The European Medicines Agency (EMA) recommended granting marketing authorization for Zavicefta (ceftazidime/avibactam) for treating patients with infections caused by resistant bacteria.
- The recommendation by the EMA Committee for Medicinal Products for Human Use (CHMP) will be sent to the European Commission for a decision about whether or not to approve the drug for use across the European Union (EU).

4.2. FDA approves first drug to treat hallucinations and delusions associated with Parkinson's disease

May 06, 2016

- The U.S. FDA approved Nuplazid (pimavanserin) tablets , the first drug approved to treat hallucinations and delusions associated with psychosis experienced by some people with Parkinson's disease.
- The approval was based on data from the pivotal phase III study -020 and other trials, which supported the use of Nuplazid.
- Nuplazid is marketed by Acadia Pharmaceuticals Inc. of San Diego, California.
- The effectiveness of Nuplazid was shown in a six-week clinical trial of 199 participants in decreasing the frequency and/or severity of hallucinations and delusions.

4.3. NICE recommends Humira as the first approved treatment for skin condition hidradenitis suppurativa May 09, 2016

- NICE has recommended adalimumab (Humira) for the treatment of active moderate to severe hidradenitis suppurativa (HS) in adult patients with an inadequate response to conventional systemic HS therapy, as per the marketing authorisation for adalimumab.
- Following this recommendation suitable patients in England and Wales should be able to access adalimumab on the NHS.

4.4. Eisai gets US FDA additional indication approval for anticancer agent Lenvima in combo with everolimus to treat advanced RCC

May 22, 2016

- Eisai Co., Ltd, a research-based human health care (hhc) company, announced that its US subsidiary Eisai Inc. has received approval from the US FDA for an additional indication for Eisai's in-house developed novel anticancer agent Lenvima (lenvatinib mesylate) in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.
- This is the only combination regimen to significantly prolong progression-free survival (PFS) when compared with a standard of care in patients with advanced renal cell carcinoma following prior anti-angiogenic therapy.
-

DRUG DEVELOPMENT AND CLINICALTRIALS

5.1. Novo Nordisk announce positive results for semaglutide in diabetes patients May 01, 2016

- Novo Nordisk has announced positive top-line results from a Phase III trial of semaglutide injection for the treatment of type 2 diabetes.
- Earlier a 30-week efficacy and safety trial of semaglutide has been reported in February 2016..

5.2. Stivarga improves survival in phase 3 liver cancer trial May 09, 2016

- According to findings from the phase 3 RESORCE trial, patients with unresectable hepatocellular carcinoma (HCC) who received Stivarga (regorafenib) had an improved overall survival (OS) rate when compared with the best supportive care, Nexavar (sorafenib).
- The safety profile for the multitargeted TKI was comparable to previously reported outcomes, according to Bayer, the manufacturer of the drug. Bayer plans to present the full results from the trial at an upcoming scientific meeting .

5.3. Merck Receives Breakthrough Therapy Designation from U.S. FDA for KEYTRUDA® in cHL

May16 , 2016

- U.S. FDA has granted Breakthrough Therapy Designation to KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL). The Breakthrough Therapy Designation in cHL is based on data from the ongoing Phase 1b KEYNOTE-013 and Phase 2 KEYNOTE-087 studies in patients with cHL.

5.4. AstraZeneca announces positive results for benralizumab phase 3 trial for asthma

May 22, 2016

- Benralizumab, an anti-eosinophil monoclonal antibody, was well tolerated and showed reduced annual asthma exacerbation rates when compared with placebo in the SIROCCO and CALIMA trials.
- AstraZeneca announced that benralizumab was well tolerated and achieved the primary endpoint in two pivotal Phase III registrational trials (SIROCCO and CALIMA).

MERGER/ACQUISITIONS/COLLABORATION

6.1. Inovio Pharmaceuticals Completes Acquisition of Needle-Free Injection Technology

May 01, 2016

- Inovio Pharmaceuticals, Inc. announced it has closed the transaction to acquire all of BioJect Medical Technologies Inc.'s assets, including pioneering needle-free jet injection technology, devices, and intellectual property, which it first announced in a definitive agreement on March 14, 2016.
- Inovio acquired BioJect for $4.3 million in Inovio common stock and $1.2 million in cash..

6.2. Mylan to acquire Renaissance derma business for ~$1 billion

May 13, 2016

- Mylan announcing its $7.2 billion deal for Sweden's Meda.
- The company said that Mylan will pay $950 million in cash and up to $50 million in additional payments for the non-sterile, topicals-focused specialty and generics business of Renaissance, a fund that invests in pharma assets.

6.3 Sanofi Genzyme Partners with Johns Hopkins for MS Research

May 16, 2016

- Sanofi Genzyme, the specialty care global business unit of Sanofi, announced a research collaboration with the Johns Hopkins School of Medicine that will focus on novel strategies aimed at advancing the understanding of underlying causes of disease progression in multiple sclerosis (MS).
- The collaboration, under guidance by a joint committee of representatives from Sanofi Genzyme and the Johns Hopkins Multiple Sclerosis Center, will leverage certain technologies and methodologies designed to inform new therapeutic approaches to treating disease progression.

6.4. Pfizer Buying Anacor Pharmaceuticals in $5.2B Deal

May 19, 2016

- Pfizer will acquire Anacor Pharmaceuticals Inc. in a deal valued at about $5.2 billion.
- Under the agreement, Pfizer will acquire Anacor with its each share valued at $99.25, with Pfizer paying the total transaction value in cash.
- The potential acquisition will allow Pfizer an access to Anacor's asset, crisaborole, differentiated, non-steroidal, topical PDE4 inhibitor with anti-inflammatory properties, which is currently being reviewed by the US FDA to treat mild-to-moderate atopic dermatitis, commonly known as eczema.

6.5. Development of Type II Diabetes Treatment with Weekly Dosing May 26, 2016

- TAlbumedix and Hebei Changshan Biochem Pharma Co., Ltd (Changshan) announced that they have entered into a supply agreement for the development of a novel type II diabetes treatment that enables once-weekly dosing.
- The agreement will see Albumedix's recombinant albumin based half-life extension platform used for the development and later commercialization of a modified glucagon-like-peptide albumin conjugate (Albenatide) for the treatment of patients living with the condition in China.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. Arbro Pharma launches bioavailable self nano emulsifying curcumin formulation, SNEC30

May 11, 2016

- Arbro Pharmaceuticals has launched SNEC30, a patented highly bioavailable self nano emulsifying curcumin formulation in 30 mg dose which is the active ingredient of turmeric/Haldi which has been widely used in traditional medicine and home remedies in India.
- Clinical research conducted over the last 25 years has shown curcumin to be effective in various diseases like cancer, pain, inflammation, arthritis, ulcers, psoriasis, arteriosclerosis, diabetes and many more pro-inflammatory conditions.

7.2. Government approves new IPR policy; India Inc hails move while pharma firms wary about changes. May 26, 2016

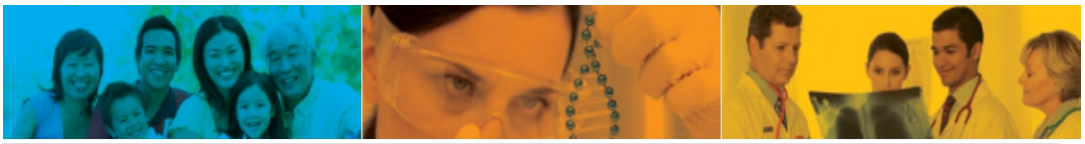
- The government has approved a new IPR policy that seeks to encourage innovation and improve access to healthcare, food security and environmental protection.
- The National Intellectual Property Rights Policy will allow compulsory licensing with restrictions in case of a public health emergency such as epidemics and it is compliant with the World Trade Organization's guidelines, finance minister Arun Jaitley said.

TECHNOLOGY/NDDS NEWS

8.1 Researchers identify out of control immune system linked to neurodegenerative diseases

May 13, 2016

- AN out of control immune system has been identified as a possible cause of neurodegenerative diseases such as Alzheimer's.
- Researchers at the University of Adelaide in South Australia have assembled strong evidence to suggest the body's immune system can develop an inflammatory response that kills brain cells.
- To identify new drug targets that will delay the onset and/or halt the progression of these devastating diseases.



LAMBDA

8.2. Haselmeier and Merck Launch Second Version of Axis-D Pen Injector May 18, 2016

- Following approval by the European Medicines Agency (EMA), GONAL-f® 2.0 was launched by Haselmeier and Merck following its original release in 2011.
- The new version is based on Haselmeier's disposable, multi-use pen Axis-D platform, which has been enhanced to make it easier to hold. It also has a larger screen for improved readability.
- These changes will help patients to clearly view their pre-set dosage, reassuring them that they have taken the correct amount. This is complemented further by a graduated scale on the transparent cartridge.