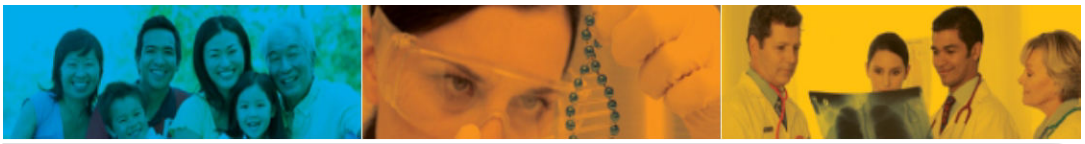

Clinical Research Newsletter Volume - 11, November 2015

LAMBDA

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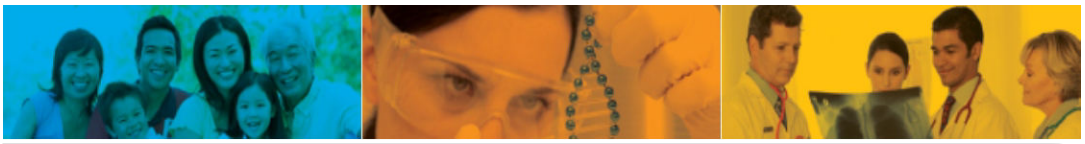


LAMBDA

GLOBAL NEWS

1.1. U.K. Approval Of Informed Electronic Consent: A Pivotal Moment In Enhancing Trial Enrollment

October 01, 2015

- The recent approval by Britain's National Health Service (NHS) for the use of electronic informed consent in a clinical trial is a pivotal moment in the global expansion of a technology that benefits both patients and sponsors of clinical research.
- Approval for the use of electronic informed consent from the California-based company, Mytrus, was granted by the Health Research Authority (HRA), a division of Britain's NHS, established to promote and protect the interests of patients participating in research.

1.2. TPP: Five years data protection for biologics in US-Asia trade deal

October 05, 2015

- Biologic drugs will be given a minimum of five years of data protection under the TPP (Trans-Pacific Partnership) trade deal, upsetting industry groups which had campaigned for 12 years.
- An Asia pacific trade deal first proposed by president Obama in 2009 was agreed now, eliminating a number of trade barriers between the US and 11 countries across Asia, Oceania and the Americas.

1.3. Increasing placebo responses over time, in the U.S. Only

October 07, 2015

- A new study finds that rising placebo responses may play a part in the increasingly high failure rate for clinical trials of drugs designed to control chronic pain caused by nerve damage. Surprisingly, however, the analysis of clinical trials conducted since 1990 found that the increase in placebo responses occurred only in trials conducted wholly in the U.S.; trials conducted in Europe or Asia showed no changes in placebo responses over that period.

1.4. Experts at CPhI Worldwide see continued growth of global pharma outsourcing industry

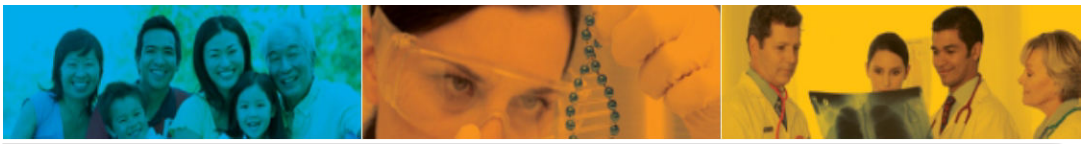
October 16, 2015

- CPhI Worldwide has announced the findings of the final section of its 2015 annual report (part iv, entitled: 'the Outsourcing perspective') live from CPhI Worldwide 2015 in Madrid in which four leading experts on the global pharma outsourcing industry have given their perspectives on the unique challenges that lie ahead in the near and medium term.
- The overall findings reveal that the experts see a continued growth in this sector, and predict further consolidation amongst players, as well as a transforming manufacturing environment with biologics increasingly taking a larger and larger share of global sales.

1.5. ICH Makes Organizational Changes

October 26, 2015

- The International Conference on Harmonisation (ICH) has renamed itself as the International Council for Harmonisation (ICH) and has now become a legal entity under Swiss law.
- ICH says its changes will help it to expand its membership, which currently includes pharmaceutical regulators from the US, EU, Japan, Canada and Switzerland.



LAMBDA

DOMESTIC NEWS

2.1. ICMR in association with PHFI and IHME launches state level disease burden initiative in India October 13, 2015

- The Indian Council of Medical Research (ICMR) in association with Public Health Foundation of India (PHFI) and the Institute for Health Metrics and Evaluation (IHME), University of Washington, Seattle, USA, has launched the state level disease burden initiative in India.
- This is the first of its kind collaborative initiative in India to generate state-level disease burden and risk factors estimation in India utilising the robust global burden of disease (GBD) methodologies in understanding regional and national disease and risk factor trends.

2.2. CDSCO Creates Induction Program to Raise Standards at Inspectorate October 20, 2015

- The Central Drugs Standard Control Organization (CDSCO) has set up an induction program to train assistant drug inspectors. A three-month training program, in which CDSCO will cover the regulatory framework in India and other topics, is the centerpiece of the induction strategy.
- CDSCO has introduced the program to address what it sees as a gap between the potential of India as a pharmaceutical market and the skill sets of its regulatory officials.

REGULATORY NEWS

3.1. Health ministry to do away with repeat animal testing for permission for new drug or clinical trial October 05, 2015

- The Union health ministry henceforth will not insist on repeat pre-clinical or toxicity studies on animals for permission for a new drug or clinical trial if authentic data on animal toxicology has been submitted with the technical data.
- The health ministry's action in this regard comes in the backdrop of the fact that the Union minister for women and child development Maneka Gandhi had written to the Union minister of health and family welfare regarding pre-clinical/toxicity studies on animals under Schedule Y of the Drugs and Cosmetics Rules, 1945.

3.2. Pharma companies may pay double penalty for violating norms October 13, 2015

- The Indian government is ready to dole out a set of stringent standards for pharmaceutical companies. The Centre has prepared a WHO-GMP compliant checklist for drug manufacturers and inspectors. Any deviation from the checklist during inspections are likely to attract penalties, which could be double of what are being slapped currently.

3.3. TGA to Migrate Clinical Trial Applications to New Online System October 14, 2015

- The Therapeutic Goods Administration (TGA) will begin migrating clinical trial forms from a paper-based system to a new online system later this month.
- TGA will be converting the paper-based CTNs it received prior to 1 July 2015 to be compatible with the new online system. The agency says it will close its internal paper-based database on 19 October 2015 to begin work on digitizing the CTNs.

3.4. FDA Warns of Deadly Liver Damage with Abbvie Hepatitis Drugs

October 23, 2015

- Federal health officials are warning doctors and patients that two hepatitis C drugs from AbbVie can cause life-threatening liver injury in patients with advanced forms of the disease.
- The Food and Drug Administration said it will require AbbVie to add new warnings to Viekira Pak and Technivie after reported deaths and liver transplants in patients who already had liver damage caused by hepatitis C.

3.5. FDA Raises Concerns about Safety of AstraZeneca's Gout Drug

October 23, 2015

- An advisory panel for the Food and Drug Administration (FDA) released a new report raising questions about the safety profile of AstraZeneca's gout therapy, lesinurad.
- Lesinurad is used in conjunction with an older gout drug called febuxostat in order to lower the production of uric acid and boost its excretion, reports Reuters.
- The 142-page preliminary review acknowledged this treatment fulfilled this purpose in clinical trials, but not without causing cardiovascular and kidney-related side effects.

DRUG APPROVALS AND LAUNCHES

4.1. US FDA approves Bristol-Myers Squibb's Opdivo to treat patients with advanced NSCLC

October 13, 2015

- The US Food and Drug Administration (FDA) has approved Bristol-Myers Squibb Company's Opdivo (nivolumab) injection, for intravenous use, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.
- Patients with EGFR mutation or ALK translocation should have disease progression on appropriate targeted therapy prior to receiving Opdivo.

4.2. FDA approves new treatment for advanced pancreatic cancer

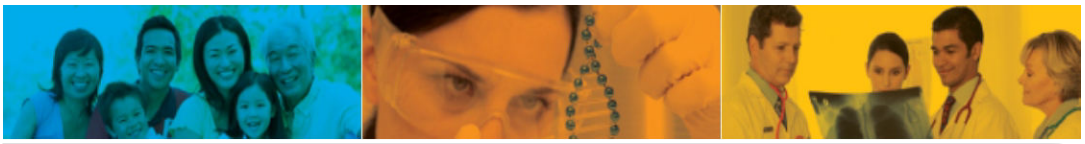
October 22, 2015

- The U.S. Food and Drug Administration approved Onivyde (irinotecan liposome injection), in combination with fluorouracil and leucovorin, to treat patients with advanced (metastatic) pancreatic cancer who have been previously treated with gemcitabine-based chemotherapy.
- Onivyde is marketed by Merrimack Pharmaceuticals Inc. of Cambridge, Massachusetts.

4.3. FDA Advisory Committee recommends the approval of lesinurad for gout patients

October 24, 2015

- AstraZeneca announced that the US Food and Drug Administration's (FDA) Arthritis Advisory Committee (AAC) voted 10 to 4 to recommend the approval of lesinurad 200mg tablets for the treatment of hyperuricemia associated with gout, in combination with a xanthine oxidase inhibitor (XOI).
- The AAC reviewed safety and efficacy data from the pivotal Phase III combination therapy programme trials, representing the largest clinical trial data set of gout patients treated with combination urate lowering therapy.



DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

5.1. Brodalumab therapy achieves 100% reduction in psoriasis symptoms October 01, 2015

- An experimental, biologic treatment, brodalumab, achieved 100 percent reduction in psoriasis symptoms in twice as many patients as a second, commonly used treatment, according to the results of a multicenter clinical trial led by Mount Sinai researchers and published in the New England Journal of Medicine.
- A therapeutic antibody, brodalumab was designed to block the function of the immune signaling protein interleukin 17 (IL-17). If not blocked, IL-17 docks into specifically shaped proteins, IL-17 receptors, to pass on signals that contribute to abnormal, psoriatic inflammation.

5.2. FDA Grants Breakthrough Therapy Designation to Lilly Cancer Drug October 08, 2015

- FDA has granted Breakthrough Therapy Designation to Eli Lilly and Company's abemaciclib for patients with refractory hormone-receptor-positive advanced or metastatic breast cancer.
- The Breakthrough Therapy Designation aims to expedite the development and review of drugs that are intended to treat a serious condition and where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

5.3. Roche: Results of clinical trials of multiple sclerosis drug ocrelizumab are positive

October 09, 2015

- Roche has revealed that results from its pivotal Phase III clinical trials of its multiple sclerosis (MS) drug ocrelizumab are promising in case of people with relapsing MS and primary progressive MS.
- Data from two identical studies OPERA I and OPERA II in people with relapsing MS, which affects approximately 85 percent of people with MS at the time of diagnosis, showed ocrelizumab was superior to interferon beta-1a (Rebif), a well-established MS therapy, in reducing the three major markers of disease activity over the two-year controlled treatment period.

5.4. Lilly Pill Trumps Humira in Arthritis Study October 15, 2015

- Eli Lilly and Co's experimental pill for rheumatoid arthritis proved superior to Abbvie Inc's leading injectable treatment Humira (adalimumab) in a large study.
- Lilly said it was the first study to show that a once-daily oral treatment was superior to $13 billion-a-year Humira, the world's best-selling drug, in improving signs and symptoms of rheumatoid arthritis.
- It was the fourth successful late-stage trial for Lilly's medicine, called baricitinib, which it is developing in partnership with Incyte Corp.

5.5. Pfizer's Inotuzumab Ozogamicin Receives FDA Breakthrough Therapy Designation for Acute Lymphoblastic Leukemia (ALL)

October 19,, 2015

- Pfizer Inc. announced that investigational antibody-drug conjugate (ADC) inotuzumab ozogamicin received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for acute lymphoblastic leukemia (ALL).
- The Breakthrough Therapy designation was based on the results of the Phase 3 INO-VATE ALL trial, which enrolled 326 adult patients with relapsed or refractory CD22-positive ALL and compared inotuzumab ozogamicin to standard of care chemotherapy.

MERGER/ACQUISITIONS/COLLABORATION

6.1. Bionomics expands collaboration with Merck to discover & develop novel pain drugs

October 10, 2015

- Bionomics Limited, a biopharmaceutical company focused on the discovery and development of innovative therapeutics for the treatment of diseases of the CNS and cancer, has extended its strategic collaboration with Merck & Co., Inc., (known as MSD outside the United States and Canada) for the discovery and development of drug candidates for the treatment of chronic and neuropathic pain.
- The latest agreement builds upon a collaboration signed in July 2013 focused on the discovery and development of novel, small molecule drug candidates for the treatment of chronic and neuropathic pain utilizing Bionomics' ionX and MultiCore drug discovery platforms.

6.2. Lilly and AstraZeneca Expand Immuno-Oncology Research Collaboration with new combinations

October 22, 2015

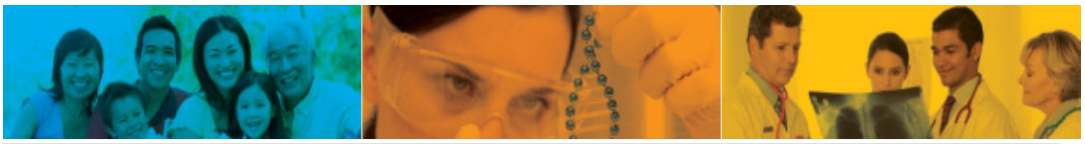
- Eli Lilly and Company and AstraZeneca announced an extension to their existing immuno-oncology collaboration exploring novel combination therapies for the treatment of patients with solid tumors.
- Under the terms of the expanded agreement, Lilly and AstraZeneca will evaluate the safety and efficacy of a range of additional combinations across the companies' complementary portfolios. Lilly will lead the execution of the studies, while both companies will contribute resources.

PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)

7.1. AstraZeneca Diabetes Drug Combination Faces Delay After FDA Rebuff

October 17, 2015

- U.S. health regulators declined to approve a fixed-dose diabetes drug combination from AstraZeneca, delaying its launch and dealing a blow to an important plank of the drugmaker's business.
- AstraZeneca said, it had received a so-called complete response letter from the Food and Drug Administration (FDA) stating that more clinical data were required before it could approve the combination of saxagliptin and dapagliflozin.



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TECHNOLOGY/NDDS NEWS

8.1. DARA BioSciences Announces U.S. Launch of the First Orally-Dissolving Buccal Tablet

October 05, 2015

- DARA BioSciences, Inc., announced the U.S. launch of Oravig - the first and only orally-dissolving muco-adhesive buccal tablet approved to treat adults with oral thrush- into the Oncology and Primary Care markets.
- Beginning this week, DARA and its marketing partner Mission Pharmacal Company will simultaneously begin promotion of Oravig, focusing on the highest prescribing physicians of oral thrush therapy.

8.2. Self-Powered Nanoparticles Travel Against Blood Flow to Stop Bleeding

October 08, 2015

- Scientists at University of British Columbia have developed an unexpected new way of treating internal bleeding using self-propelled particles that can swim against the flow of blood. While various anti-coagulants have been developed, getting them to the bleeding locations can be very difficult.
- The carbonate particles, which come in the form of a powder, release carbon dioxide once placed in an aqueous solution. They also have tranexamic acid, an antifibrinolytic agent, attached to their surface. When injected into a blood vessel, the particles bubble the carbon dioxide gas with enough force to be able to propel through oncoming blood.
- The particles were tested in two animal models with considerable success, including a mimic of a gunshot wound.