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Contact Us

Dr. Mrinal Kammili, Director Global Head - BD  
mrinal@lambda-cro.com

Mr. Akshaya Nath, COO  
akshayanath@lambda-cro.com

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## ▶ GLOBAL NEWS

### 1.1. HIV/AIDS Drugs Interfere with Brain's Insulation

December 01, 2015

- In a new study, researchers from the University of Pennsylvania and The Children's Hospital of Philadelphia teamed up to investigate the underlying reasons for these impairments with HIV/AIDS drugs.
- They found that commonly used antiretroviral medications disrupted the function of oligodendrocytes, crucial brain cells that manufacture myelin, the fatty material that serves to insulate neurons, helping them transmit signals in the brain fast and efficiently.

### 1.2. Oral Contraceptive Use Leads to Better Outcomes in Patients With Ovarian Cancer

December 02, 2015

- In Women who develop ovarian cancer are more likely to have better outcomes if they took oral contraceptives prior to their diagnosis, according to a new study by researchers at Mayo Clinic.
- In an analysis that examined outcomes of patients treated at Mayo Clinic between 2000 and 2013, investigators found that those who had taken birth control pills prior to their cancer diagnosis had improved progression-free survival (PFS) and length of time that they lived with the disease without it worsening compared with those who had not taken contraceptives.

### 1.3. Risk of childhood wheeze from antibiotic use in third trimester of pregnancy

December 03, 2015

- Antibiotic use during the third trimester of pregnancy leads to an increased risk of childhood wheeze, according to new findings.
- The findings, published online in the European Respiratory Journal, suggest that although prenatal antibiotic exposure and infant wheezing can largely be explained by confounding factors, when these factors were accounted for, the risk associated with taking antibiotics in the third trimester of pregnancy remained.

### 1.4. Head-to-Head Test of Biologic Agents Finds Similar Efficacy in RA

December 21, 2015

- A head-to-head test of seven biologic agents finds that all are similarly effective in treating rheumatoid arthritis.
- The new study, presented November 8 at the annual meeting of the American College of Rheumatology in San Francisco, found no differences in efficacy between abatacept, adalimumab, certolizumab, etanercept, infliximab, rituximab and tocilizumab in a real-world registry of patients.

## ▶ DOMESTIC NEWS

### 2.1. Cipla set to launch low-dose HIV drug Efavirenz 400 mg

December 01, 2015

- On the eve of World AIDS Day, Cipla Ltd., a global pharmaceutical company, announced its readiness to supply its combinations Tenofovir/Emtricitabine/Efavirenz and Tenofovir/ Lamivudine /Efavirenz with a dose of 400 mg of Efavirenz as a first-line initial therapy for HIV infection.
- Studies now support the use of Efavirenz 400 mg as a substitute for Efavirenz 600 mg in cases where there is no co-infection with tuberculosis. Efavirenz 600 mg is currently used in antiretroviral therapy (ART) and is highly effective.



## 2.2. Availability of vaccines against swine flu

December 04, 2015

- The Government of India has recommended trivalent inactivated influenza vaccine which is available in the country and can be obtained as per the requirement.
- Based on epidemiological evidence, the advice of World Health Organization (WHO), Indian Council of Medical Research (ICMR) and subject experts, the Government of India recommends vaccination of high risk groups with seasonal influenza vaccine.

## 2.3. Government may exempt Sanofi's dengue vaccine from large-scale clinical trials

December 22, 2015

- As India reported a record number of dengue cases during the year, the health ministry is exploring the possibilities to accelerate the marketing authorisation for a preventive vaccine, health industry sources said.
- Dengvaxia, the brand name of the vaccine developed by Sanofi Pasteur, a unit of French pharmaceutical giant Sanofi, is being examined by the Indian drug regulatory agency for exemption from large-scale clinical trials on patients, the sources said. If cleared, the step may eventually pave the way for its availability via the wide government distribution system and private channels.

## REGULATORY NEWS

### 3.1. EMA Takes a Firmer Stance on GCP Non-Compliance

December 01, 2015

- Drug and biotech companies cannot replace pivotal clinical trials that are non-compliant with good clinical practice (GCP) standards during the assessment of marketing authorization applications, according to a new position paper from the European Medicines Agency (EMA).
- Stressing the importance of GCP compliance, the EMA says it's an "essential prerequisite" for assessing a medicinal product's safety and efficacy. The agency also clarifies that when a study is found to be GCP non-compliant during an inspection, the applicant/marketing authorization holder (MAH) have several options, including commenting on the inspection findings, providing a re-analysis of the data that excludes the non-GCP compliant data, and/or presenting a justification why specific data are actually reliable.

### 3.2. FDA Strengthens Label Warnings for SGLT2 Inhibitor Class of Type 2 Diabetes Drugs

December 07, 2015

- The Food and Drug Administration (FDA) has updated the labels for sodium-glucose cotransporter 2 (SGLT2) inhibitors to include the risks for ketoacidosis and serious urinary tract infections. Drugs in the SGLT2 inhibitor class include Invokana (canagliflozin), Farxiga (dapagliflozin), and Jardiance (empagliflozin).
- In May 2015, the FDA issued a drug safety communication cautioning about the risk for ketoacidosis with SGLT2 inhibitors and saying the agency would continue to study this issue.



### 3.3. EMA Offers New Pharmacovigilance Updates

December 17, 2015

- The European Medicines Agency (EMA) has released a batch of draft pharmacovigilance documents. EMA covers multiple aspects of good pharmacovigilance practice (GVP) in the texts, from changes to a template for direct healthcare professional (HCP) communication, to tweaks to a biologics-focused document.
- In total, EMA published four draft documents. Two of the documents address aspects of communicating with HCPs. EMA is proposing multiple changes to the template letter used by marketing authorization holders (MAHs) to inform HCPs of safety concerns. Many of the changes amount to a reordering of existing elements, but EMA has also added new lines, such as the need to frame the alert in the context of the therapeutic indication.

## ▶ DRUG APPROVALS AND LAUNCHES

### 4.1. Empliciti (Elotuzumab) Approved By FDA For Multiple Myeloma

December 01, 2015

- The United States Food and Drug Administration (FDA) has approved elotuzumab for the treatment of multiple myeloma. The drug will be sold under the brand name Empliciti, and it will be marketed by the U.S. pharmaceutical company Bristol-Myers Squibb.
- Empliciti's approval is for use in combination with Revlimid (lenalidomide) and dexamethasone (Decadron) in multiple myeloma patients who have received one to three prior therapies.

### 4.2. Baxalta Receives FDA Approval for VONVENDI

December 08, 2015

- VONNVENDI has been approved for on-demand treatment and control of bleeding episodes in adults with von Willebrand disease. The FDA approval was based on positive results from a Phase III multicenter, open-label clinical trial that assessed the safety, efficacy and pharmacokinetics of VONNVENDI with and without recombinant FVIII.

### 4.3. FDA approves Basaglar long-acting diabetes drug

December 17, 2015

- Eli Lilly and Boehringer Ingelheim Pharmaceuticals have secured approval from the US Food and Drug Administration (FDA) for their long-acting Basaglar diabetes drug.
- Basaglar is indicated to improve glycemic control in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes. It is considered as a biosimilar of Sanofi's Lantus diabetes drug. Basaglar has the similar amino acid sequence as the currently marketed insulin glargine product.

### 4.4. EMA Fast-Tracks New Oral Treatment For Non-Small Cell Lung Cancer

December 19, 2015

- The European Medicines Agency (EMA) has recommended granting a conditional marketing authorization for Tagrisso (osimertinib) for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a specific mutation (T790M) of the epidermal growth factor receptor (EGFR). The Committee for Medicinal Products for Human Use (CHMP) reviewed Tagrisso under EMA's accelerated assessment program and recommended conditional approval for the medicine.



#### 4.5. Martindale Pharma launches first oral liquid suspension formula of riluzole in UK

December 21, 2015

- Martindale Pharma has launched the first oral liquid suspension formula of riluzole, Teglutik, which is the only licensed drug for patients suffering from amyotrophic lateral sclerosis (ALS), a common form of motor neurones disease (MND).
- Teglutik is an oral liquid form of riluzole, which comes with a syrupy consistency. The new formula has been treated as a bioequivalent to riluzole tablets and is claimed to extend life or the time to mechanical ventilation for patients with ALS unable to swallow due to discomfort, which is a complication of the disease.

#### 4.6. FDA approves anti-dengue vaccine in PH

December 23, 2015

- The Food and Drug Administration (FDA) has finally approved the much-awaited vaccine against the deadly dengue virus, making the Philippines the first in Asia to make a vital step in the prevention of the disease.
- The use of Dengvaxia in the Philippines followed closely the first approval in Mexico, where dengue has also been endemic. It also noted that the FDA approved the vaccine for the prevention of the mosquito-borne disease caused by all four dengue strains in people aged nine to 45 years old living in endemic areas in the country.

### ➤ DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

#### 5.1. US FDA grants fast track status to Trevena's oliceridine for pain management

December 05, 2015

- The US FDA has granted Fast Track designation to Trevena's oliceridine (TRV130) for the management of moderate-to-severe acute pain. Oliceridine is being developed as a potential replacement for currently approved intravenous opioid analgesics.
- In a recently completed phase 2 study in postoperative pain, oliceridine matched the analgesic efficacy of morphine with an improved safety and tolerability profile. Trevena expects to initiate phase 3 development of oliceridine in the first quarter of 2016.

#### 5.2. Acorda Initiates Phase 1 Clinical Trial of CVT-427, Inhaled Therapy for Acute Treatment of Migraines.

December 05, 2015

- Acorda Therapeutics, Inc. announced initiation of enrollment in the first clinical study of CVT-427, an investigational agent under development for the acute treatment of migraines which represents an innovative approach to acute treatment of migraines.
- CVT-427 is a novel, inhaled formulation of zolmitriptan that uses the Company's proprietary ARCUS® technology. Zolmitriptan belongs to a class of drugs known as triptans, which are a leading therapy for acute treatment of migraines.



### 5.3. Kite Pharma Receives FDA Breakthrough Therapy Designation for KTE-C19

December 07, 2015

- Kite Pharma, announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation status to the Company's lead product candidate, KTE-C19, for the treatment of patients with refractory diffuse large B cell lymphoma (DLBCL), primary mediastinal B cell lymphoma (PMBCL), and transformed follicular lymphoma (TFL).
- KTE-C19 is an investigational therapy in which a patient's T cells are genetically modified to express a chimeric antigen receptor designed to target the antigen CD19, a protein expressed on the cell surface of B cell lymphomas and leukemias.

### 5.4. USFDA grants breakthrough drug discovery status to Wockhardt's antibiotic drug

December 08, 2015

- Wockhardt announced that US Food and Drug Administration (USFDA) has granted breakthrough qualified infectious disease product (QIDP) drug discovery status to the new antibiotic product of the company targeted for gram negative terrain for complicated Urinary Tract Infections and Hospital-acquired bacterial pneumonia (HABP).
- WCK 5222, an antibiotic from new drug discovery in anti defectives, is the fourth product from the drug firm to receive this coveted status. Wockhardt is the only company globally whose four products achieved this status from USFDA in quick succession.

### 5.5. Lilly's Type 2 Diabetes Candidate Succeeds in Phase 3 Trial

December 09, 2015

- The usefulness of chondroitin in the treatment of osteoarthritis (OA) has long been debated, but new research coming out of the American College of Rheumatology Annual Meeting, reports that for the first time, chondroitin sulfate was shown to be more effective in reducing long-term progression of knee OA than celecoxib, a drug often used as first-line therapy in the disease.
- "This study demonstrates that both chondroitin sulfate and celecoxib are equally effective at reducing the symptoms of knee OA patients. However, only chondroitin sulfate was found to be capable of slowing down the progression of the disease by reducing the loss of cartilage," said Dr. Pelletier.

### 5.6. AstraZeneca (AZN) Issues Encouraging Update on Durvalumab ATLANTIC Trial in NSCLC

December 18, 2015

- AstraZeneca provided an update on preliminary findings from the ATLANTIC trial of durvalumab as 3rd-line or later stage therapy in patients with locally advanced or metastatic programmed death ligand-1 (PD-L1) positive non-small cell lung cancer (NSCLC) that lacks epidermal growth factor receptor (EGFR) or ALK alterations.
- An initial analysis supports durvalumab's clinical activity, with durable responses and an established safety profile in these difficult-to-treat patients. ATLANTIC investigated the efficacy and tolerability of durvalumab in patients who received at least two prior systemic treatment regimens including platinum-based chemotherapy, and who have limited options for further therapy.



## ➤ **MERGER/ACQUISITIONS/COLLABORATION**

### **6.1. Biovista Inc. Announces Drug Repositioning Collaboration with Astellas Pharma**

December 02, 2015

- Biovista entered into a drug repositioning collaboration with Astellas Pharma Inc. The collaboration is focused on identifying new indications for a number of undisclosed Astellas compounds using Biovista's Clinical Outcome Search Space (COSS) technology.

### **6.2. Cypralis, Janssen in Neurodegenerative Pact**

December 07, 2015

- Cypralis has entered into a collaboration with Janssen Pharmaceuticals Inc., facilitated by Johnson & Johnson Innovation, to develop new cyclophilin inhibitors for neurodegenerative diseases. The terms were not disclosed. Cypralis focuses on the discovery of therapeutics for the modulation of peptidyl-prolyl isomerases (PPlases).

### **6.3. Halozyme and Lilly partner to develop new drugs using Enhance platform**

December 22, 2015

- US-based biotechnology firm Halozyme Therapeutics has entered a global collaboration and licence agreement with Eli Lilly and Company to develop and commercialise new drugs that combine compounds with the Enhance drug delivery platform.
- Enhance is based on Halozyme's recombinant human hyaluronidase enzyme (rHuPH20), which is designed to allow injection of some biologics and compounds that are now administered intravenously.

### **6.4. Bayer and CRISPR to form JV to develop new treatments for serious genetic diseases**

December 22, 2015

- Bayer has entered an agreement with CRISPR Therapeutics to establish a joint venture (JV) to develop new breakthrough therapeutics for curing blood disorders, blindness and congenital heart disease.
- The new JV will combine CRISPR-Cas9 gene editing technology with Bayer's protein engineering and disease expertise. Under the deal, Bayer will invest a minimum of \$300m in the JV over the next five years for research and development works.

## ➤ **PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)**

### **7.1. NYBC researchers awarded patents for discoveries to protect blood supply & advance vaccine therapies**

December 10, 2015

- New York Blood Center (NYBC), one of the largest non-profit, community-based blood centers, announced that the award of several new patents in 2014/15, continuing its unique role as an independent, community-based blood center that also operates a successful research institute dedicated to developing products and services that benefit patients worldwide. Key innovations of the Life saving missions include solvent/detergent inactivation of viruses in plasma, the first HIV drug that acts as a fusion inhibitor, fibrin "glue," and the hepatitis B vaccine, among many others.



**7.2. Amrantus gets US patent covering method of treating Parkinson's disease levodopa-induced dyskinesia** December 17, 2015

- Amarantus BioScience Holdings, Inc. (AMBS), a biotechnology company has received a Notice of Allowance from the US Patent and Trademark Office (USPTO) covering the use of combination 5HT1A and 5HT1B agonists, including eltoprazine, for the treatment of Parkinson's disease levodopa-induced dyskinesia (PD-LID).

**7.3. BiondVax's universal flu vaccine receives Israel patent** December 23, 2015

- Amaranthus BioScience Holdings, Inc. (AMBS), a biotechnology company has received a Notice of Allowance from the US Patent and Trademark Office (USPTO) covering the use of combination 5HT1A and 5HT1B agonists, including eltoprazine, for the treatment of Parkinson's disease levodopa-induced dyskinesia (PD-LID).
- The USPTO issues a Notice of Allowance after it makes a determination that a patent should be issued based on examination of the filing.

**▶ TECHNOLOGY/NDDS NEWS**

**8.1. FDA Approves Device That Can Plug Gunshot Wounds in 15 Seconds** December 08, 2015

- The U.S. Food and Drug Administration has cleared the use of the XSTAT 30 an innovative sponge-filled gunshot wound dressing device for use in the general population. Approved last year for battlefield use, the device can plug a gunshot wound in just 15 seconds.
- The XSTAT Rapid Hemostasis System is an expandable, multi-sponge dressing that's used to control severe, life-threatening bleeding from wounds in bodily areas where a traditional tourniquet is of no use, such as the groin or armpit. It works by pumping expandable, tablet-sized sponges into the wound, staunching bleeding while a patient is rushed to hospital.

**8.2. Irradiated white blood cells release substances that have positive effect upon tissue repair**

December 14, 2015

- Hendrik Jan Ankersmit's research group at the Clinical Department of Thoracic Surgery of MedUni Vienna has successfully shown that irradiated white blood cells release substances that reduce the severity of the damage caused by a heart attack or stroke and in spinal injuries and have a positive effect upon tissue repair.
- The positive effects have already been explored in large animal models wherein damage caused by heart attacks can be significantly reduced. Currently studies are being planned in dermatology and cardiology.