



CONTENTS

<b>1. GLOBAL NEWS</b>	<b>2</b>
1.1. Scientists record real-time dopamine release in Parkinson's patients	2
1.2. Cancer Genetics targets India acquisitions	2
1.3. EU plans export waiver for pharma manufacturing	2
1.4. Antibiotic Class Linked to Risk of Sudden Cardiac Death	2
1.5. Menopause Therapy: 'Don't Suffer Silently,' Says UK NICE	3
1.6. Ex-Italian medicines chief heads EMA	3
<b>2. DOMESTIC NEWS</b>	<b>3</b>
2.1. Accreditation of ethics committees vital for high quality research & trials for new drugs	3
2.2. Government promoting acceptance of Indian drug norms in various markets	3
<b>3. REGULATORY NEWS</b>	<b>4</b>
3.1. FDA issues statement on long-term clopidogrel Tx and risk of death	4
3.2. FDA Recommends Change to Label of Antibacterial Drugs	4
3.3. Indian Govt To Promote Clinical Research Step-By-Step	4
<b>4. DRUGS APPROVAL AND LAUNCHES</b>	<b>4</b>
4.1. Nucala (mepolizumab) approved for treatment of asthma patients	4
4.2. FDA Approves Genvoya for the Treatment of HIV	5
4.3. US FDA approves Tagrisso to Treat Non-Small Cell Lung Cancer	5
4.4. Narcan (Naloxone Hydrochloride) Nasal Spray Approved by U.S.FDA	5
4.5. FDA Approves New Flu Vaccine With Extra Ingredient	5
4.6. Novartis announces EC approval of Cosentyx for of ankylosing spondylitis, psoriatic arthritis	5
<b>5. DRUGS IN DEVELOPMENT AND CLINICAL TRIALS</b>	<b>6</b>
5.1. Merck Receives Breakthrough Therapy Designation from FDA	6
5.2. In Knee OA Study, Chondroitin Beats Common First-Line Tx in Disease Progression	6
5.3. Amgen Biosimilar ABP501 SHOWS Clinical Equivalence With Adalimumab: Phase 3 study	6
<b>6. MERGER / ACQUISITION / COLLABORATION</b>	<b>6</b>
6.1. Novo Nordisk and UW to collaborate on exploring role of the brain glucose homeostasis	6
6.2. Thermo Fisher Collaborates On Diagnostic Test To Improve Prostate Cancer Screening	7
6.3. LEO Pharma to Acquire Global Dermatology Portfolio from Astellas	7
<b>7. PATENT (NEW APPROVAL/ LITIGATION/SETTLEMENTS)</b>	<b>7</b>
7.1. Levolta Pharmaceuticals gets US patent for novel therapy for controlling osteoarthritis	7
7.2. Researchers Design & Patent Graphene Biosensors	7
<b>8. TECHNOLOGY/NDDS NEWS</b>	<b>8</b>
8.1. Scientists Discover How to Better Map Brain Tumors	8
8.2. New computational method helps predict ADR's better than traditional computing methods	8
8.3. Researchers develop novel technology for chronic arthritis	8

Contact Us

▶ Dr. Mrinal Kammili, Director Global Head - BD ▶ Mr. Akshaya Nath, Chief Operating Officer  
 mrinal@lambda-cro.com akshayanath@lambda-cro.com

**Disclaimer:** "The information compiled and published in this newsletter have been collected from various public domain resources available on web and relevant magazines. The Public Domain information is not confidential and may be freely distributed and copied. However, transmission or reproduction of protected items beyond that allowed by fair use as defined in the copyright laws requires the written permission of the copyright owners, if any. Lambda directly or indirectly shall not be responsible for any legal/ethical litigation claimed by any professional agency / bodies."

**GLOBAL NEWS****1.1. Scientists record real-time dopamine release in Parkinson's patients**

November 03, 2015

- Scientists have reported first-ever measurements of a key neurotransmitter involved in learning with unprecedented precision in the brains of people with Parkinson's disease. The measurements, collected during brain surgery as the conscious patients played an investment game, demonstrate how rapid dopamine release encodes information crucial for human choice. The findings may have widespread implications not just for Parkinson's disease but for other neurological and psychiatric disorders as well, including depression and addiction, researchers from Virginia Tech Carilion Research Institute noted.
- The researchers detected changes in the levels of dopamine a thousand times faster than had previously been recorded in humans. These rapid measurements, combined with enhanced chemical specificity, led the scientists to discover that dopamine - a crucial neurotransmitter involved in learning and decision-making - has a far more complex role than formerly thought.

**1.2. Cancer Genetics targets India acquisitions**

November 03, 2015

- In the US, nearly 50 per cent of breast cancer cases are detected using genomics testing. In contrast, it is less than 2 per cent in India. While the cost of diagnosis using DNA-based genome tests is coming down in the US, it is prohibitive for most people in India. "However, big ticket investments are flowing into research in this area, and in the near future, the tests will become affordable", says Panna Sharma, CEO of Cancer Genetics Inc (CGI).
- In its bid to expand into India, CGI acquired BioServe Biotechnologies in Hyderabad, in 2014. In addition to expanding its sales and clinical teams in India, it has lined up four-five major research collaborations and several partnerships with leading hospitals.

**1.3. EU plans export waiver for pharma manufacturing**

November 03, 2015

- The European Commission plans to bring in an export waiver for supplementary protection certificates, in order to boost pharma industry manufacturing in Europe.
- In the European Economic Area (EEA) supplementary protection certificates (SPCs) extend a company's intellectual property rights for a drug following the expiry of the original patent for medicines and biologics. The certificates were created to compensate companies for the long approval time for products.

**1.4. Antibiotic Class Linked to Risk of Sudden Cardiac Death**

November 10, 2015

- Macrolides are associated with a small but measurable increased risk of sudden cardiac death, according to research published in the Nov issue of the Journal of the American College of Cardiology.
- In the new report, the investigators analyzed 33 studies that were conducted between 1966 and 2015, and included a total of more than 20 million patients. The studies compared patients who took macrolides, other types of antibiotics, or no antibiotics.



### 1.5 Menopause Therapy: 'Don't Suffer Silently,' Says UK NICE

November 13, 2015

- The UK National Institute for Health and Care Excellence (NICE) has issued its first-ever guidance on menopause, which emphasizes that help and information are available to women suffering from symptoms and that a range of treatment options, such as hormone-replacement therapy (HRT) as well as nondrug treatments, can be discussed with their doctors.
- the guidelines received unprecedented media coverage in the United Kingdom, in particular with regard to the issue of whether or not women should take HRT.

### 1.6. Ex-Italian medicines chief heads EMA

November 16, 2015

- Professor Guido Rasi began his second term as Executive Director of EMA on 16 November 2015. From November 2014 to mid-November 2015, Professor Guido Rasi served as EMA's Principal Adviser in Charge of Strategy.
- From November 2011 to November 2014 he was the Executive Director of the European Medicines Agency and a member of its Management Board in the three years prior to this.

## ▶ DOMESTIC NEWS

### 2.1. Accreditation of ethics committees vital for high quality research & trials for new drugs, Dr Y K Gupta

November 18, 2015

- Certification and accreditation of institutional ethics committees who approve clinical trials, clinical investigators and trial sites are vital for high quality clinical research and clinical trials of new drugs, medical equipments and procedures, according to Dr Y K Gupta, national scientific coordinator for Pharmacovigilance Programme of India (PvPI).
- He said while the government has brought about stringent regulations to ensure patient safety in clinical trials and research as suited to India and also in accordance with global standards, the three major components involved in this ethical committees, investigators and clinical sites have to be brought up to desired standards. For this, training and attitudinal changes are needed.

### 2.2. Govt. promoting acceptance of Indian drug norms in various markets

November 29, 2015

- Pharmaceuticals Export Promotion Council of India (Pharmexcil) is in talks with various semi regulated markets in Africa, ASEAN, SAARC regions to accept the Indian Pharmacopoeia instead of British Pharmacopoeia (BP) or the United States Pharmacopoeia (USP).
- To build up support for the initiative, Pharmexcil has invited 10-15 drug regulatory heads from various countries to take part in the Indian Pharmaceutical Congress in Mysore in December, 2015.
- It is expected that the move would help Indian drug makers that only follow IPC to save costs and time for them to upgrade and adopt either BP or USP. However the task to convince these countries would not be easy as confidence has to be instilled in them regarding Indian manufacturing facilities and standards, according to Pharmexcil.



## ▶ REGULATORY NEWS

### 3.1. FDA issues statement on long-term clopidogrel Tx and risk of death

November 06, 2015

- Based on reviews of the Dual Antiplatelet Therapy (DAPT) trial and several other large, long-term clinical trials, the FDA has concluded that there is no evidence of either a harmful or beneficial effect of clopidogrel on all-cause mortality or cancer-related deaths in a population with, or at risk for, coronary artery disease.
- In order to investigate the signals of increased risk of death and cancer-related death from the DAPT trial, the FDA evaluated the DAPT trial and performed trial-level meta-analyses of other large, long-term trials that had available data on rates of death, rates of death from cancer, or rates of cancer adverse events.

### 3.2. FDA Recommends Change to Label of Antibacterial Drugs

November 13, 2015

- An FDA advisory panel voted last week to recommend making changes to the label of fluoroquinolone antibacterial drugs for the treatment of acute bacterial sinusitis, uncomplicated urinary tract infections, and chronic bronchitis.
- In a 21-0 margin, a joint meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee agreed that data on the risks and benefits of fluoroquinolones one of the most potent FDA-approved drugs do not support their use in treating acute bacterial sinusitis.

### 3.3. Indian Govt To Promote Clinical Research Step-By-Step

November 13, 2015

- The government of India in a new medical advancement introduced a series of steps that would help promote more clinical research in the country.
- The Central Drug Standard Control Organization (CDSCO) said if a new drug was already approved outside India after conducting pre-clinical/toxicological studies on animals; such studies are not required to be repeated while approving their proposal for import or manufacture in India unless some specific concerns are raised.

## ▶ DRUG APPROVALS AND LAUNCHES

### 4.1. Nucala (mepolizumab) approved for treatment of asthma patients

November 05, 2015

- The U.S. FDA approved Nucala (mepolizumab) for use with other asthma medicines for the maintenance treatment of asthma in patients age 12 years and older. Nucala is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.
- Nucala is administered once every four weeks by subcutaneous injection by a health care professional into the upper arm, thigh, or abdomen. The safety and efficacy of Nucala were established in three double-blind, randomized, placebo-controlled trials in patients with severe asthma on currently available therapies.



#### 4.2. FDA Approves Genvoya for the Treatment of HIV

November 05, 2015

- Gilead announced that the US FDA has approved Genvoya (elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide) tablets for the treatment of HIV-1 infection in patients age 12 years or older
- Genvoya is indicated for patients who have no anti-retroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable regimen for ≥6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.

#### 4.3. US FDA approves Tagrisso to Treat Non-Small Cell Lung Cancer

November 13, 2015

- The US FDA has approved Tagrisso (osimertinib; AstraZeneca) for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.
- This indication is approved under the FDA's accelerated approval process based on tumor response rate and duration of response.

#### 4.4. Narcan (Naloxone Hydrochloride) Nasal Spray Approved by U.S. FDA

November 19, 2015

- First Ready-to-Use Needle-Free Nasal Spray Treats Opioid Overdose Emergency. Adapt Pharma Limited ([www.adaptpharma.com](http://www.adaptpharma.com)) announced that the U.S. Food and Drug Administration (FDA) has approved NARCAN® (naloxone hydrochloride) Nasal Spray for the emergency treatment of known or suspected opioid overdose.
- NARCAN Nasal Spray requires no assembly or priming prior to use. It can be administered in an emergency by family members, caregivers or others to reverse the effects of opioid overdose until help arrives.

#### 4.5. FDA Approves New Flu Vaccine With Extra Ingredient

November 25, 2015

- FDA approves Fluad, the first seasonal influenza vaccine containing an adjuvant. Fluad, a trivalent vaccine produced from three influenza virus strains (two subtype A and one type B), is approved for the prevention of seasonal influenza in people 65 years of age and older
- Adjuvant Mf59 a compound that helps stimulate the immune system so that a vaccine is more effective.

#### 4.6. Novartis announces EC approval of Cosentyx for treatment of ankylosing spondylitis, psoriatic arthritis

November 25, 2015

- Novartis announced today that the European Commission (EC) has approved Cosentyx® (secukinumab) for the treatment of people living with ankylosing spondylitis (AS) and psoriatic arthritis (PsA). For AS, this is the first new treatment advance in 16 years since the development of the current standard of care, anti-tumor necrosis factor (anti-TNF) therapy. Cosentyx is the first in a new class of medicines called interleukin-17A (IL-17A) inhibitors to be made available in Europe for AS and PsA.



## ➤ DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

### 5.1. Merck receives Breakthrough Therapy Designation from FDA

November 02, 2015

- Merck announced that the FDA has granted Breakthrough Therapy Designation to KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, for the treatment of patients with microsatellite instability high (MSI-H) metastatic colorectal cancer. This is the third Breakthrough Therapy Designation granted for KEYTRUDA

### 5.2. In Knee OA Study, Chondroitin Beats Common First-Line Tx in Disease Progression

November 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.

### 5.3. Amgen Presents Detailed Results From Phase 3 Study Demonstrating Clinical Equivalence Of Biosimilar Candidate ABP 501 With Adalimumab

November 09, 2015

- Amgen presented detailed findings from a head-to-head Phase 3 study comparing the safety, efficacy and immunogenicity of biosimilar candidate ABP 501 with adalimumab in patients with moderate-to-severe rheumatoid arthritis. The results were presented in an oral presentation at the 2015 American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Meeting in San Francisco.
- The study met the primary endpoint, which was achievement of ACR20 (20 percent or greater improvement in ACR assessment) at week 24.

## ➤ MERGER/ACQUISITIONS/COLLABORATION

### 6.1. Novo Nordisk and UW to collaborate on exploring role of the brain in regulating blood glucose and obesity

November 03, 2015

- Novo Nordisk announced that a research collaboration has been initiated with Dr Michael Schwartz, director of The Diabetes and Obesity Center of Excellence at UW Medicine.
- The collaboration aims to understand factors mediating brain control of blood glucose and appetite with the ultimate goal of developing new therapeutic agents for the treatment of diabetes and obesity. The research will be conducted at UW Medicine's South Lake Union research campus in Seattle, Washington, and at Novo Nordisk.



## 6.2. Thermo Fisher Scientific Collaborates On Diagnostic Test To Significantly Improve Prostate Cancer Screening November 09, 2015

- Thermo Fisher Scientific Inc., the world leader in serving science, announced the results of its collaboration with the Karolinska Institute on a groundbreaking clinical study, called Stockholm 3 (STHLM3), aimed at developing a more effective test for prostate cancer than using the prostate-specific antigen (PSA) alone.
- The results of the clinical study, published in The Lancet Oncology, pertain to the so-called STHLM3 model, which analyzes a combination of six protein markers, more than 200 genetic markers and other clinical data.

## 6.3. LEO Pharma to Acquire Global Dermatology Portfolio from Astellas November 11, 2015

- LEO Pharma A/S, a global healthcare company dedicated to helping people achieve healthy skin, and Japanese pharmaceutical company Astellas Pharma Inc. Announced that they have entered into an Asset Purchase Agreement under which Astellas will transfer its global dermatology business to LEO Pharma for € 675 million..
- Under the terms of the agreement, the assets and associated responsibilities relating to Astellas' global portfolio of dermatology products - which include Protopic®, treatment for eczema, and other products for the treatment of acne and skin infection - will be transferred to LEO Pharma.

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

### 7.1. Levolta Pharmaceuticals gets US patent for novel therapy for controlling osteoarthritis November 03, 2015

- Levolta Pharmaceuticals, an emerging leader in developmental osteoarthritis (OA) therapy, announced recently that the US PTO has awarded the company a patent for its novel VOLT01, a derivative of zoledronic acid (ZA), a proposed commercial product that has shown promise as a disease-modifying drug in clinical trials.
- Formerly known as Voltarra Pharmaceuticals, Levolta's patent claims methods for treating osteoarthritis by intravenously administering a combination of prednisolone, or a pharmaceutically acceptable salt thereof, and ZA, or a pharmaceutically acceptable salt thereof, in a single infusion.

### 7.2. Researchers Design & Patent Graphene Biosensors November 16, 2015

- The Moscow Institute of Physics and Technology is patenting biosensor chips based on graphene, graphene oxide and carbon nanotubes that will improve the analysis of biochemical reactions and accelerate the development of novel drugs.
- One of the most promising applications for graphene is biomedical technologies. The sensors enable researchers to detect low concentrations of biologically significant molecular substances (RNA, DNA, proteins, including antibodies and antigens, viruses and bacteria) and study their chemical properties



## ▶ TECHNOLOGY/NDDS NEWS

### 8.1. Scientists Discover How to Better Map Brain Tumors

November 04, 2015

- Scientists have discovered a protein that helps map the edge of brain tumors more clearly so they show up on magnetic resonance imaging (MRI) scans, according to new research presented at the National Cancer Research Institute (NCRI) Cancer Conference in Liverpool
- For the first time, scientists have identified a protein inside blood vessels found at the invasive edge of brain tumors - highlighting the area from where cancer is most likely to spread.
- This protein is produced as part of an inflammatory response caused by the brain tumor. Mapping this inflammation gives scientists a more complete picture of the cancer.

### 8.2. New computational method helps predict adverse drug reaction better than traditional computing methods

November 04, 2015

- A new integrated computational method helps predicting adverse drug reaction-which are often lethal--more reliably than with traditional computing methods. This improved ability to foresee the possible adverse effects of drugs may entail saving many lives in the future.
- Most computer tools employed today to detect possible adverse effects of compounds that are candidates for new medicines are based on detecting labile fragments in the drug's structure. These fragments can potentially transform to form reactive metabolites, which can have toxic properties. This is what is known as idiosyncratic toxicity and is a big headache for the pharmaceutical industry, as it tends to be detected in late development stages of the drug and even when it is already on the market, often causing the drug to be withdrawn.

### 8.3. Researchers develop novel technology for chronic arthritis

November 06, 2015

- To improve the early detection of different types of arthritis, a European consortium composed of several research institutions and companies led by the Fraunhofer Institute for Biomedical Engineering IBMT in Saarland, Germany is currently developing an alternative diagnostic technique combining ultrasound technology with novel detection methods.
- Specifically, this involves the use of a 3-D finger scanner that searches joints for sites of inflammation as well as other pathological changes. "One of the advantages of this method is that it enables us to detect the condition while it is still in its early stages, since many forms of arthritis affect the fingers first", says Dr. Marc Fournelle, IACOBUS project manager at Fraunhofer IBMT