Lambda Research Newsletter

July 2018

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Research Accelerated

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Clinical Research

NEWS letter

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GLOBAL NEWS

1. Pelgraz® gets positive nod from CHMP

Intas/Accord's pegfilgrastim (Pelgraz) has been approved by the Committee for Medicinal Products (CHMP).

Pelgraz is a pegylated granulocyte-colony stimulating factor (G-CSF), which is indicated for reduction of the duration of neutropenia and febrile neutropenia in patients undergoing chemotherapy.

Pelgraz has been approved based on a PK and PD study in healthy volunteers as well as a phase 3 study in patients with breast cancer who were receiving docetaxel, doxorubicin, and cyclophosphamide chemotherapy.

Accord has long-standing experience in the European biosimilars space with its filgrastim biosimilar, Accofil, which was approved in 2014. "Since then the product has been used over 2 million times," said Mr. Binish Chudgar, vice chairman and managing director of Intas Group, Accord's parent company. "Accord has gained valuable experience in bringing biosimilar medicines to the market. Our continued focus on bringing biopharmaceuticals to Europe has enabled us to be the first to launch a biosimilar of pegfilgrastim, and as a first mover, we expect to gain an even bigger market share with Pelgraz," he added.

Source: prnewswire.com

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GLOBAL NEWS

2. Air pollution linked to increased risk of diabetes

A study conducted by the Washington University School of Medicine in St. Louis and the Veterans Affairs (VA) St. Louis Health Care System has linked air pollution to diabetes.

This new research published in *The Lancet Planetary Health Journal* linked outdoor air pollution - even at levels deemed safe - to an increased risk of diabetes globally. These results raise the possibility that reduction in the pollution may lead to a decreased incidence of diabetes in heavily polluted countries such as India and in less polluted countries such as the Unites States.

Air pollution is thought to reduce insulin production and trigger inflammation, preventing the body from converting blood glucose into energy that the body needs to maintain health.

Researchers also mark that there is higher risk of pollution-related diabetes in India and in other countries such as Afghanistan, Papua New Guinea and Guyana, while there is less chances of pollution-related diabetes in countries like France, Finland and Iceland. The Unites States has a moderate risk of pollution-linked diabetes.

Source: medicalxpress.com

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GLOBAL NEWS

3. Majority (60%) of employees with migraine miss a week of work per month

The European Migraine and Headache (EMHA) and Novartis declared the initial findings of their largest global My Migraine Voice Study. This study included over 11,000 patients from 31 countries who had at least four migraine days per month with nearly 90% patients having tried at least one preventive treatment.

These findings were presented in San Francisco at the 60th Annual Scientific Meeting of the American Headache Society (AHS). The study showed that 60% patients on an average missed work for 4.6 days in a week. Study also showed the impact of migraine during working hours by using the Work Productivity and Activity Impairment (WPAI) questions. It is calculated by the overall work impairment measurement by reduced productivity with the help of parameters such as, the work hours during employment (presenteeism) and work time missed due to migraine (absenteeism).

Patients showed a reduction of 53% in overall productivity, and this figure increased to 56% in view of those with two or more preventive treatment failures.

Source: worldpharmanews.com

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GLOBAL NEWS

4. Childhood cancer survivors have higher chances to develop hormone diseases

People who have survived cancer in their childhood may be at an increased risk for developing hormones disorders that may lead to thyroid disease, testicular dysfunction and diabetes, largely due to exposure to radiation therapy. The International Endocrine Medical Society has published Clinical Practice Guidelines in *The Journal of Clinical Endocrinology and Metabolism (JCEM)*, to warn healthcare providers about these risks.

Childhood cancers are rare and five-year survival rates exceeding up to 80% are noted. Of these 50% of patients have chances of developing endocrine disorders in their lifetime. If radiation is exposed to key glands such as hypothalamus, pituitary, thyroid and gonads, it leads to higher chances of developing hormones diseases.

The guideline includes sections on the early diagnosis, long-term screening and possible treatment options in childhood cancer survivors.

Source: indiatimes.com

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PHARMA INDIA

1. Lupin expects single digit growth in 2018 – 2019

Lupin expects to achieve single-digit sales growth this fiscal with sluggish US business likely to impact overall global business of the company. However, the company has eye on double digit growth in Latin America, South Africa and also in India.

Lupin has reported a negative growth in 2017-18 for the first time in a decade. With net sales dropping to Rs 15,560 crore, a decline of 9% from 2016-17 is reported.

Country	Growth (%)	Total business (INR Cr)
North America	-28.7%	5,893.9
India	+10.7	4,125.3

Last year, the company had also reported a growth of 1.6% in its active pharmaceuticals business (API) business during the last fiscal.

Source: indiatimes.com

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PHARMA INDIA

2. Cipla targets $1 billion revenues in FY2019 from domestic market

Cipla is confident on its growth in this upcoming financial year for a billion dollar consolidated revenue in the domestic market in FY19.

The company reported revenues of Rs 15,219 crore, growing 6 per cent, with income from the India operations seeing a 6.3 per cent jump at Rs 5,687 crore. Also, the company is expecting few in-licensing deals with innovator companies. This will focus on certain therapeutic segments as well as on the sales force productivity, which will help growth in India. For the next financial year, the company plans to continue its growth trajectory in key markets.

The company wants to focus on its consolidated revenue in other countries such as South Africa, Europe, US and in other emerging markets too. This financial year, it continues with its significant investments in research and developments, and especially in respiratory clinical trials.

Source: indiatimes.com

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PHARMA INDIA

3. DCGI to introduce trace and track mechanism to spot fake drugs

The Central Drugs Standard Organization (CDSCO) has taken another step in the process of introducing an effective "trace and track" mechanism. This step will try to weed out counterfeit drugs from the Indian market. The national drug regulatory body has already identified the top 300 brands on the basis of moving annual total (MAT) and has decided to discuss its implementation with their manufacturers. This mechanism will be implemented across India on a trial basis to spot out counterfeit drugs.

Under this proposal, the pharmaceutical company will print a unique number on each strip or bottle of the drug. It will also print a phone number where the customer can dial and enter the aforesaid unique number and get the name and address of the manufacturer, the batch number, manufacturing and expiry date of the medicine.

A meeting notice issued by office of the DCGI states that the meeting will discuss the "modalities" on how to implement this proposal. The notice added: "The top 300 brands have been identified based on moving annual total (MAT) data provided by AIOCD AWACS - a pharmaceutical market research company formed by All Indian Origin Chemists & Distributors Ltd.

Source: pharmabiz.com

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PHARMA INDIA

4. Government plans to cap the prices of essential medicines

The government is considering a proposal to make essential medicines more affordable by capping prices at the first 'point of sale' rather than retail price — a move intended to curb margins offered to hospitals, distributors and doctors to push particular brands.

The Niti Aayog, in a proposal submitted to the Prime Minister's Office, suggested tweaking the current price fixation mechanism "to check exorbitant prices" of essential medicines. At present, the government caps prices of essential drugs based on the average 'price to retailer' of all brands of any particular medicine with at least 1% market share. This price includes all trade margins, except for the retailer margin, which is fixed at 16% and added to the ceiling price to arrive at an MRP.

Market and institutional data such as costs at central, state and private hospitals will be used to arrive at ceiling prices.

Source: indiatimes.com

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REGULATORY ROUND-UP

1. CDCSO lists implantable medical devices defined as 'drug'

The Central government put another step for its plan to bring all implantable devices under the purview of Section 3 (b) (iv) of the Drugs and Cosmetics (D&C) Act 1940 with other critical medical equipment for ensuring quality and reliability.

The Central Drugs Standard Control Organization (CDSCO) issued the list of devices going to be regulated under the D&C Act.

The list includes computed tomography (CT) scan equipment, magnetic resonance imaging (MRI) equipment, defibrillators, dialysis machine, positron emission tomography (PET) equipment, X-Ray machine and bone marrow cell separator apart from all implantable medical devices. Once the act comes into force, the manufacturers and importers need to take market approval from the national drug regulatory for selling their devices in India. These devices will be considered as 'drugs' under the D&C Act to ensure quality and price, and it can be further regulated by using the Medical Devices (MD) Rules 2017. Also, five laboratories have been designated in the public sector for testing and evaluating MD to help in implementing new MD rules.

Source: pharmabiz.com

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REGULATORY ROUND-UP

2. FDA releases guidance for oncology radiopharmaceuticals

The US Food and Drug Administration (USFDA) has released a guidance document on oncology therapeutic radiopharmaceuticals to guide sponsors on designing and labeling nonclinical studies. This guidance document focuses on sections such as pharmacology, animal bio-distribution, dosimetry, toxicology, first-in-human dose selection as well as labeling recommendations.

The FDA has also given the definition for therapeutic radiopharmaceutical substance as “that contains a radionuclide and is used in patients with cancer for treatment of the disease or for palliation of tumor-related symptoms (e.g., pain)”.

The guidance further explains about the administration of therapeutic oncology radiopharmaceuticals: these are generally administered intravenously and are intended to deliver cytotoxic levels of radiation to select tumor sites. The draft also discusses on the sections such as: evaluation of toxicities from the ligand (e.g. an antibody previously evaluated for safety and efficacy in cancer treatment; evaluation of radiation toxicities; information for product labeling as related to reproductive toxicity, genotoxicity, carcinogenicity, contraception, and use in lactating women.

Source: raps.org.

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REGULATORY ROUND-UP

3. FDA finalizes the guidance for BsUFA II

The US Food and Drug Administration (FDA) have finalized the guidance which explains the changes to its user fee program for the biosimilar products as well as for the industries that comes under the Biosimilar User Fee Amendments of 2017 (BsUFA II). There are no substantive changes in the final guidance to that of the released version of guidance issued in November 2017.

In this repeated version, there are changes in the type of fees paid by the industry and on the process of fees collection. These changes are negotiated by both, FDA as well as by the pharmaceutical industry. Under the program BsUFA II, the sponsors have to pay three types of fees:

1. Fees for initial and annual biosimilar biological product development program (BPD)
2. Fees for biosimilar biological product application, and
3. Fees for biosimilar program

Source: raps.org

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REGULATORY ROUND-UP

4. Two new programs released by FDA on quality metrics for pharmaceuticals

Two new programs have been released by the US Food and Drug Administration (FDA) for collecting the feedback on the usage of quality metrics. This will provide ways to the industry for engaging their agencies and revert to FDA on the usage of quality metrics.

One of these programs known as Quality Metrics Feedback Program is meant for encouraging the new drug application holders for requesting Type C meetings. It will also encourage abbreviated new drug application (ANDA) holders for submitting pre-ANDA meeting requests for discussing quality metrics.

The second program is designed to offer the experience to FDA staff for developing quality metrics program entitled 'Quality Metrics Site Visit Program'. Also, the FDA staff members will observe the procedure of gathering and reporting metrics to the management.

Source: raps.org.

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Celgene collaborates with Skyhawk for neurological diseases

Celgene and Skyhawk entered into a five-year collaboration for drug discovery and development for neurological diseases with an upfront payment of $60m by Celgene Therapeutics. The payment may be supplemented by future license fees, milestone payments and royalties.

Celgene will develop new treatment options for neurological diseases such as amyotrophic lateral sclerosis and Huntington's disease using Skyhawk's small molecule therapies for alternative splicing of RNA (STAR) technology platform. Celgene will receive global intellectual property rights for up to five programmes to create therapeutic candidates.

Skyhawk's team of world-leading experts and Celgene neuroscience and imaging research collaboration will assist each other and hope to bring innovative therapies to the patients.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Sanofi completes $3.9 billion acquisition of Ablynx

Sanofi has been completed $3.9bn procurement of Ablynx, a biopharmaceutical company following the expiry of the Squeeze-out procedure.

The Squeeze-out period commenced on May 22, 2018, in accordance with applicable Belgian and U.S. law, following the acquisition by Sanofi of over 95% of the outstanding shares of Ablynx upon settlement of the initial acceptance period of its tender offer for Ablynx.

The acquisition is expected to support Sanofi's research and development strategy and help to develop technologies to address multiple disease targets with single multi-specific molecules.

Source: pharmaceutical-technology.com

MERGERS /ACQUISITIONS /COLLABORATIONS

3. AbbVie and Calibr to jointly develop new therapies for cancer

AbbVie and Calibr will jointly develop novel T-cell therapies for targeting various solid tumors. AbbVie has formed an alliance with Scripps Research's non-profit drug discovery unit Calibr to develop next-generation T-cell therapies that are aimed at targeting various cancers, including solid tumors.

This collaboration broadens AbbVie's oncology research to access advanced precision medicine technology to expand the development of potentially life-changing treatments for patients with cancer.

Calibr designed a new cell therapy programme to improve safety, versatility and efficacy of chimeric antigen receptor T-cell (CAR-T) therapies which are currently limited due to rapid activation and expansion of cells, resulting in adverse events.

The combination of AbbVie's oncology discovery and early development expertise and Calibr's novel switchable CAR-T therapy platform aims to advance the current standard of care, with the potential to rapidly advance new treatment options for patients.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Lupin and Mylan partner to commercialize etanercept biosimilar

Lupin and Mylan will partner to commercialize a biosimilar to Enbrel® (etanercept). Through their partnership agreement, Mylan will commercialize Lupin's proposed etanercept biosimilar in Europe, Australia, New Zealand, Latin America, Africa and most markets throughout Asia.

Etanercept is a cytokine inhibitor which inhibits TNF-α and is indicated for the treatment of certain autoimmune diseases including rheumatoid arthritis, psoriatic arthritis, plaque psoriasis and ankylosing spondylitis.

Enbrel had global brand sales of approximately $11.6 billion for the 12 months ending Dec. 31, 2017, according to IQVIA. Lupin successfully completed its etanercept biosimilar Phase 3 clinical trial in February 2018. Lupin has filed the product with the European Medicines Agency and plans to file in other jurisdictions soon.

Under the terms of the agreement, Lupin will receive an up-front payment of $15 million and potential commercial milestones, together with an equal share in net profits of the product.

Source: prnewswire.com

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DRUGS: APPROVALS AND LAUNCHES

1. Plazomicin approved for complicated UTI

Achaogen, Inc., a biopharmaceutical company developing and commercializing innovative antibacterial agents to address multidrug resistant (MDR) gram-negative infections, announced that the U.S. Food and Drug Administration (FDA) has approved Zemdri (plazomicin) for adults with complicated urinary tract infections (cUTI).

Zemdri is an intravenous infusion, administered once daily. It is a potent in managing active for difficult-to-treat MDR infections, including CRE and ESBL- producing *Enterobacteriaceae*.

But the FDA has issued a complete response letter (CRL) regarding Zemdri for the treatment of blood stream infection (BSI) because there is no evidence about the effectiveness of plazomicine in BSI. The company intends to meet with the FDA to determine whether there is a feasible resolution to address the CRL.

Source: globalpharmaupdate.com

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DRUGS: APPROVALS AND LAUNCHES

2. FDA approves Epidiolex: First drug directly purified from cannabis

The U.S. Food and Drug Administration (FDA) have approved the first cannabinoid preparation – Epidiolex. It is developed for the treatment of rare, severe and difficult to treat childhood seizures such as Lennox-Gastaut Syndrome or Dravet syndrome.

Epidiolex contains cannabidiol (CBD), a chemical component of the cannabis sativa plant, more commonly known as marijuana. CBD does not cause intoxication or euphoria that comes from tetrahydrocannabinol (THC), the primary psychoactive component of the drug.

A clinical trial published in NEJM, demonstrated that Epidiolex reduced monthly drop seizures to 37.2% and 41.9% in 10mg/kg and 20mg/kg doses, respectively, in one month compared to placebo (17.2%).

Source: globalpharmaupdate.com

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DRUGS: APPROVALS AND LAUNCHES

3. Pfizer's Trazimera, a biosimilar trastuzumab, approved in EU

The European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has granted approval for Trazimera - a Pfizer's biosimilar of Roche's Herceptin (trastuzumab). It was approved after initial rejection by the FDA in April 2018.

Trazimera is indicated in the treatment of adult patients with HER2-positive metastatic and early breast cancer, as well as in combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of adult patients with HER2-positive metastatic gastric cancer. Trazimera will join Herzuma, Kanjinti, and Ontruzant in the EU market to seize share from Roche.

Herceptin of Roche is still leading the EU market for the HER2-positive breast cancer monoclonal antibodies since its approval in 2000.

Trazimera data has shown a similar safety and efficacy to Herceptin. The overall response rate of Trazimera was 62% compared to 66.5% for Herceptin. Trazimera showed a similar safety profile with a similar incidence of adverse events to Herceptin. Trazimera is Pfizer's fourth biosimilar to receive a positive CHMP opinion from the EMA, it is the company's first therapeutic oncology biosimilar.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

4. Akynzeo launched in India for prevention of drug dependent side effect

Glenmark pharmaceutical company and Helsinn, a Swiss pharmaceutical company, have launched a fixed dose combination (FDC) drug Akynzeo in India.

Akynzeo is the combination of two drugs netupitant 300 mg and palonosetron 0.5 mg in a single dose oral capsule. The product has been developed by Helsinn and Glenmark under a licensing agreement. The drug is used for the prevention of acute and delayed phase chemotherapy dependent side effect of nausea and vomiting.

Using this drug can improve patient's conveniences, and improve patients' quality of life. Akynzeo is already being marketed in the EU and US; the drug was approved in EU in 2015. Akynzeo oral is indicated in the EU for adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

Source: Fiercepharma.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Pfizer announces results from Phase 3 PALOMA-3 trial of IBRANCE

Pfizer has announced the results from the Phase 3 PALOMA-3 trial with Ibrance (palbociclib) in combination with fulvestrant. Ibrance is an oral inhibitor of CDKs 4 and 6, which are crucial regulators of the cell cycle that activate cellular progression.

The study evaluated the efficacy of palbociclib and fulvestrant combination against placebo plus fulvestrant in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer with uncontrolled disease after prior endocrine therapy.

Overall, the study showed a positive trend in the hazard ratio supporting the Ibrance combination, while this trend did not achieve statistical significance. The results were not statistical significant in extending the overall survival (OS). However, the OS was not the primary endpoint of this study. The primary endpoint of this study – progression free survival (PFS) – was achieved with the Ibrance combination where at an interim analysis it showed a statistically significant and clinically meaningful improvement in PFS for Ibrance plus fulvestrant compared against placebo plus fulvestrant.

“While the difference in overall survival narrowly missed the threshold for statistical significance – a high bar for any trial in this patient population – it is similar, in absolute terms, to the improvement in median progression-free survival previously demonstrated in this trial” said Pfizer’s chief development officer Dr Mace Rothenberg.

Source: globalpharmaupdate.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Phase 3 results out for esketamine nasal spray for treatment-resistant depression

Janssen has presented its Phase III data for esketamine nasal spray for treatment-resistant depression for the first time in Europe at the International College of Neuropsychopharmacology in Vienna, Austria. Esketamine is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist that restores the synaptic connections in brain cells.

This was a randomized, double-blind, multi-center study conducted in 705 adult patients. The combination of esketamine with an oral antidepressant when given beyond 16 weeks showed statistically significant and clinically meaningful reduction in the time to relapse to the symptoms of depression when compared with an oral antidepressant + placebo nasal spray.

Esketamine nasal spray received breakthrough therapy designation from the US Food and Drug Administration in November 2013 for treatment-resistant depression and in August 2016 for major depressive disorder with imminent risk for suicide.

Source: globalpharmaupdate.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Positive data from real-world study of Novartis' ruxolitinib

Novartis has announced that they have received positive data from its comparison study of Jakavi (ruxolitinib) conducted to treat patients with rare blood cancers like polycythemia vera (PV). A significant decrease in the risk of thrombosis (blood clots) and death in PV patients who are resistant or intolerant to hydroxyurea were reported with ruxolitinib when compared to those treated using the 'best available therapy'. These results are based on comparing the Phase 3 RESPONSE Jakavi clinical trial participants and the real-world Spanish GEMFINI patient registry.

Ruxolitinib is an oral JAK 1 and JAK 2 tyrosine kinases inhibitor. Ruloxitinib is approved by the European Commission to treat adult PV patients and those patients that are resistant to hydroxyurea, and disease-related splenomegaly. Currently, the drug has been approved in more than 101 countries for myelofibrosis patients and in >75 countries to treat patients having PV.

Source: globalpharmaupdate.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Quizartinib shows positive results in acute myeloid leukemia

Daiichi Sankyo's FLT3 inhibitor quizartinib significantly improved patient outcomes in relapsed/refractory (R/R) FLT3-ITD-mutated acute myeloid leukemia (AML), a population with a high unmet need and currently no approved targeted therapies – details from pivotal data presentation at European Hematology Association (EHA) annual meeting.

Results from the Phase 3 QUANTUM-R trial demonstrated significantly improved overall survival (OS) for quizartinib-treated patients (median OS: 6.2 months) versus those treated with salvage chemotherapy (4.7 months), with a hazard ratio of 0.76. The toxicity profile of quizartinib was superior to that observed in the salvage chemotherapy.

The FDA has granted fast track designation to Quizartinib, which could substantially accelerate its approval once data have been submitted.

Source: pharmaceutical-technology.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Eli Lilly wins over Alimta in patent case with Dr Reddy's

Eli Lilly and Company wins the patent case filed in the USA against Dr Reddy for Alimta (pemetrexed for injection), a drug used in the treatment of various types of cancer. The US District court for the Southern District of Indiana has given the decision in favor of Eli Lilly and Company.

The court also said that the patent would be infringed by the competitor that had stated its intent to market alternative salt forms of pemetrexed prior to the patent's expiration in May 2022.

These rulings mean Dr.Reddy's Laboratories and Hospira will be prevented from launching their alternative salt forms of pemetrexed until the patent expires.

Source: indiatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. One more patent issued for Eagle Pharma's Bendeka

Eagle Pharmaceuticals, Inc. declared that they had added one more patent in their patents list. The patent is in relation to its drug Bendeka (bendamustine HCl) Injection. The United States Patent and Trademark Office (USPTO) patent number 10,010,533 will expire in January 2031. The USPTO has now issued 15 patents of Bendeka family that will start expiring from 2026 to 2033.

The newly issued patent will be listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) bringing Eagle's total Orange Book listed patents for Bendeka to 13.

Due to the court decision,, as long as Bendeka remains designated as Orphan Drug Exclusivity (ODE), the FDA won't approve any drug application regarding Bendeka. The ODE will expire in December 2022.

Source: pharmpro.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Amneal Pharma wins patent for Zolmitriptan nasal spray

Amneal Pharma has received decision in their support for patent infringement issue with Lannett Holdings. Amneal had filed a complaint at the US District Court in the District of Delaware, accusing Lannett of infringing on their nasal spray patents based on the filing of Lannetts's Abbreviated New Drug Application (ANDA) relating to Zolmitriptan Nasal Spray, 5mg, which is the generic version of Zomig Nasal Spray.

The case was referred by the US court of Appeals as the federal Circuit had put the decision in support of Amneal Pharma. Lannett Holdings failed to prove that Amneal has invalid Zolmitriptan nasal spray patents.

Amneal Pharma is now looking forward to supply this spray to patients and they will actively protect their nasal spray patents.

Source: ippropatents.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Suven Life gets product patents from India, S. Korea and Singapore

Suven Life Sciences confirmed that have been awarded patents from India, Singapore, South Korea and Israel for a new chemical entity (NCE) used in the treatment of neurodegenerative disorders. The company declared that the patents are valid through 2031, 2034, 2034 and 2036, respectively.

The granted claims of patents are being developed as therapeutic agents useful in the treatment of cognitive impairment associated with neurodegenerative disorders.

These disorders include

- Alzheimer's disease
- Attention deficient hyperactivity disorder (ADHD)
- Huntington's disease
- Parkinson's
- Schizophrenia

Source: indiatimes.com

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TECHNOLOGY /NDDS

1. New device approved for treating breathing difficulty in severe emphysema

Pulmonx Inc's Zephyr Endobronchial Valve (Zephyr Valve), which is intended to treat breathing difficulty associated with severe emphysema (a type of Chronic Obstructive pulmonary disease), has been approved by the U.S. Food and Drug Administration (FDA). As the device is non-invasive in nature, it can offer another treatment option for these patients.

Zephyr valve has comparable size to that of pencil erasers, are placed into the diseased areas of the lung airways using a flexible bronchoscope. Its design prevents air in entering the damaged parts of the lungs and aids trapped air and fluid to esacpe out from the diseased areas. During the breathing procedure, when the patient inhales the air, the valves close preventing the air from entering the diseased areas, and when the patient exhales air out, the valve opens which releases the trapped air and fluids to come out from the damaged areas of the lung, ultimately relieving the pressure.

The FDA has reviewed the device data from a multicenter study of 190 patients with severe emphysema. The FDA has granted breakthrough designation to this device.

Source: prnewswire.com

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TECHNOLOGY /NDDS

2. Peptide vehicle as a new drug delivery system for anti-cancer drugs

Cation antimicrobial peptides (AMPs) have shown promising effects in the field of anti-cancer therapeutics due to their cytotoxic activity in drug-resistant cancer. These are peptides containing compounds that contain two or more amino acids linked in a chain. A proaptotic domain (PAD) peptide [KLAKLAK]2 disrupts the mitochondrial membrane and there by shopws antimicrobial activity.

Most of the AMPs have antitumor functions be through the multifunctional host defense system of multicellular organisms. However, these compounds don't have cell permeability. Alone, they have little toxicity to the cells. Earlier studies have shown that these PAD peptides permeate through cell membranes in conjugation with other compounds such as cell-penetrating peptides (CPPs).

A study showed that cyclic decapeptide, which is also termed as peptide 1, mimics the dimerization arm of the EGF receptor (EGFR). So, the binding of peptide 1 and EGFR will potentially retard the growth of cancer cells as EGFR is involved in cancer progression.

A study in EGFR positive lung cancer cell lines showed that PAD peptide alone did not have any significant effects, but conjugated peptide 2 composed of peptide 1, the PAD peptide, and a linker cleavable with a protease showed significant suppression of proliferation.

These study findings suggest that peptide 1 is a promising lead compound for therapeutically effective peptides as a new intracellular delivery vehicle. The study is published in the journal *Bioconjugate Chemistry*.

Source: pharmpro.com

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3. MicroRNA can be a biomarker to diagnose neurodenegeration

Early evidence showed that the tiny snippets of genetic material microRNA may provide early detection of conditions such as Alzheimer disease. MicroRNA plays a regulatory role in either increasing or decreasing the number of proteins that are encoded by mRNAs. Function of tens or hundreds of proteins is affected by a single snippet of the microRNA. Due to their stability in blood and in urine, there are higher chances of the microRNA to be used as biomarkers.

A study evaluated and compared the results of messenger RNA and microRNA in genetically modified dementia patients versus healthy group. They found that there are higher deviations from normal levels in the microRNA group before the development of any physical symptoms. MicroRNA 142 causes neuroinflammation. Earlier studies have shown that there is significant contribution of neuroinflammation to cause neurodegeneration. The study is published in *Nature Scientific Reports*.

Source: drugtargetreview.com

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4. Ventripoint receives market approval by FDA for its heart analysis system

The U.S. Food and Drug Administration (FDA) has approved the market authorization application of VMS+ machine of Ventripoint Diagnostics Ltd in the United States.

The machine has a four-chamber heart analysis system. The intended use of this machine is to analyze the ejection fraction (function) and also to measure the volume of any of the heart chambers, to be tested by using 2D ultrasound.

It is the first simple echocardiography system approved by the FDA, which measures ejection fraction. Ejection fraction is a most critical measurement for evaluating heart function and its predictable outcomes. It is used in diseases such as heart failure, abnormal heart rhythms, congenital heart disease, pulmonary hypertension and hypertension. By the use of this machine, the important information will be available in an easy, rapid way with cost effective nature.

Source: mpo-mag.com

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WHAT'S NEW AT LAMBDA

1. Bioanalytical phase inspection by Portuguese inspectors

The bio-analytical phase at Lambda was inspected by two Portuguese inspectors. The Portuguese inspectors verified the study data and all associated system data including software validation records during this 3 days inspection. This was a successful inspection for Lambda facility with only two minor recommendations provided by the inspectors.

2. New software 'Di Soft' for central imaging independent review

Lambda has procured a new software called 'Di Soft' for clinical imaging solutions. Di Soft is a validated, 21 CFR part 11 and USFDA guidance complied software that facilitates Central Imaging Independent Review in all therapeutic segments. This software allows uploading imaging data electronically from the clinical trial sites via a web portal. This technology and service provides flexibility as well as qualitative and quantitative clinical trial endpoints solution pertaining to the imaging analysis.

3. FDA bioanalytical method validation guideline

Lambda has implemented the revised USFDA bioanalytical method validation guidelines. Henceforth all upcoming method validations, method validation reports and bio-analytical study reports will be in compliance with the revised guidelines. The list of validate methods currently exceed 1000.

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