Lambda Research Newsletter

March 2017

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Volume 3 / March 2017

Clinical Research NEWSletter

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Contents

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Research Accelerated

Volume 3 / March 2017

Clinical Research NEWSletter

www.lambda-cro.com

Contents

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter

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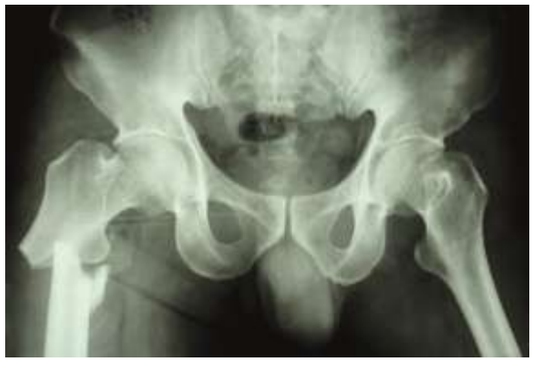
GLOBAL NEWS

1. Increased hip fracture risk with antidepressants use in Alzheimer's disease



Researchers found that hip fractures were associated with the use of anti-depressive drugs among community-dwelling individuals with Alzheimer's disease. The new registry based study from the University of Eastern Finland, has shown the highest risk while initiating the use of antidepressants which remained increased even after four years.

The International Journal of Geriatric Psychiatry has published this finding. The study was conducted in a huge population, about 50,000 patients compared with nearly 100,000 without AD (mean age: 80 years).

The study found that the risk of hip fracture doubled with increased frequency. The risk was associated with all the most frequently used antidepressant drug classes: selective serotonin reuptake inhibitors (SSRI drugs), selective noradrenaline reuptake inhibitors (SNRI drugs), and mirtazapine.

Antidepressants are not only used to manage depression, but also as a treatment to manage chronic pain and other behavioral and psychological symptoms of dementia like insomnia, anxiety and agitation. If Alzheimer's patients are planned to start on antidepressants then they have to be regularly monitored, and other risk factors for falling should also be considered.

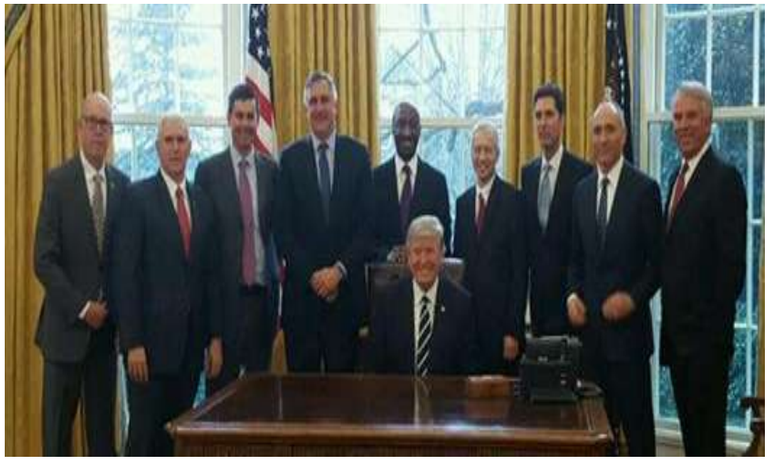
Source: news-medical.net

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

2. Trump emphasizes on faster FDA approvals



The US president Donald Trump met the CEOs of leading big pharmaceutical companies. Before the meeting, he mentioned that his administration would be "cutting regulations at a level no one has ever seen before."

President Trump met the CEOs of PhRMA, Merck, Novartis, Johnson & Johnson, Celgene and others, assuring that he would try to streamline the process for drug approval and also reduce the waiting period for the approval of new drugs, which currently takes many years.

He also wanted the drug prices to be lowered and better negotiations between the firms and Medicare.

With reference to the FDA's rulemakings, guidance, he told "Instead of it being 9,000 pages, it'll be 100 pages." He emphasized on the elimination of 75% to 80% of government regulations.

Trump also mentioned that he would soon make an announcement regarding his choice for FDA commissioner.

Source: raps.org

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

3. Biosimilars in cancer care: ESMO

As mentioned in the documents from the European Society for Medical Oncology (ESMO), biosimilars can create opportunities for sustainable cancer care.

The documents highlight the approval standards for biosimilars and also their safe introduction into the clinic depicting the potential benefits for patients and healthcare systems.

As mentioned by the chairman of the ESMO Cancer Medicines, biosimilars can provide an excellent opportunity in different countries to afford and sustain cancer treatment.

In Europe, the costs of the biosimilars are forecasted to be reduced from 20% to 40%, by 2020. The patents of most of the monoclonal antibodies are set to expire by 2020, which will provide a great opportunity for biosimilars to change the oncology landscape.

This paper sets out a number of principles to ensure better quality, safety and efficacy of biosimilars.

Source: thepharmaletter.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

GLOBAL NEWS

4. New Research on regulation of depression and anxiety by brain

The researchers from Abo Akademi University in Finland in collaboration with US researchers have discovered a new molecule that eases anxiety and depressive behaviors in rodents.

The research involves a protein called JNK, which inhibits new neuron generation in the hippocampus. Hippocampus regulates emotions and learning. When JNK was inhibited in the newly generated nerve cells in hippocampus, anxiety and depressive behaviors reduced in mice.

The inhibitors of JNK, like the one used by the researchers in this study, can be a new potential therapeutic option for managing anxiety and depression, which are widely prevalent.

The findings have been published in the Nature Publishing Group Journal, Molecular Psychiatry.

Source: news-medical.net

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

PHARMA INDIA

1. The Indian pharmaceutical exports may have double digit growth in FY17

As stated by a senior commerce and industry ministry official, the Indian pharma exports can see their growth in double digits in the current fiscal year, similar to that of last year.

After showing the growth at about 8% in the last month, the pharma exports have done comparatively better despite overall contraction and slowdown in the market according to Mr. Sudhanshu Pandey, Joint Secretary, Commerce Ministry. It is estimated to grow about 8 to 10% this year.

The export business of Indian Pharmaceuticals reached $ 16.9 billion in the previous financial year from $ 15.4 billion in 2014-15. The business has shown the growth at 9.44% with $ 5.7 billion worth of exports to USA and $ 3.3 billion to Africa, as per data from Pharmexcil.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

PHARMA INDIA

2. Drugs and medical devices will become more affordable in India

The "Drugs and Cosmetics Rules" will be amended by the Indian government to ensure availability of medicines at reasonable prices and advocate the use of generic drugs so that the overall cost of treatment would reduce for the patients. The government will also formulate new norms for reducing the cost of medical devices.

"These rules will be internationally harmonized and attract investment into this (medical devices) sector," said by Mr. Arun Jaitley- the Union Minister for Finance and Corporate Affairs, in his budget speech. Coronary stents have already been brought under price control and National Pharmaceutical Pricing Authority has been asked to fix its ceiling price.

An action plan has also been prepared by the government to eliminate diseases like kala-azar and filariasis by 2017-18, leprosy by 2018, measles by 2020 and tuberculosis by 2025.

Source: livemint.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

PHARMA INDIA

3. New medical devices rules will ease the and renewal process

The health ministry has brought forward new rules for medical devices on 31st January 2017. The new rules are framed on the same lines as that of the Global Harmonization Task Force (GHTF), and to align with the best international practices.

The new rules will ease doing business in India by removing regulatory bottlenecks and ensuring the convenience of better medical devices for patient care and safety.

Under the new rules, the medical devices will be classified according to the GHTF practice, and as per the severity risks. Under this classification,

- low risk devices will be included into Class A,
- low to moderate risk devices will be included in Class B,
- moderate to high risk devices will be included in Class C and
- Class D will include only the high risk devices.

The risk proportionate regulatory requirements should be met by the manufacturers of medical devices, as specified by the rules.

Class A and class B medical devices will get the license from the State Licensing Authorities, while the Central Licensing Authority will regulate the devices of Class C and Class D. If required, the authority will take the help of experts or authorized bodies.

Periodic renewal of license will not be required under the new rules. The whole process beginning from submission of application to granting the license will be handled through the on-line electronic platform.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

REGULATORY ROUNDUP

1. EMA reviews safety of Actelion's Uptravi following 5 deaths in France

The European Medicines Agency (EMA) has advised the doctors to continue using Actelion Pharmaceuticals' Uptravi (selexipag) to manage patients with pulmonary arterial hypertensive. The EMA has taken this decision with a preliminary review of the available data after 5 patients who were on the drug died in France.

Uptravi was approved in US on 22nd December 2015 and in Europe on 12th May 2016 and is an oral IP prostacyclin receptor agonist.

Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA is now exploring all available data, and the final safety conclusion will be published after completion of this review.

The EMA has advised doctors to follow the recommendations and precautions carefully as per the current prescribing information of the medicine until the final conclusions are made.

Source: raps.org

LAMBDA
Research Accelerated
Volume 3 / March 2017

REGULATORY ROUNDUP

2. New US FDA guidance on biosimilars interchangeability

The US FDA has released a new draft guidance for public consultation on the interchangeability between biosimilars and the reference biologic drugs. According to the guidance, the sponsors will need to conduct one or more switching studies to prove that the alternative use of the two products by the patient will be safe without compromising the efficacy.

As compared to more than 20 biosimilars approved by the Europeon regulatory authorities, only 4 biosimilar products have been approved in the US, and none of them are considered interchangeable.

As per the guidance, for any patient, the interchangeable product should produce the same clinical outcome as the reference product. Also, if the biosimilar has to be administered more than once, the risk for the safety and efficacy for alternating or switching between the use of the original and the reference product must be shown to be not greater than the risk by using only the reference product.

According to the FDA, sponsors should consider the "totality of the evidence" and "reduction of residual uncertainty" approaches for their product to demonstrate the interchangeability. Also, the interchangeable applications will have to comprise the data from the switching study or studies where the biosimilar is targeted to be used.

The guidance notes that the postmarketing data of a biosimilar is not enough to demonstrate interchangeability without data from corresponding switching studies. This draft also stresses on the important aspects that both the presentation of the interchangeable product and its design attributes need to be the same as that of the reference product to effect a simple substitution.

Source: raps.org; fdalawblog.net

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

REGULATORY ROUNDUP

3. Fluoroquinolones and the risk of disabling and persistent side effects: Health Canada

According to the review of the Health Canadian Authority, the class of antibiotics called fluoroquinolones has been found associated with a range of persistent or disabling side-effects. This includes tendonitis (tendon inflammation), peripheral neuropathy (nerve damage of brain) and central nervous system disorders like anxiety, dizziness and confusion.

To update these issues in the product monographs, Health Canada is working now with the manufacturers. Also, Health Canada is coordinating with the Drug Safety and Effectiveness Network and the Canadian Agency for Drugs and Technologies in Health to better identify the use of fluoroquinolones by conducting additional studies for the drugs of this group.

Fluoroquinolones are widely used antibiotics used to treat mostly respiratory and urinary tract infections and include ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin, norfloxacin etc.

This review by the authority has focused on previously experienced and labeled adverse reactions associated with the use of the fluoroquinolones which had resulted in persistent disability. This was prompted by US FDA Administration's benefit/risk assessment findings.

Source: thepharmaletter.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

1. Eli Lilly boosts pain management portfolio with acquisition of CoLucid

Eli Lilly and Company has entered an agreement to acquire CoLucid Pharmaceuticals for a cash deal of about $960 million. This agreement will increase the existing portfolio of Eli Lilly in pain management for migraine.

CoLucid is developing lasmiditan, a novel, first-in-class oral 5-HT1F agonist to treat acute migraine. The company has completed its phase 3 study for lasmiditan in September 2016 which demonstrated positive results. The results of a second late stage study is expected in the second half of 2017. The company targets application for US market submission by 2018.

Lasmiditan would be the first in class therapy, which does not work through vasoconstriction to treat migraine, and would be beneficial in patients at cardiovascular risk or those dissatisfied with their current therapies.

This deal is expected to close by the end of the current quarter.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novo Nordisk and University of Oxford collaborate for type 2 diabetes research

Novo Nordisk has collaborated with the University of Oxford to increase the focus on type 2 diabetes management. The collaboration may lead to innovative approaches to treat type 2 diabetes in future. As a part of this collaboration, a new research centre will be developed in the University of Oxford premises. Up to 100 researchers will be recruited by the Novo Nordisk Research Centre at the University research centre. The company will invest ~115 million British pounds in the coming 10 years on innovation within early stage research that has potential to substantially impact future treatment of type 2 diabetes and its complications.

The cross-fertilization of innovative ideas is intended between the Novo Nordisk's employees and University researchers that will pave the way for new medicines for the management of type 2 diabetes and its complications.

Oxford University's Medical Sciences Division: It is one of the biggest biomedical research centers in Europe, which involves 2,500 researchers and at least 2,800 students. The University is considered to be the best in the world for medicine, and also rated as the UK's top-ranked medical school.

Novo Nordisk: This company is a leader in diabetes care, with more than 90 years of innovation and leadership in diabetes care.

Source: worldpharmanews.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Piramal buys Mallinckrodt's spasticity and pain control drugs for Rs 1162 crores

Indian pharmaceutical giant - Piramal Pharmahas agreed to acquire the intrathecal spasticity and pain management drug portfolio from UK based Mallinckrodt LLC for $171 million (around Rs 1,162 crore).

Gablofen (baclofen), the drug for severe spasticity management, currently marketed in the US, is included in this portfolio acquired by Piramal Pharma's crictical subsidiary. Also, the other two products currently under development for the pain management are also included.

These acquisitions add branded products that are in enticing specialties.
Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHS

1. FDA approves LINZESS (linaclotide) with additional dosing for Chronic Idiopathic Constipation

Chronic idiopathic constipation (CIC) is a gastrointestinal disorder with infrequent bowel movements, <3 times/week, and impacts nearly 35 million adult Americans.

LINZESS (linaclotide) was launched in 2012 and now, the US FDA has granted approval for the additional dosing of 72 µg. LINZESS is now available in 3 dosage strengths: 290 µg, 145 µg, and the new 72 µg, which will allow physicians flexible dosing as per individual needs and tolerability.

The approval was based on the results from a phase 3 study including 1,223 adult patients with CIC. The 72-µg dose of the drug successfully showed the improvement in complete spontaneous bowel movements compared to a placebo over a 3 month period. The incidence of diarrhea was comparatively lower compared to the 145 µg dose.

LINZESS is a guanylate cyclase-C (GC-C) agonist and increases intestinal fluid secretions and accelerates transit, and also reduces the activity of pain-sensing nerves in the intestine.

LINZESS is also used to manage irritable bowel syndrome with constipation.

LINZESS is administered once daily and has to be taken half an hour before the first meal of the day.

Source: prnewswire.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

DRUGS: APPROVALS AND LAUNCHS

2. Crizotinib now approved for ROS-1 mutation in NSCLC

Pfizer's Crizotinib (Xalkori) is now approved by the US FDA to treat the patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have ROS1 gene mutation. It was first approved in 2011 to treat patients with NSCLC with anaplastic lymphoma kinase (ALK) gene mutations.

According to the research, about 1% of patients with NSCLC have shown ROS1 mutations.

The current approval was based on the results from a single-arm study of 50 patients with advanced NSCLC having ROS1 mutations. The participants received oral crizotinib 250 mg twice daily. The study results were published in the New England Journal of Medicine in 2014.

The safety of crizotinib in patients with ROS1 mutations was found to be consistent with that found in the patients with ALK-positive metastatic NSCLC, during earlier trials. The most common adverse effects observed were vision disorders (82%), diarrhea (44%), nausea (40%), vomiting (34%), edema (40%) and constipation (34%). Also, neutropenia (10%), hypophosphatemia (10%), and an elevated level of alanine aminotransferase (4%) grade 3 adverse events were reported in the phase I trial.

Source: cancernetwork.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: APPROVALS AND LAUNCHS

3. Novel option Parsabiv approved by FDA to treat hyperparathyroidism

Secondary hyperparathyroidism (HPT) is a condition in which excessive secretion of parathyroid hormone (PTH) is produced by the parathyroid glands as a result of decreased renal function and impaired mineral metabolism. It is a chronic and serious disease that affects around two million people globally.

The US FDA has granted approval for Amgen's Parsabiv (etelcalcetide) to treat adult patients with secondary hyperparathyroidism (HPT) having chronic kidney disease (CKD) and who are on hemodialysis.

Parsabiv is the 1st therapy in 12 years to be approved for this condition. Also, it is the only calcimimetic available for intravenous administration. It needs to given thrice a week at the end of the hemodialysis session.

Parsabiv was approved in the US based on the data from two placebo-controlled phase 3 trials that achieved their primary endpoints.

The approval comes after an earlier rejection by the FDA in August 2016. The European Commission granted the commercialization for Parsabiv to treat secondary hyperparathyroidism in adult patients with CKD on hemodialysis, in November 2016.

Source: thepharmaletter.com; amgen.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Acorda's CVT-301 hits main goal of phase 3 trial for Parkinson's disease

CVT-301

ACORDA® THERAPEUTICS

To provide a faster onset and avoid gastro intestinal side-effects, the standard Parkinson's medicine- levodopa has been recently developed in an inhaler form – CVT-301, which will deliver the drug through the lungs.

In the phase 3- SPAN-PD trial including 339 patients with Parkinson's disease who experienced 'Off Periods' (re-emergence of Parkinson's symptoms), CVT-301 showed clinically significant improvement in motor functions in patients.

The primary endpoint was the change at week 12 in Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS III) score relative to placebo at 30 minutes post-treatment for the higher dose of CVT-301. The results showed that UPDRS III change for the higher dose of CVT-301 was -9.83 compared to -5.91 for placebo.

Meanwhile, key secondary endpoints measured at week 12 include the proportion of participants achieving an ON state within 60 minutes of treatment and maintained at 60 minutes, as well as change in UPDRS III score at 10 and 20 minutes following treatment. The company plans to seek US FDA approval by the end of the 2nd quarter of 2017, and for its application in Europe by the end of 2017.

The detailed results of the study will be shown at a future medical meeting. There are two other studies ongoing to assess the long-term safety profile of CVT-301 and the study results are expected by the end of the first quarter of 2017.

Source: firstwordpharma.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Sanofi initiates phase 2 clinical trial to evaluate Parkinson's therapy

Sanofi Genzyme has initiated a phase 2 study for its investigational oral therapy GZ/SAR402671 for the treatment of patients with Parkinson's disease, who have a single copy mutation of the glucocerebrosidase (GBA) gene. This study will assess the dynamics, efficacy and safety of the drug.

This is the first phase 2 clinical trial designed for the population, who have genetically defined Parkinson's disease. The clinical trial known as "MOVES-PD' will be performed in two phases: 1st phase will be a dose escalation study, and the 2nd phase will be conducted for the drug's efficacy and safety.

The primary endpoint of the randomized, double blind study is to determine the change in score from baseline with the scale that can measure Parkinson's disease progression. This also includes self-evaluation of daily life activities and motor experience, as well as a clinician-scored motor evaluation.

The drug has already shown positive outcomes in the preclinical phase.

Source: businesswire.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Positive results from ibalizumab in pivotal phase 3 trial

According to new data presented at the Conference on Retroviruses and Opportunistic Infections (CROI) 2017, the HIV monoclonal antibody and long-acting investigational antiretroviral ibalizumab showed a mean increase in CD4+T cell of 48 cells/μL after 24 weeks of treatment among the patients with multidrug resistant (MDR) HIV-1 infection in a phase 3 study.

The data were presented by Thera Technologies for the additional secondary efficacy and safety endpoint results of ibalizumab.

Ibalizumab has significantly reduced the viral load with a single intravenous dosing of 2,000 mg. It was also found as safe as previously observed in the phase 2b trial.

As told by the vice president of the company, if ibalizumab gets approval, it will be the first treatment as an antiretroviral with a new mechanism of action in the last 10 years.

Ibalizumab: It is the humanized monoclonal antibody, currently in phase 3 investigation.

Source: prnewswire.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Patent litigation settled for topiramate (Qudexy XR) of Zydus Cadila

Pharma major Zydus Cadila has settled all pending patent suits with the US based Upsher-Smith Laboratories, Inc for the anti-seizure product - Qudexy XR (topiramate) extended-release capsules.

Zydus Pharmaceuticals (USA) Inc, the subsidiary of Zydus Cadila, has confirmed the agreement with Upsher-Smith Laboratories, to settle all pending patent litigation for Qudexy XR.

Zydus gets the license from Upsher-Smith to commercialize the generic version of Qudexy XR starting on or before March 19, 2020 under the agreement.

Source: health.economictimes.indiatimes.com

LAMBDA
Research Accelerated
Volume 3 / March 2017
Clinical Research NEWSletter
www.lambda-cro.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. DRL gets adverse ruling in US over patent infringement case for palonosetron injection

The pharmaceutical major Dr Reddy's Laboratories got an adverse ruling regarding a patent infringement case over its anti-nausea injection Aloxi by the US district court of New Jersey. Aloxi (palonosetron HCl) injection is used for the treatment of chemotherapy-induced nausea and vomiting.

The patent infringement claim was made by the Switzerland-based pharma company Helsinn Healthcare SA. According to the Court's findings, palonosetron hydrochloride 0.25 mg/5 mL proposed by Dr. Reddy's infringes on certain claims of the US patents. However, DRL intends to appeal in due course of time against the decision.

Earlier, Dr Reddy's had filed the new drug application (NDA) for Aloxi three years back, which was challenged by Helsinn Healthcare.

Source: moneycontrol.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWS letter
www.lambda-cro.com

TECHNOLOGY /NDDS

1. Novel '5-D fingerprint' technique could give insights for neurodegenerative diseases

The researchers from the University of Michigan engineering have developed a new technique that could pave the way for the patients suffering from neurodegenerative diseases such as Alzheimer's and Parkinson's. The novel method known as, "5-D fingerprint" can accurately measure the properties of individual protein molecules.

Proteins are heterogeneous molecules which vary in shape. Sometimes, they are not formed properly and may make clumps as amyloids that lead to brain-cell degeneration and disease. However, the mechanism of formation of amyloids and clumping is not well understood.

This method could help by measuring the individual molecule's important properties like shape, volume, electrical charge, rotation speed, and propensity for combining with other molecules. For tracking detailed measurements, a tiny nanopore was developed which facilitates only 1 protein molecule to pass through at a time from the gap. The movement of the protein molecule through this gap of nanopore can create the measurable fluctuations in the electric current.

"5-D fingerprint" technique could help doctors in tracking the status of the patients with neurodegenerative diseases like Alzheimer's, Parkinson's or others. It may also help in the development of new treatment options for these diseases.

The detailed method was published in Nature Nanotechnology.

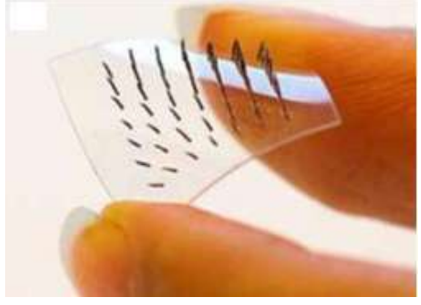
Source: sciencedaily.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

TECHNOLOGY /NDDS

2. Positive phase 3 results for novel microneedle migraine patch 'zolmitriptan'



The lead compound of Zosano pharma 'M207' achieved positive results to treat migraine attacks in a phase 3 clinical trial. The compound allows rapid delivery of zolmitriptan, a selective 5-HT1B/1D receptor agonist.

M207 – the zolmitriptan-coated microneedle patch is designed to deliver the drug rapidly during the migraine attack. The drug has shown a significant pharmacokinetic profile compared to oral zolmitriptan in the phase 1 trial with a minimum side effect profile.

'ZOTRIP' is an 8-week, double-blind study that compared the three doses of M207 (1.0 mg, 1.9 mg, and 3.8 mg) with placebo in 333 patients who had a history of at least 1 year of migraine episodes with or without aura, and who had 2–8 migraine attacks per month.

The 3.8 mg dose achieved significance in the secondary endpoints of pain freedom, and showed durability of the effect on pain freedom at 24 and 48 hours; pain freedom and being free from most bothersome symptoms with 3.8 mg dose vs. placebo in patients who had 2 hours migraine onset: 41.5% vs. 14.3% and 68.3% vs. 42.9%. M207 was not associated with any serious adverse events.

Source: empr.com

LAMBDA
Research Accelerated
Volume 3 / March 2017

Clinical Research NEWSletter
www.lambda-cro.com

TECHNOLOGY /NDDS

3. New gene sequencing software for early detection and treatment of cancer

The novel computational software, developed by researchers from US and Canada, can determine the presence of an epigenetic add-on in human DNA sample that is associated with cancer and other adverse health conditions.

Cytosine is one of the four main genetic building blocks that can make- up the altered version of itself by methylation process in the DNA and can harm healthy cells.

The new software works with the Nanopore Technology, which will directly characterize DNA methylation from the smaller samples of tissues. By this unique technique, DNA can be pulled through the small pores of the device. Distinctive changes in the electric current allow the software to recognize the sequence of the DNA and the methylation marks.

The synthetically methylated DNA was used by the researchers to train the software to differentiate between methylated cytosine and regular cytosine. This software process was then tested on the samples of DNA strains of human breast cancer cells and it successfully identified the changes in methylation between the samples of cancerous cells and normal cells.

The nanopore sequencing software, to detect the DNA methylation, is freely available at https://github.com/jts/nanopolish

Source: sciencedaily.com

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