Lambda Research Newsletter

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GLOBAL NEWS

1. Health ministry planning to waive off clinical trials of drugs for critical diseases

Health ministry of India is planning to waive off clinical trials for selective medicines for critical diseases like tuberculosis, HIV and hepatitis. This waive off will vary case to case and will be given to the drugs which are already available in the market of developed countries from the last two years.

The list of developed countries includes European Union, US, Australia, Canada and Japan. Such waive offs are already approved by the drug regulator but now the ministry is planning to bring this program legally. This will provide a standard procedure and criteria to regulators for new drug approvals.

This progressive idea is for making essential drugs available in India. According to the Drugs Controller General of India, waiver will be given to only those drugs which are essential for Indian population and when no alternative is available.

After introducing drug into the market, pharmaceutical companies need to complete postmarketing trials and submit Phase 4 data of the drugs. This process will reduce the clinical trials cost and time required to introduce new drugs into the market.

Source: health.economictimes.indiatimes.com

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GLOBAL NEWS

2. Intas Pharmaceuticals once again in race to acquire Teva's oncology and women's health divisions in Europe

Within a year, this is for the second time Intas is vying for Teva's assets. Last year, Intas pharma bid for Teva's Actavis UK Ltd and Actavis Ireland Ltd, and Intas won the bid. Now, Intas is bidding for Teva's oncology and women's health divisions in Europe.

Teva is planning to divest some assets to reduce the amount of debt. Assets of TEVA for bidding include its global women's health and European cancer and pain-treatment divisions.

Intas is reaching to several banks for financing this acquisition. Total cost for the bid will be around between $500 million and $1 billion.

After the completion of this deal, it could be the biggest overseas acquisition by an Indian company. Before this, the largest acquisition was Lupin Ltd's acquisition of Gavis Pharmaceuticals llc. and Novel Laboratories Inc. for $880 million in 2015.

Source: biospace.com, health.economictimes.indiatimes.com, livemint.com

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GLOBAL NEWS

3. Relocation of EMA regulators will hit MHRA researchers

Relocation of European Medicines Agency (EMA) regulators from UK after Brexit will leave a deep impact on the business of two main research organizations; Medicines Health and Regulatory Agency (MHRA) and Veterinary Medicines Department (VMD) of UK.

Relocation after Brexit in 2019 will not only relocate the headquarter of EMA to another EU state but will also result in reduction or withdrawal of MHRA and VMD work.

As MHRA is responsible for 20-30% of the licensing work and vigilance work of EMA, this relocation will change the relationship between MHRA and EMA.

MHRA and VMD were involved for providing various services to EMA including regulatory advices, research assignments along with scientific support.

Source: theguardian.com

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GLOBAL NEWS

4. Diabetes prescriptions increased by 80% in a decade

According to the latest data provided by the National Health Services (NHS), prescription of diabetic drugs is rising over all the other drugs. The latest data shows prescription of diabetic treatment items increased to 80.1% in primary care centers as compared to the last decade (46%).

According to report diabetic drugs prescribed in England in 2006/07 grew more than twice in 2016/17. Whereas number of patients diagnosed with diabetes is raised by 54% as compared to the last decade.

This rise in prescription also indicates the better identification of disease in early stages of life and more accurate treatment according to guidelines. But this large population suffering with type 1 and type 2 diabetes is posing major challenges to NHS. As diabetes is associated with various other complications like cardiovascular and kidney disease, new programs and drugs are required to overcome these.

Source: pharmatimes.com

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PHARMA INDIA

1. Government reduces knee implants prices up to 69%

After the announcement by PM Mr. Narendra Modi on Independence Day, prices of knee surgery have been reduced by the National Pharmaceutical Pricing Authority (NPPA). The cost of devices used to replace the knee joint and its components reduced by as much as 69%. But unlike the stents, knee implants are not kept in the essential medicines list.

In India, every year, about 1-1.5 lakh orthopaedic knee procedures are done. According to the ministry, this decision will lead to saving of an amount of about Rs. 1,500 crores every year.

This is for the second time the Government of India has taken such a decision for reducing cost of surgeries in India, after it was done for coronary stents recently.

The GST is not included in the new prices of knee implants but margins of hospitals, distributors and manufactures are included in the new cost. The new ceiling prices are based on the type of material used.

Type of knee implant	Ceiling price (GST excluded) (Rs.)	Average MRP (before) (Rs.)	Expected price reduction
Cobalt chromium (Widely used)	54,720	1.58 lakh	65%
Titanium and oxidized zirconium	76,600	2.49 lakh	69%
High-flexibility	56,490	1.82 lakh	69%
Revision (Repeat surgery)	1,14,000	2.77 lakh	59%

Source: health.economictimes.indiatimes.com, economictimes.indiatimes.com

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PHARMA INDIA

2. AI to reduce cost and speed the access of new drug in the Indian market

Under Union government's Digital India Programme, Artificial Intelligence (AI) is being adopted by large drug companies of India. To save costs and to speed the market access of new drugs, a number of companies are planning to use AI.

AI has the potential for new discoveries in clinical trials, identification of disease, Pharmacovigilance along with post marketing surveillance. This system has a very important role in research and development as it can help in the interpretation of massive data.

This system is used in the research titled 'Amplifying Human Potential – Towards Purposeful AI' by Infosys pharmaceuticals. AI also plays a vital role in clinical trials, analysis of the drug and also can help fast track the launch of new products.

Benefits of AI is not limited upto companies only, AI also provides benefits to patients, healthcare professionals, regulators and other key stakeholders by introducing new drugs in the market at the earliest.

AI system is integrated with the current safety data base system and directed to generate notifications and follow up of the patients. AI tool is able to translate any language and decode hand written report forms.

Source: pharmabiz.com

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PHARMA INDIA

3. Pharma marketing rules of India rejected by country's law ministry

The Department of Pharmaceuticals (DoP), Govt. of India was preparing new laws for preventing unethical marketing of pharmaceutical products since long.

After two year of deliberations, now the country's law ministry has rejected the draft of marketing rules by saying that these rules are not acceptable under proposed legal framework. This rejection is a big setback for the health groups who want to end bribery and corruption in the country. The first version of this draft was submitted in 2011, which was amended in January 2015. But after this rejection, the DoP need to prepare a new draft for marketing rules of pharmaceutical products in India.

India is one of the biggest drugs manufacturing countries with a 1 billion population along with growing incidences of several diseases. But in India there are no rules for marketing drugs. In India, drug manufacturing companies offer incentives to doctors and pharmacists for prescribing their products.

Source: economictimes.indiatimes.com

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PHARMA INDIA

4. Government of India forms new panel to make drugs more affordable

The Government of India has formed a committee consisting of joint secretaries for ensuring and enhancing affordability, availability and accessibility of the drugs to the public.

According to the health ministry, this would suggest different ways to reduce the cost of the drug in favor of poor people. This committee will also collect the marketing data of medicines to strengthen the market.

The panel will also keep a watch on the procedural improvements and process of re-engineering for ensuring better and quicker implementation of the policies. This process will also reduce litigations and review petitions.

Source: economictimes.indiatimes.com

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REGULATORY ROUND-UP

1. FDA revises draft guidelines for solid dosage forms

The US Food and Drug Administration (FDA) released a new draft guideline due to increased demand of repackage solid dosage forms into unit dose containers. The draft doesn't include any changes or actions regarding stability studies and assigning of expiration date of the drugs other than some certain conditions.

These draft guidelines were previously revised in 2005. A draft is provided by the US FDA with some regulatory guidelines for the finished pharmaceutical drugs explaining that each product should bear expiry date along with appropriate stability testing.

The latest guidelines are amended with some changes including:

- shortening of expiration date of solid dosage forms under certain conditions of repackaging in unit- dose containers from 12 to 6 months or 25% of the remaining time given in the original manufacture's product
- increase in time of expiration date by 6 months if products have data from appropriate studies and meet other conditions
- excludes scope of guidance of other dosage forms other than solid dosage forms
- extended use of containers meeting USP Class B standards meeting some certain conditions.

Source: raps.org

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REGULATORY ROUND-UP

2. EMA to get new ways for developing drugs to meet needs of elderly people

The European Medicines Agency (EMA) is now working to develop new ways for designing, assessing and packaging of drugs by considering the needs of elderly people. The EMA is mainly working to remove the difficulties faced by the elderly patients for breaking tablets and opening containers.

The EMA members are working to form a draft, which will outline various approaches for designing and packaging of medicines affecting older people. For this, the EMA is working mainly on three points:

- for breaking the tablet, a break-mark is given on the tablet from which a patient can divide the tablet into 2 parts and this is given to all type of patients but it's very difficult for elderly patients to break the tablet from the break-mark, EMA wants to avoid this
- EMA wants drug developers to develop at least one formulation of their products suitable for the feeding tube as some people rely on this route of administration
- Use of multi-dose dispensing and multi-compartment for compliance aid entails removal of drug from its original packing and putting them into compartments, which may affect the stability of the drug and according to EMA, companies need to study this.

Source: raps.org

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REGULATORY ROUND-UP

3. Australia proposes to align device regulations with EU

The Australian drug regulator Therapeutic Goods Administration (TGA) is proposing to align its medical devices regulations with Europe. TGA is collecting responses from the European regulators to reclassify its surgical mesh.

After these feedbacks, TGA will ask manufacturers to manufacture Class III mesh devices instead of Class IIb. The manufacturers need to examine certification of each mesh device and have to follow the Class III pathway. For smooth transition from Class IIb to Class III, TGA is providing a 3 year window to the manufacturers till November 2020.

Other than surgical mesh, TGA is also seeking advice on its second proposal based on implantable medical devices.

Under implantable medical devices plan, TGA wants to provide patients cards to manufacturers of orthopedic products and implants for better communication between doctor, patient and the manufacturer regarding any special requirements. Manufacturers can provide direct information to the patient regarding life span and basic information of the device.

Source: raps.org

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REGULATORY ROUND-UP

4. EMA revises pharmacovigilance guidelines

The Regulatory agency of Europe has revised its guidelines of good pharmacovigilance practice (GVP) after the big problem flagged up by Danish regulators regarding merging of duplicate safety reports in draft version.

Changes from the European Medicines Agency (EMA) mitigate the risks associated with the marketing authorization holders (MAHs) as well as with the national agencies by independently merging the duplicate safety reports.

In the GVP guidelines of draft VI, individual case safety reports (ICSRs) chart was given by the EMA. The chart was passed to MAHs and national competent authorities (NCAs) and they find duplicate case report when adding the ICSR to the data base.

Now EMA will create a master case for merger and then MAH and NCA will incorporate the changes done by EMA in their own data base. Adoption of new processes for handling duplicates is the new adoption by EMA.

Source: raps.org

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MERGERS/ ACQUISITIONS/ COLLABORATIONS

1. Panacea Biotec collaborates with Bionpharma for generic business

Panacea Biotec has entered into a strategic joint collaboration with Bionpharma Inc. for the development, manufacturing as well as selling of seven complex generic drugs. The seven drugs in the collaboration are not specified but most of the drugs involved in the collaboration belong to the class of immuno-suppressants.

The seven drugs have a market potential of about $800 million.

After this collaboration, both the companies will have their different roles. Panacea, in this collaboration, will be responsible for the development, filing, registration, manufacture and supply of the seven generic drugs; Whereas Bionpharma will import, warehouse, sales and distribute these ANDAs in the United States and its territories.

So far Panacea Biotec has filled seven ANDAs with the US Food and Drug Administration but from these seven, two drugs tacrolimus and rizatriptan are already commercialised by Bionpharma. Tacrolimus belongs to the class of immuno-suppressive drugs whereas rizatriptan is an antimigraine drug.

Source: health.economictimes.indiatimes.com

MERGERS/ ACQUISITIONS/ COLLABORATIONS

2. Bristol-Myers Squibb to acquire IFM Therapeutics for strengthening cancer pipeline

Bristol-Myers Squibb is going to acquire IFM Therapeutics (IFM) for strengthening its cancer pipeline. Bristol-Myers Squibb and IFM signed a definitive agreement and according to that agreement, Bristol-Myers Squibb will acquire all of the outstanding capital stock of IFM Therapeutics.

This acquisition of IFM will provide all the rights to Bristol-Myers Squibb for IFM's preclinical stimulator of interferon genes (STING) and NLRP3 agonist programs. Both of these programs are mainly focused on the enhancement of innate immune responses for the treatment of cancer.

According to this agreement, Bristol-Myers Squibb will pay $300 million upon the closing of the transaction. Company is also going to give additional contingent payment to stockholders of IFM up to $1.01 billion for the first products from the two programs.

This transaction will be closed by the end of third quarter of 2017.

Source: prnewswire.com

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MERGERS/ ACQUISITIONS/ COLLABORATIONS

3. Mallinckrodt acquires InfaCare and its development product stannsoporfin

Mallinckrodt and InfaCare Pharmaceutical have signed an agreement under which Mallinckrodt will acquire InfaCare Pharmaceutical along with its development product stannsoporfin. This acquisition includes an upfront payment of $80 million, and based on the regulatory and sales it can be upto $345 million.

Stannsoporfin is a heme oxygenase inhibitor and is currently under investigation for use in the treatment of severe jaundice in newborns. This drug has the potential of reducing production of high-levels of bilirubin which is associated with severe jaundice in newborns.

Stannsoporfin can also be used for various other conditions associated with elevated level of bilirubin, which may affect the central nervous system. The US Food and Drug Administration (FDA) have granted fast track designation to stannsoporfin in December 2016.

Source: pharmaceutical-technology.com

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MERGERS/ ACQUISITIONS/ COLLABORATIONS

4. Takeda and Shattuck Labs collaborate for the development of cancer immunotherapy

Takeda Pharmaceutical has entered into a strategic collaboration with Shattuck Labs for the development of cancer immunotherapy. The partnership companies are going to study and develop a check point protein with the potential to act as advance immunotherapy for the treatment of cancer.

Shattuck Lab is going to create a fusion protein by combining two binding domains by its Agonist Redirected Checkpoint (ARC) platform. This fusion protein will be capable of restoration and improvement of the immune system function.

Under this collaboration, companies will conduct two preclinical trials and four discovery stage programs and Takeda will invest for both pre-clinical and clinical developments.

After this partnership, Takeda will have the rights for global development and marketing of up to four molecules from this research.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. AstraZeneca's faslodex (fulvestrant) receives approval from European Commission for the treatment of metastatic breast cancer

Faslodex (fulvestrant) of AstraZeneca has received approval from the European Commission (EC) for the treatment of metastatic breast cancer. This drug is mainly for the treatment of oestrogen-receptor positive breast cancer in postmenopausal women, which were not previously treated with endocrine therapy.

Faslodex slows down the growth of the tumor by binding and degrading the oestrogen receptors. Oestrogen receptor is the major factor associated with metastatic breast cancer in women. This is the only hormonal therapy available for the treatment of advanced breast cancer.

Approval of Faslodex by the European Union (EU) was given on the basis of a randomized, double-blind, multicenter, Phase 3 FALCON trial, for the effectiveness of the drug at 500 mg over anastrozole 1mg. Results of the study were published in the journal *The Lancet*.

Progression-free survival was significantly longer with fulvestrant compared with anastrozole (hazard ratio [HR]: 0.797, 95% confidence interval [CI]: 0.637-0.999, p=0.0486).

FALCON trial demonstrates that faslodex at 500 mg can be used as a first line treatment option for the treatment of postmenopausal women suffering with metastatic breast cancer.

Source: pharmaceutical-technology.com, Robertson JFR et al, Lancet. 2016;388(10063):2997-3005

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DRUGS: APPROVALS AND LAUNCHES

2. FDA approves AbbVie Inc's MAVYRET

The US food and drug administration (FDA) has approved a fixed dose combination of glecaprevir/pibrentasvir as MAVYRET for the treatment of hepatitis C virus (HCV).

Glecaprevir is an HCV NS3/4A protease inhibitor whereas pibrentasvir is an HCV NS5A inhibitor. Combination is indicated for the treatment of chronic HCV genotype 1-6 infections in adult patients.

Safety and efficacy of MAVYRET were evaluated by a clinical trial conducted on 2,300 adults with genotype 1-6 HCV infections suffering with mild or no cirrhosis.

Results of this trial show that 92-100% patients treated with MAVYRET for 8, 12 and 16 weeks were detected with no virus after completion of 12 weeks treatment.

The fixed dose combination of MAVYRET tablet contains 100 mg glecaprevir and 40 mg pibrentasvir. Recommended dose for the combination is three tablets once daily with food.

Source: hepatitisc.hcvadvocate.org

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DRUGS: APPROVALS AND LAUNCHES

3. FDA's accelerated approval to nivolumab for metastatic colorectal cancer

Bristol-Myers Squibb Company's nivolumab have received accelerated approval from the U.S. Food and Drug Administration for the treatment of metastatic colorectal cancer patients (CRC). The drug is developed for the patients suffering with mismatch repair deficient (dMMR) and microsatellite instability high (MSI-H) type of cancer.

The biologic is developed for the treatment of those patients in whom fluoropyrimidine, oxaliplatin, and irinotecan failed to prevent progression of disease. The drug was approved on the basis of the data from study CA209142 (CHECKMATE 142).

This study was a multicenter, open-label, single arm study which was conducted on 74 patients detected with dMMR or MSI-H metastatic CRC, who had disease progression after the treatment of fluoropyrimidine, oxaliplatin, and irinotecan. All the patients were treated with a dose of nivolumab 3 mg/kg intravenously with the recommended dose of 240 mg/kg every 2 weeks. Complete results of the study were published in the journal *The Lancet Oncology*.

Out of 74 patients, 40 (54%) had received three or more previous treatments. After following-up for12.0 months (Interquartile range (IQR) 8.6-18.0), 23 (31.1%, 95% CI 20.8-42.9), 74 patients achieved an investigator-assessed objective response and 51 (69%, 57-79) patients had disease control for 12 weeks or longer.

Source: fda.gov, Overman MJ et al, Lancet Oncol. 2017;S1470-2045(17)30422-9

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DRUGS: APPROVALS AND LAUNCHES

4. US FDA approves Idhifa (enasidenib) for the treatment of AML

Idhifa (enasidenib) of Celgene Corporation have received the U.S. Food and Drug Administration approval for the treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients. This drug is mainly for patients with specific gene mutation in the IDH2 gene.

Idhifa is an isocitrate dehydrogenase-2 inhibitor targeted therapy. Idhifa is associated with complete treatment in some patients whereas in some patients results in reduction in the transfusion of both platelets and red blood cells.

The drug was approved on the basis of a single-arm trial on 199 patients with relapsed or refractory AML who had IDH2 mutations as detected by Real Time IDH2 Assay.

The study shows that within six months of treatment, 19% patients experience complete remission whereas 4% show complete remission with partial hematologic recovery. Out of 157 patients who require blood or platelet transfusion, 34% no longer require transfusion.

Source: fda.gov

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Cabotegravir/ Rilpivirine of ViiV shows positive result for Phase 2b trail

Long-acting injectable anti-HIV formulation of ViiV Healthcare showed positive results in Phase 2b trial. Formulation is composed of Cabotegravir and Rilpivirine.

This was an open level (LATTE 2) investigational study conducted to check the safety and efficacy of the two drugs. This study shows that Cabotegravir/ Rilpivirine improves adherence in HIV patients who find difficulty to follow daily oral dosing. Thus this will reduce the risk of resistance acquired due to bad compliance.

LATTE-2 trial was a 96 weeks trial conducted on 309 patients. In this trial, cabotegravir/rilpivirine were compared with Janssen's novel intramuscular formulation and nucleotide reverse transcriptase inhibitor Epzicom (abacavir/lamivudine).

Two different regimens used for the trail were:

- for 4-week interval: cabotegravir 400 mg + rilpivirine 600 mg; two 2 ml injections
- for 8-week interval: cabotegravir 600 mg + rilpivirine 900 mg; two 3 ml injections

The outcomes of the study were presented at the annual conference of the AIDS Society in Paris. Viral suppression rate for the injections were found to be 87% and 94% for four weeks and eight weeks respectively. Complete results were published in the journal *The Lancet*.

Source: pharmaceutical-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Ablynx's caplacizumab receives fast track designation for treatment of aTTP

The US Food and Drug Administration (FDA) provided fast-track designation to Ablynx's caplacizumab for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP).

Caplacizumab is a nanobody, which is the first drug in the class of anti-von Willebrand factor (vWF). Caplacizumab is useful for the treatment of patients suffering from aTTP which is a life-threatening autoimmune blood clotting disorder. Caplacizumab blocks the interaction between ultra-large vWF multimers (ULvWF) and platelets.

aTTP is a disorder that results in the formation of clots in the blood vessels in the body which can lead to thrombocytopenia, ischemia and organ damage. The drug is designated as fast track to fulfill the unmet need in the patients with aTTP.

The effectiveness of the drug was evaluated in the TITAN study, which was a Phase 2 trial conducted on 75 patients. The trial shows that the drug was well-tolerated and resulted in a 39% reduction in time to platelet count normalization as compared to placebo. Complete results were published in *The New England Journal of Medicine (NEJM)*.

Now, for further efficacy and safety of caplacizumab in patients with aTTP, a randomized, double-blind, placebo-controlled Phase III HERCULES trial will be conducted.

Source: pharmaceutical-technology.com, Abdelghany MT et al, N Engl J Med. 2016;374(25):2497

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Stem cell treatment as a new treatment option for various lung conditions

Researchers of UNC School of Medicine and North Carolina State University (NCSU) have developed a new stem cell treatment for various lung conditions like chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis (IPF), and cystic fibrosis.

The complete research is published in the journal *Respiratory Research*. In this study, researchers explain that they can harvest stem cells of lungs from people using a relatively non-invasive, doctor's-office technique. Then they will multiply the harvested cells to yield enough cells for human therapy.

In a study published in the journal *Stem Cells Translational Medicine*, researcher explains the successful treatment of rodent for IPF.

As the previous trials which were conducted on animal models were successful, now, the researchers are discussing with FDA for clinical trials. The cells used for the treatment will be the patient own cells so this will reduce the risk of rejection.

Source: medicalxpress.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Lasmiditan shows positive results for the treatment of acute migraine

A new drug from Eli Lilly and Company, lasmiditan showed positive results in a Phase 3 trial for the treatment of acute migraine. Lasmiditan is the first drug for the treatment of acute migraine.

Primary and secondary end points of the drug were studied in the Phase 3 SPARTAN trial. The trial was conducted against placebo and after 2 hours of the first dose of lasmiditan, patients were migraine free.

At two hours after the first dose of lasmiditan, the percentage of patients who were migraine pain-free was statistically significant as compared to placebo in all dosing groups: 28.6 % for 50 mg ($p=0.003$); 31.4 % for 100 mg ($p<0.001$); 38.8 % for 200 mg ($p<0.001$) vs 21.3 percent for placebo.

Statistically significantly more patients treated with lasmiditan were also free of their migraine-associated most bothersome symptom (MBS) compared to placebo at two hours following the first dose: 40.8 percent for 50 mg ($p=0.009$); 44.2 percent for 100 mg ($p < 0.001$); 48.7 percent for 200 mg ($p < 0.001$) and 33.5 percent for placebo.

Dizziness, nausea, somnolence, fatigue, paresthesia, and lethargy were the common adverse events associated with the drug.

Eli Lilly is planning to submit a new drug application to the U.S. Food and Drug Administration (FDA) in the second half of 2018.

Source: pharmpro.com, investor.lilly.com

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PATENTS: NEW APPROVALS/ LITIGATIONS/ SETTLEMENTS

1. Feldan Therapeutics receives patent for its peptide-based protein delivery technology, the Feldan Shuttle from USPTO

The United States Patent and Trademark Office (USPTO) granted a patent to Feldan Therapeutics, Inc., for its Feldan Shuttle platform. Feldan Shuttle is a peptide based drug delivery system prepared for the introduction of foreign proteins inside the cells.

The patent is entitled as "Polypeptide-based shuttle agents for improving the transduction efficiency of polypeptide cargos to the cytosol of target eukaryotic cells, uses thereof, methods and kits relating to same".

Patent will also protect the use of Feldan Shuttle in the delivery of various other cargos such as growth factors, cytokines, transcription factors, hormones, nucleases and antibodies to different cell types.

This unique drug delivery system has lifesaving therapeutic applications and patent will provide valuable protection to this platform.

Source: biospace.com

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PATENTS: NEW APPROVALS/ LITIGATIONS/ SETTLEMENTS

2. Prevenar 13 of Pfizer receives patent in India for the treatment of pneumococcal diseases

The Controller General of Patents, Designs & Trade Marks (CGPDTM) of India granted a patent to Prevenar 13 of Pfizer. This patent to Prevenar 13 is granted for the treatment of pneumonia in pediatrics. Pneumonia is responsible for seven deaths per every 1000 live births in India.

Prevenar 13 vaccine is active against 13 strains of *Streptococcus pneumonia*. Prevenar 13 was launched in 2010 in India. The patent was supported by extensive clinical research and real-world experience. Each dose of Prevenar 13 vaccine requires two and a half years to production along with 400 different raw materials, 580 manufacturing steps, and 678 quality tests.

Prevenar 13 has captured 18% of total Indian vaccine market. This patent application was opposed by Panacea Biotec and Médecins Sans Frontières (MSF) for lack of novelty. But CGPDTM dismissed all the arguments.

Source: health.economictimes.indiatimes.com

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PATENTS: NEW APPROVALS/ LITIGATIONS/ SETTLEMENTS

3. vTv Therapeutics receives US patent for methods of treatment using Azeliragon for Alzheimer's disease

The U.S. Patent and Trademark Office have granted a patent to vTv Therapeutics Inc. for the method of treatment of Alzheimer's disease using azeliragon. Azeliragon is an antagonist of the Receptor for Advanced Glycation Endproducts (RAGE) available as oral formulation by the company for the treatment of mild Alzheimer's disease.

This patent is granted till October 2034 for the methods of treating mild Alzheimer patients using 5 mg/day azeliragon.

For the treatment of disease, azeliragon targets mainly amyloid-ß, tau and chronic inflammation which are main pathologies associated with the disease.

Presently vTv is the only company developing treatment by targeting RAGE for Alzheimer's disease. Azeliragon is currently under Phase 3 study withs a randomized, double-blind, placebo-controlled study. The results of the study are expected to come out in late March 2018.

Source: pharmiweb.com

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PATENTS: NEW APPROVALS/ LITIGATIONS/ SETTLEMENTS

4. Korea United receives patent from Korea Intellectual Property Office for combined oral formulation technology

Korea United Pharmaceuticals received patent from the Korea Intellectual Property Office (KIPO) for its new combined oral formulation technology. Patent is registered for "CombiGel Technology". Combination contains a statin-based drug tablet incorporated with omega-3 fatty acid ester in a capsule.

The patent is granted for the use of combination in hypercholesterolemia and hypertriglyceridemia in the patients where triglyceride levels are not regulated.

The patent granted will have exclusivity on technology till 2035. The statin drugs included in the patent are Atorvastatin, Pravastatin, Lovastatin, Rosuvastatin, Simvastatin, and Fluvastatin.

Other than Korea, United company has filed the patent in Vietnam, Indonesia, China and Philippines and is currently under review.

Source: koreabiomed.com

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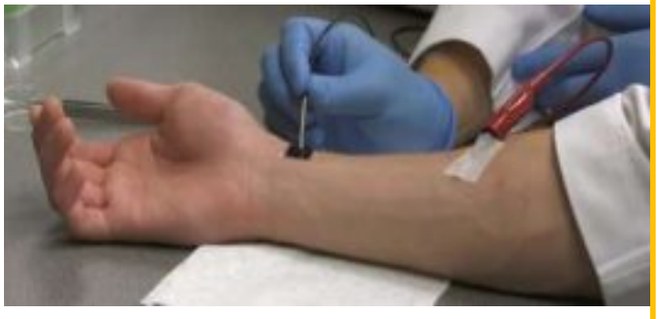
1. A touch from new device could heal organs

Tissue Nanotransfection (TNT) is the new technology by the researchers of Ohio State University, which can repair injured tissues, nerves and blood vessels with a touch only. TNT device is a chip which can convert skin cells into other cell type of the body.



TNT technology has two major components:

- a chip based on nanotechnology to deliver cargo to adult cells in the body and
- design of specific biological cargo for cell conversion

The cargo when delivered using chip converts an adult cell from one type to another. Implantation of TNT does not require any kind of laboratory-based procedures and may be implanted at the point of care. The research was published in the journal *Nature Nanotechnology*.

This device is only tested on mice and pigs but researchers were able to reprogramme skin cells into vascular cells. The trial was conducted on injured legs. Within a week, active blood vessels appeared and by the second week the leg was healed.

In the lab, TNT was able to reprogram skin cells into nerve cells which were injected into brain injured mice to recover them from stroke.

Source: health.economictimes.indiatimes.com, theguardian.com

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2. Bioactive tissue paper as regenerative medicine

Researchers of Northwestern Medicine institute have invented new bioactive tissue papers for the natural hormone production in cancer patients and wound healing.

These bioactive tissue papers are made up of proteins obtained by processing kidney, liver muscles, ovary, uterus, and heart of pig and cows. Different tissue paper has different properties based on the organ used to prepare.

The proteins used for manufacturing of tissue papers are excreted by the cells and responsible for providing shape and structure to the organs. These proteins combine with polymers to make the material pliable.

For preparing tissue papers, the cells of the organ are removed, leaving a structural protein termed as extracellular matrix, which is dried into powder and processed to form tissue papers. The study is published in the journal of *Advanced Functional Materials*.

In cancer patients and in menopause women, a strip of ovarian paper with follicles can be placed under arm to restore normal hormone production.

Source: news-medical.net

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3. Blood test to detect breast cancer patients at high risk of brain metastasis

Researchers of Houston Methodist Research Institute are developing a blood test, which can identify the patients of breast cancer who are at high risk of developing brain metastasis. The test can also monitor the progress of the disease and response of therapy given, in real life time.

Researchers detected a different group of circulating tumor cells (CTCs) that are associated with the brain metastasis.

Researchers explained in the study that the CTCs in the patients of breast cancer brain metastases are different from other type of CTCs. The study is published in the journal of *Nature Communications*.

Breast cancer cells can be dormant in the bone marrow and other organs of the patients like brain, lungs or liver, even after surgical removal. These dormant cells are associated with brain metastasis in the later stages.

Source: news-medical.net

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4. New peptide based drug delivery system to improve efficacy of drugs

Researchers from IIT Delhi are working on nanoconjugates to provide a new drug delivery system that is more effective against *E. coli* and *Salmonella typhi* at very low doses. This formulation will be useful for the treatment of cancer patients suffering from bacterial infections.

Nanoconjugates contain a peptide called as sushi-peptide, bound to gold nanoparticles of drug and able to kill 50% of bacteria at much lower concentrations (400nM). This peptide in not yet approved for clinical application.

This drug delivery system provides better efficacy and improved bioavailability of the drug, so a very low dose is enough to kill the bacteria. This reduction of dose provides a strategy against resistance of antibiotics.

This drug delivery system is more beneficial in cancer patients as after chemotherapy, immunological response decrease due to reduction of cells responsible for providing immunity resulting in increased chances of infection.

Source: thehindu.com

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WHAT'S NEW AT LAMBDA

IRIS Scanner to Identify Volunteers for Clinical Trials

The clinical pharmacology and medical affairs (CPMA) department at Lambda Therapeutic Research Ltd. is moving ahead with the best use of technology in this tech-savvy world. Lambda has already established itself amongst the first CROs which moved from paper to paperless.

The modern era popularity of IRIS Acquisition device is gaining momentum mainly perhaps as one of the most accurate methods to identify a person's identity. Automated method for biometric identification is Iris recognition which studies iris mathematical patterns in images of an individual, from one or both eyes. Iris scan's the colored ring of the eye controlling the pupil and its size, expansion and contraction, directing the amount of light entering eyes and further to the retina. These devices have an ability to accommodate a large group of volunteers by faster identification and return faster responses than any other methods or technologies.

Addition of this IRIS Scanner (Software) for Subject/Volunteer identification process for better compliance has been introduced in the month of August 2017 at Lambda. Volunteers are registered accordingly through IRIS software and in future visits are verified from the IRIS reading device.

Written by: Dr. Anshul Attrey


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