Lambda Research Newsletter

January 2020

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Research Accelerated

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NEWS letter

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GLOBAL NEWS

1. Novel drug delivery approach to treat renal disease

The researchers at the New York have reported a novel drug delivery approach for treatment of renal disease. In which the researchers have chosen three different sized vectors in the study including:

- Small adeno-associated virus (AAV) vectors (25 nm)
- Larger adenovirus vectors (100 nm)
- Lentiviral vectors (120 nm)

However, some vectors may leak out of the kidney and create off-target tissue effects. The researchers have tested two different direct injection in to kidney using bypass filer mechanism. This direct mechanism is to be most superior with compared to intravenous Injections.

Mayo Clinic has performed a comparison of novel delivery system with currently available techniques and found positive results. The study is published in the "*Journal of Human Gene Therapy*".

Source: economictimes.indiatimes.com

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GLOBAL NEWS

2. New modification research on gene expression

THE UNIVERSITY OF CHICAGO

A team of scientists at Chicago University have discovered a new modification research of gene expression.

The researchers have found that the messenger RNA was making their own efforts on protein production using reversible methylation chemical reaction.

Chromosome-associated regulatory RNA and carRNA are using same methylation reaction but they do not code protein and protein translation. The reaction is not a one time and one way, but it could be erased. The researchers have worked with laboratory mice but not fully explain everything.

The researchers have also identified number of reader protein that identify methylated mRNA, stability and translation of target mRNA. This new discovery was launched in the USA as modern era of RNA modification research. Gene expression is critically used in wide range in biological process and affects transcription of targets in the cell line.

This discovery provides an extent opportunity to guide disease identification for testing inhibitors.

Source: news-medical.net

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GLOBAL NEWS

3. Novel T-cell can destroy most types of cancer cells

A team of researchers from the Cardiff University have discovered a new immune T cell that can destroys most of the cancer cells. The new T cells have discovered accidently in the laboratory that can fight potentially against cancer cells. The study is published in the "*journal Nature Immunotherapy*".

Currently, doctors have used CAR-T therapy, in which getting patient's immune cells and genetically modified them and placed in the body, T cells start to kill cancer cells. However, this therapy is only used in lymphomas, not effective in solid cancers.

The novel T-cell is believed to have the ability to differentiate cancer cells and healthy cells. Almost in all body cells, the new T cell attaches with MR1 surface molecule, but they may present differently on cancer cells. The researchers have found that the immune cells with new receptor was disclosed to destroy solid cancers such as skin, lung cancers.

Source: ews-medical.net

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GLOBAL NEWS

4. Discovery of new treatment for skin cancer

The researchers at Bath University have discovered a new treatment for skin cancer. In laboratory, the researchers have investigated 245 lncRNAs (non-coding RNAs) that are associated with melanoma. They have found one DIRC3 (Disrupted In Renal Carcinoma 3) act as tumor suppresser and inhibit to spread tumors. This study is published in the "*PLOS Genetics*".

The reduction of DIRC3 increased "anchorage-independent growth" (ability of a cell to proliferate) that is potential sign of malignant cancer spared. Furthermore, the DIRC3 switches on the IGFBP5 gene that plays important role in expression of gene for tumor growth.

Currently, the investigation on DIRC3 is ongoing to understand how it works and inhibit the spread of tumors in details at molecular level. The DIRC3 activation is a new way to treat skin cancer. This research would be helps in patients who have not responded to current therapies or drug resistant over time.

Source: pharmatimes.com

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PHARMA INDIA

1. In FY20 Indian pharmaceutical market growth of 9.6%

According to AIOCD-AWACS market, the Indian pharmaceutical market growth down of 9.6% till 31 December. This is much slower than previously quarter and below industry expectations.

Indian drug companies mainly depend on domestic sales because of they face pricing pressure and exchange rate fluctuations with foreign countries such as the US and Europe.

AIOCD has expected correction in the growth for the month, but the market growth goes down on an annual average. The increment of new products in anti-diabetic market and cardiac market can help Indian market cross the double-digit growth on the month.

Source: moneycontrol.com

Company	Sale growth (%)	Sales December (Rs Cr)
Sun Pharma	10	3038
Abbott	8.3	2287
Cipla	7	1744
Cadila	12.1	1531
Lupin	10.9	1400
Alkem	10.9	1316
Torrent Pharma	11.9	1145
Dr Reddy's	22.7	912
Glenmark	13.9	891

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PHARMA INDIA

2. Karnataka DC set up PMRU to monitor reasonable price breaching

The Karnataka Drugs Control Department is currently working on Price Monitoring Research Unit (PMRU), it is known as Consumer Awareness Publicity and price Monitoring (CAPPM).

The PMRU set up to check compliance and price of medicines across the states, it is registered with representative of drug control department and health and family welfare. The main objective of this project is to generate a message to the consumer and general public regarding reasonable prices of medicines that are notified by the government.

Consumer should be taking a precaution while purchasing medicine such as MRP, manufacturing and expiry dates, bill of the medicines and further encourage the requirement of prescription of generic drug.

Source: pharmabiz.com

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PHARMA INDIA

3. Researchers uses electroporation method to prevent malaria

A team of scientists from Hyderabad's Centre for Cellular and Molecular Biology (CCMB) is working on malarial parasites to prevent spread of malaria using genetic modification. They have used electroporation method to modify plasmodium genes. The malarial parasites are grown in oxygen carrying red blood cells, RBC playing a protection role for parasites.

The researchers have found the Lyse release method is the best way for gene delivery. The RBC cells lyse when salt concentration is lower outside then inside. In this situation the researchers can fill circular DNA in the RBC, this circular DNA enable to alter malarial parasites.

In laboratory, by increasing the salt concentration researchers are enabled DNA inserted in plasmodium. The parasites go in to the RBC and take DNA from the RBC and eventually destroy the parasites nucleus.

The electroporation method is effective, easy to set up and works with 10 times less DNA.

Source: pharmabiz.com

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PHARMA INDIA

4. Health ministry work on SUGAM portal for digital Indian Pharmaceutical

Indian Drug Manufactures Association (IDMA) and Union Health Ministry are working with CDSCO to develop effective, accountable, transparent and digital pharmaceutical industry.

The Central Drug Standard Control Organization (CDSCO) has already provided services on SUGAM portal in 2016 for filing application, licensing and registration and offers online services for cosmetics and biologics. Recently the Union Health Ministry has also planned to regulate all medical devices under Drugs and Cosmetic acts for safety and quality purpose.

They have started separate online portal for new medical device related applications and in-vitro diagnostics for effective compliance.

Sugam portal is enabling for online submission of permission of drugs, clinical trials, ethics committee, medical devices, vaccines and cosmetics. System also maintain approved drugs database, manufactures and formulations, retailers and wholesalers in India.

Portal is also providing single window for stakeholders to access the services and implement the role-based actions, the application will be tracked on applicant's dashboard.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. FDA updating guideline on radiological medical devices

Food and Drug Administration has released a latest version of 2012 radiological medical device guideline "Clinical *performance Assessment: Considerations for computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device data in Premarket Notification (510(k)) submissions"* impact on reclassification of medical image analyzers.

FDA classifies three radiology devices in to class II:

- Genetic device type for Quant X will be referred as radiological computer-assisted diagnostic software for suspicious cancer.
- Generic device type for ContaCT will be referred as computer aided triage and notification software.
- Third device used as special control of Quant X and ContaCT and identify risks and mitigation measure for safety and effective purpose.

FDA has reclassifying from class III to class II image analyzer under the product code MYN, which consists of computed assisted devices for mammography and breast ultrasound as well as radiographic detection of lung nodules and dental carries.

Source: raps.org

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REGULATORY ROUND-UP

2. New guideline: targets device cyber security under MDR, IVDR

The Medical Device Coordination Group (MDCG) has developed a new guideline regarding cyber security of Medical Devices Regulation (MDR) and in-vitro Diagnostic Regulation (IVDR)

The 47-pages guideline has explained pre and post market requirement to help ensure benefits and risks during operation modes. Two types security issues:

- Week security
- Restriction security

Week security to access control allow malicious alteration of an implanted cardiac devices and restrictive security provides high level of protection. The guideline also explains how manufacture will need to share cyber security information. Annex II explain the difference between incidence and serious incidence from cyber security point of view.

The European Commission also included MedCert (Germany's notified body designed) under MDR. Netherland also appointed under MDR and IVDR, NBs will be designated by the first quarter of 2020.

Source: raps.org

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REGULATORY ROUND-UP

3. FDA drafts guidance: biosimilar and reference product

The US Food and Drug Administration has developed a new draft to promote reference and biosimilar products without any misleading way.

The 10-pages draft guidance involves determination, representations that suggests clinically meaningful differences between the reference products and its biosimilars. The presentation or suggestions create an impression that the biosimilars are not a highly similar to its reference product.

Many companies are claiming that bio similar is less safe or lower effective compared to its reference product, FDA suggests because biosimilars are licensed for fewer indications then the reference product would be misleading. The licensed biosimilars have been found minor differences in clinically inactive components that are not clinically meaningful differences between biosimilar and reference product for safety, purity and potency purpose.

The FDA and the Federal Trade Commission (FTC) announced a public seminar on 9th March to discuss regarding biosimilars and reference products.

Source: raps.org

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REGULATORY ROUND-UP

4. USFDA revised third version of ISO

The US Food and Drug Administration has revised third, new and standard version of International Organization for Standardization (ISO) risk management for medical devices with more than 100 other consensus standards.

The standard involves topics such as anesthesiology, biocompatibility, materials, physical medicine, radiology, software and sterility.

FDA updates its standards lists quarterly, and according to the guidance 2018, standards have published to the agency's database. FDA also publishes Federal Register listing for newly recognized standards.

FDA still accept declarations of conformity to the previous version, in support of premarket submissions until 25 December 2022. After this transition period, declarations of conformity will not be accepted.

FDA recognized AAMI TIR97 principles for medical device security, they provide detailed guidance for maintaining the security of a medical device during its entire life cycle.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Novartis merged with NHS for new approach of CVD

Novartis has entered into a research collaboration with NHS to address new approach for cardiovascular disease (CVD).

CVD is a world's most leading cause of mortality due to thickening and loss of elasticity of arterial wall and it is responsible for 64,000 deaths each year in the UK.

The investigational drug inclisiran may secondary preventive drug for atherosclerotic CVD. It would be save up to 30,000 lives. Currently, inclisiran will be studied in the UK as large scale at NHS clinical trial. The result will be expected in second half of this year. It will generate leading scientific evidence and accelerate access for patients. It is the big opportunity to open a new chapter for treatment of cardiovascular disease.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Eli Lilly acquire Dermira for expanding Immunological drug pipeline

Eli Lilly has planned to acquire Dermira for Phase III lebrikizumab drug and expanding its immunological drug pipeline.

Lebrikizumab is a novel, investigational, monoclonal antibody drug designed for potentially bind with interleukin-13.

IL-13 is a central pathogenic mediator that drives multiple aspects of sign and symptoms of moderate to severe atopic dermatitis. Lebrikizumab is a significant unmet treatment for moderate to savior atopic dermatitis patients.

According to the agreement Lilly will begin a tender offer to acquire all shares of the biopharmaceutical company in price $18.75 per share.

The US Food and Drug Administration has approved drug as fast tract designation in December 2019 after being license from Roche to Dermira.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. New fast track system launched for hearing loss

The National Institute for Health Research (NIHR), London Hospitals BRC, Nottigham BRC, Manchester BRC, and the Cell and Gene Therapy Catapult have jointly launched a new hearing medicines discovery of treatments for hearing loss or tinnitus.

Globally, hearing loss affects 0.5 billion people and, in the UK, almost 12 million people were affected. Still there are no therapeutic treatments for hearing loss or tinnitus.

The collaboration will provide unique knowledge, expertise and specialized network to conduct research in hearing therapeutics and support innovators to bringing new therapeutics in this area of unmet need.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Bayer and Evotec expand collaboration for PCOS

Bayer has announced to expand its partnership with Evotec to develop selective candidates for treatment for polycystic ovary syndrome (PCOS). The companies will be jointly contribute drug targets and to develop high-quality technology platforms for treatment options.

PCOS is the endocrine metabolic disorder in women and the most common cause of female infertility.

Majority 93% pregnancy related complications caused by PCOS and estimated 5-10% women suffering from PCOS. According to the agreement, Bayer will be responsible for subsequent clinical development and marketing.

Evotec will receive €6.5m upfront payment and €10 million research payment as well as to receive pre-clinical, clinical and sales over €330 million.

Source: businesswire.com

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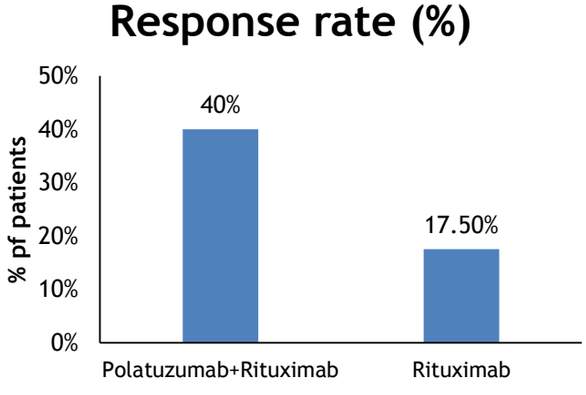
DRUGS: APPROVALS AND LAUNCHES

1. EU nodes Roche's polatuzumab for critical lymphomas

The European commission has approved Roche's polatuzumab vendotin (Polivy) for patients who have previously treated in critical lymphoma

The commission has been authorized of this drug with combination of bendamustin and rituximab for treatment of relapsed or refractory diffuse Large B-cell lymphoma (DLBCL) but not for a hematopoietic stem cell transplant patient. DLBCL is the most common type of non-hodgkin lymphoma (NHL).

The approval of this drug based on the results of Phase Ib/II GO29365 study, the clinical trial shown higher response rates and improve overall survival rates compared to rituximab in the patients, from the data 40% patients were achieved complete response treated with combination of rituximab with polatuzumab and 17.5% response were achieved with only rituximab.



Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

2. NICE approved palbociclib for treatment breast cancer

NICE
National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) has approved Ibrance (palbociclib) for treatment of breast cancer. Ibrance inhibits cyclin-dependent kinase 4 and 6 (CDK4/6) protein in cancer cells and preventing growth of cells.

Drug will be available in combination with fulvestrant and other two NICE approved drugs ribociclib and abemaciclib.

The approval of the drug based on the Phase III PALOMA-3 clinical trial and delay disease progression by 6.6 months compared to fulvestrant alone. The treatment could be option who have already had endocrine treatment. Palbociclib will be available within the Cancer Drugs Funds as a treatment option for patients with breast cancer.

Source: pharmatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. Novel EZH2 inhibitor approved by USFDA

The US Food and Drug Administration has approved TAZVERIK™ (Tazemetostat) for treatment of adults and pediatric patients aged 16 year or below with metastatic or locally advanced epithelioid sarcoma (ES). There are limited therapeutic options for treatment of ES.

Epithelioid sarcoma is an aggressive and life-threatening cancer that affect young adults. TAZVERIK™ is first and only FDA approved EZH2 inhibitor of specific treatment for ES patients.

The Discovering, developing and receiving of FDA approval of TAZVERIK™ is based on its novel mechanism of action. Epizyme's Phase III trial support its potential to provide clinically positive responses and tolerability for ES patients, the commercial launch of the drug is ongoing.

Source: finance.yahoo.com

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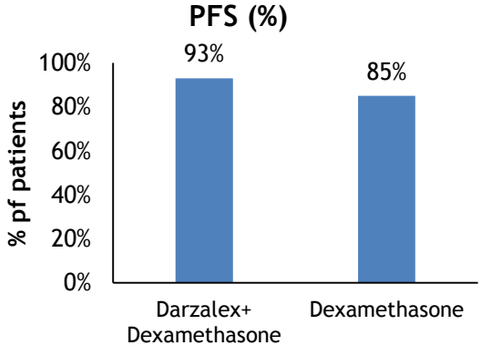
DRUGS: APPROVALS AND LAUNCHES

4. Darzalex get EU nod for MM treatment

The European Commission (EC) has granted authorization for Darzalex (Daratumumab) combination for newly diagnosed multiple myeloma (MM). The combination consists of bortezomib, thalidomide and dexamethasone. This is the first approved regimen in over six years for newly diagnosed patients who are eligible for stem cell transplant. Patients have an option to treat with monoclonal antibody.



MM is an incurable type of blood cancer that starts in the bone marrow, it is characterized by an excessive multiplication of plasma cells. In the Europe, more than 48,200 people were diagnosed with MM in 2018, with more than 30,800 MM related mortality.

The approval was based on the Phase III CASSIOPEIA (MMY3006) study, the results shown positive response. The median follow-up of 18.8 months, PFS was 93% in the Darzalex with dexamethasone group with compared to 85% of dexamethasone group. The effectiveness of first line treatment is critical to maximize time until relapse.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. New test developed to prevent glaucoma-related blindness

The researchers from Australia has suggested genetic test to detect glaucoma. Glaucoma is the genetic disorder and it is characterized by progressive damage and degeneration of the optic nerve which leads to loss of vision. It is leading cause of irreversible blindness, globally expected 76 million people affected by glaucoma in 2020.

The researchers are identifying a new genes to develop glaucoma polygenic risk score (PRS), using this score can predict eye disease. They can also find that how a person was to develop the disease and who should be offered early treatment by analyzing DNA collected from saliva or blood.

Glaucoma can arise at any age but most of those affected are in their 50s or older, so our aim is to offer blood tests to people of that age to find out if they are at risk, and then hopefully act on it.

Source: economictimes.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Bavencio shown positive results for urothelial carcinoma

Merck gets positive results from Phase III JAVELIN bladder 100 study of Bavencio (avelumab) for treatment of metastatic urothelial carcinoma (UC).

UC accounts for about 90% of all bladder cancer, it becomes harder to treat as it metastatic, spreading through the layers of the bladder wall, meaning there is urgent needs for additional treatment for improve overall survival.

Bavencio is the first immunotherapy to shown statistically positive results in overall survival as a first-line treatment for patients with advanced urothelial carcinoma. The safety result was consistent with drug.

Source: pharmatimes.com

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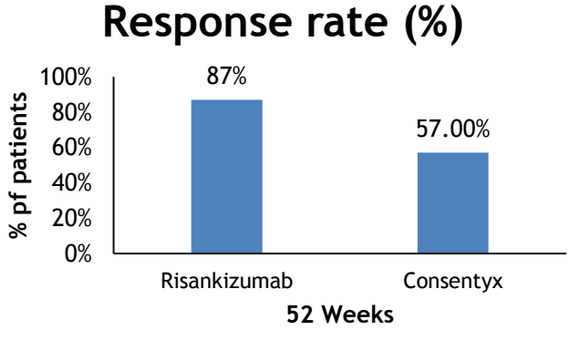
DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Skyrizi gets primary and secondary endpoints for plaque psoriasis

AbbVie, bio pharmaceutical company, they have announced skyrizi (Risankizumab) gets primary and secondary endpoints for treatment of moderate to severe plaque psoriasis.

Abbvie has performed Phase III. Multicenter, randomized, open-label, efficacy assessor-blinded and active-comparator study.

The study was conducted to evaluate the safety and efficacy of skyrizi compared with cosentyx in adult patients with moderate to severe plaque psoriasis.



Patients treated with skyrizi and achieved 87% Psoriasis Area and Severity Index (PASI 90) compared to 57% cosentyx treated patients at 52 weeks, skyrizi gets other primary endpoints of non-inferiority with 74% patients achieving PASI 90 compared with cosentyx achieved 66% at 16 weeks.

Skyrizi also showed positive response in all secondary endpoints, including PASI 100, and PASI 75, as well as a static Physician Global Assessment Score at week 52. The safety profile of skyrizi was consistent. No any adverse events observed through week. There were no deaths in either treatment group.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Lilly open phase III trial for RET-mutant medullary thyroid cancer

Lilly has performed randomized Phase III LIBRETTO-531 clinical trial of selpercatinib for the treatment of RET-mutant medullary thyroid cancer (MTC). Medullary thyroid cancer is a rare cancer, approximately 60% of people suffering from medullary thyroid cancer have an activating RET point mutation, and still there is no ideal treatment for this indication.

The trial will enroll 400 patients with advanced or metastatic RET-mutant MTC who have received no prior systemic therapy for metastatic disease. The primary efficacy endpoints are progression-free survival (PFS), treatment failure free survival (TFFS), overall survival (OS), overall response rate (ORR), and duration of response (DoR).

Selpercatinib is also known as LOXO-292, the drug is highly selective and potent, oral investigational medicine develop to treat cancer patients that abnormallity in the rearranged during transfection (RET) kinase. RET mutations occur across multiple tumor with difference frequency. Selpercatinib was designed to prevent native RET signaling as well as anticipated acquired resistance mechanism.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Jury ordered Gilead Science to pay $752 million for CART-T patent

The top pharma companies Bristol-Mayer and Gilead Sciences fight for CART-T patent. Last month Jury ordered Gilead to pay $752 million for CART-T patent infringement.

Jury found Gilead's kite pharma stepped on BMS patent, Juno Therapeutics had licensed from the researchers of Sloan and Memorial Sloan cancer center. Jury also ordered kite to pay $752 million for damage.

Source: fiercepharma.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Patents for NLRP3 inflammasome-inhibiting compounds granted in US and Europe

Inflazome has announced that the US and European patent will approve patent for NLRP3 inflammasome inhibiting compound.

The patent application (WO2016/131098) has accepted by the US and EU patent office on 21 January 2020 and 15 January 2020 respectively.

NLRP3 inhibiting compound (Inzomelid and Somalix) can be used in Parkinson's, Alzheimer's and motor neuron disease.

Source: europeanpharmaceuticalreview.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Teva become first company to launch generic Linzess in the USA

Teva Pharmaceutical Industry become the first company to launch a generic version of drug Linzess (linaclotide) as a result of a patent litigation settlement and sending the firm's shares 2.95% higher to 3,592 shekels.

Teva has deal with Ironwood Pharmaceuticals and Allergan to market generic versions of 145 µg and 290 µg drug before expiration of the companies' patents.

This settlement does not approve any license with regard to its 72 µg generic of Linzess to Teva. Under the agreement, Teva will start marketing of 145 µg and 290 µg strength of Linzess in the beginning in the USA FROM 31st Match 2029.

As legal requirement, Teva will submit the settlement agreement to the US Federal Trade Commission and the US Department of Justice for review.

Source: thepharmaletter.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Adamas settled agreement with Sandoz

Adamas Pharmaceuticals has settled agreement with Sandoz for ongoing litigation of abbreviated new drug application seeking approval by the US Food and Drug Administration to market a generic version of GOCOVRI (amantadine) extended release capsules.

Under the agreement, Sandoz will use a non-exclusive license to make, use, sell, offer to sell and import the products as of 4th March 2030, or earlier in certain circumstances and consisting a potential license date, if the unit sales of drug in the 12-month period ending 31 July 2025 or12-month period reduced by a specified percentage below the sales of GOCOVRI in the 31st December 2019.

Source: investingnews.com

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TECHNOLOGY /NDDS

1. New contact lenses can prevent "Dry Eye Syndrome"

Dry eye syndrome is a major problem with contact lense due to reduced blinking of eyes and increased moisture evaporation.

TOHOKU UNIVERSITY

Dry eye syndrome leads to inflammation in cornea, to resolve this problem the researchers at Tohoku University have developed a new self-moisturizing smart contact lense that can prevent dry eyes. This novel mechanism maintains fluid between the lenses and eyes.

In this contact lenses used electroosmotic flow (EOF), when voltage is applied to hydrogel causes fluid to flow upward from patient's temporary tear reservoir to surface of the eyes. The researchers have also investigated the wireless power supply for the contact lenses.

They analyzed two types of battery 1) Magnesium-oxygen battery 2) Enzymatic fructose-oxygen fuel cell. These bio batteries are safe and non-toxic for living cells. However, the further investigation is require to improve this mechanism.

Source: mpo-mag.com

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TECHNOLOGY /NDDS

2. Scientists have developed super human red blood cells

The researchers at McMaster University have developed super human red blood cells that can find specific target and deliver a drug. It could be a perfect stealth drug carrier.

The researchers have modified RBC surface them attracted and stick with certain tissues, organs or bacteria.

Team has replaced molecular insides with drug and reconstructs the cell membrane using combined synthetic and biological material.

Source: medgadget.com

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3. Morph DNA catheter to guide cell delivery in to heart tissue

BioCardia has developed a morph DNA catheter device in to the heart with the help of CardiAMP cell therapy. CardiAMP involves in the depositing a patient's own bone marrow cells in to heart tissue to do start body's natural healing process. Morph DNA catheter has won FDA clearance.

Inside the heart, catheter is used to guide the helix delivery system around multiple targets. The helix injects cell therapy directly in to heart tissue for potential benefits to patients.

According to company the bi-directional morph DNA having ergonomic design and visible under the fluoroscope. This catheter uses pull and braided in to helix similar to DNA strands. The morph DNA guide enables navigation within cardiac and beneficial for controlling the delivery of therapeutic catheters like helix. The ergonomic design can reduce procedural delays.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. Tiny new smaller micra AV pacemaker to treat AV block

FDA has approved small pacemaker with micra atrioventricular (AV). This device intended to treat AV block and enough small to remain inside the heart, it doesn't have weight and create any problem with them.

MIcra AV can detect movement of heart and co-ordinate the pacing of the ventricle. It works efficiently in conjunction with the atrium.

Micra AV is a new treatment option with advantages of leadless pacing, although more frequent complications with traditional pacemakers, they are more expensive to treat. Micra has shown 63% reduction in major complications compared to traditional pacemakers in real-world use.

Source: medgadget.com

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WHAT'S NEW AT LAMBDA

1. Successful completion of USFDA inspection at Lambda bioanalytical phase

Surprised USFDA inspection was completed of Lambda Therapeutic Research Limited at Ahmedabad for bioanalytical phase, they have inspected four studies for small and large molecules. The inspection was carried out on 20 January 2020. Overall, the inspection was successful with only one minor observation in editorial changes.

This is a first time inspection for bioanalytical phase in large molecule.

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