Lambda Research Newsletter

July 2019

LAMBDA

Research Accelerated

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Clinical Research NEWSletter

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WHAT'S NEW AT LAMBDA

1. Successful completion of NPRA inspection at Ahmedabad facility

The National Pharmaceutical Regulatory Agency (NPRA) of Malaysia completed its inspection of the bioavailability/bioequivalence (BA/BE) facility of Lambda Therapeutic Research Limited at Ahmedabad in Gujarat, India, from 08 July 2019 to 19 July 2019 for a total of 5 studies.

Overall, the inspection was successful without any major/critical observations.

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GLOBAL NEWS

1. p38 protein inhibits new blood vessel formation in colon cancer

The inhibition of p38 protein is known to boost the formation of blood vessels in colon cancers as evidenced in the study by Institute for Research in Biomedicine (IRB Barcelona) which is published in the journal *Nature Communications*.

The mesenchymal stem cells (MSCs) play an important role in tumor development and have been shown to be related to the regulation of angiogenesis in this study. The p38 protein curbs the angiogenesis by acting particularly in MSCs. The study demonstrated using genetic mouse models that p38 inhibition leads to growth of new blood vessels. This happens in tumors and also while repairing damaged tissue.

The study results highlight the mechanisms for blood vessel formation regulation and may help in the optimization of chemotherapy treatments.

Source: technologynetworks.com

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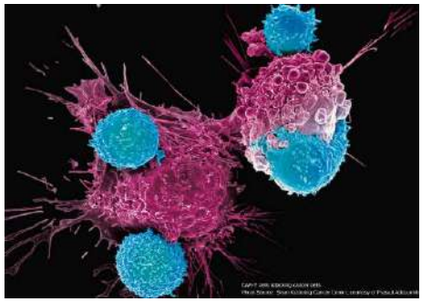
GLOBAL NEWS

2. CAR-T cell: extensive range for research & immunotherapy



In response to the accelerated progress in research on the therapeutic uses of CAR-T cells, several new best-in-class CAR-T cells, engineered CAR-T target cells, peripheral blood mononuclear cells (PBMC), cell media and activation beads were announced by AMSBIO. All these T cells by AMSBIO are produced from either a group of donors or from individual donor transduced with Chimeric antigen receptor (CAR) - lentivirus.

Different tumor antigens that are highly expressed in tumors including CD19, CD133, Her-2, EGFR, VEGFR-2 or mesothelin can be targeted by these CAR-T cells.

AMSBIO offers a wide range of engineered cell lines in addition to these off-the-shelf CAR-T cell products. These cell lines include CAR-T/NK cells and target cells (GFP-Raji cells).

These CAR-T cells are produced from AMSBIO's new CAR T-cell Expansion Medium that is specifically optimized to provide 100-fold greater expansion than normal media. CD28 / CD3 cell activation / expansion beads have been introduced to activate and expand human T cells: CD4+, CD8+ T cells, antigen specific T cells or polyclonal T cells.

Source: technologynetworks.com

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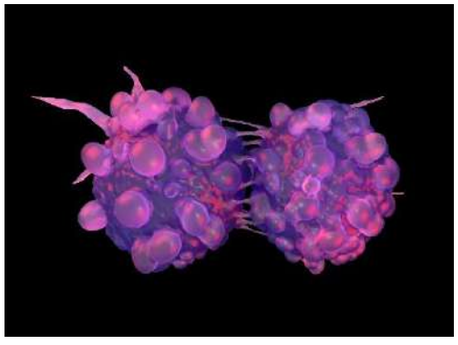
GLOBAL NEWS

3. Scientists identify a new drug target for cancer



Researchers at the University of California San Diego School of Medicine and the Ludwig Institute for Cancer Research at UC, San Diego, have identified an enzyme called LPCAT1. This enzyme causes the alteration in the phospholipid composition of the cancer cells' plasma membrane, allowing amplified and mutated growth factor signals to spur tumor growth. Tumors cannot survive without LPCAT1 enzyme.

The researched genetically depleted LPCAT1 in multiple types of cancer in mice and observed a dramatic shrinkage of the malignancies and improved survival times.

The study demonstrated that LPCAT1 is an important enzyme that gets dysregulated in cancer resulting to aggressive tumor growth. This may be due to the linking of common genetic alterations in the tumors leading to changes in metabolism.

These findings also corroborate that LPCAT1 may be a very compelling new drug target in a wide variety of cancer types.

Source: technologynetworks.com

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GLOBAL NEWS

4. New anti-cancer agents could eradicate cancer stem cells

Researchers at the College of Pharmacy and Pharmaceutical Sciences, University of Toledo, have uncovered a new class of therapeutic molecules that could lock on to and kill cancer stem cells. Their findings are reported in a paper recently published in the journal *Scientific Reports*. Their discovery can be a breakthrough in cancer management and also ensures that cancer does not relapse.

The cancer stem cells that can potentially re-grow the tumors, can be locked on to with these tiny molecules that can ultimately kill them by blocking their absorption of an amino acid called cysteine.

Currently, there are no drugs available, which can kill the cancer stem cells. As these new molecules have the potential to kill cancer stem cells, they can be used along with chemotherapy to provide a more comprehensive treatment.

Source: technologynetworks.com

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PHARMA INDIA

1. Biological data storage, access and sharing policy of India released

DEPARTMENT OF BIOTECHNOLOGY
GOVERNMENT OF INDIA

The Department of Biotechnology (DBT), Govt. of India, has issued the 'Biological data storage, access and sharing policy of India' in order to define guidelines for sharing of data generated by scientists in India using modern biotechnological tools and methods.

The new guidance document captures the details for broad guidelines for biological data pertaining to modern high-throughput high-volume data.

The data in the biotechnology sector are generated to further advance the knowledge, gain deeper insights into biological and other processes, and for translation. These data are meant to be used for the benefit of humankind.

Comments are invited on this new 'Biological Data Storage, Access and Sharing Policy of India' from various stakeholders including government agencies, institutions and industry/researchers engaged in research & development in Biological Sciences.

Certain principles are required to be followed in the responsible data-sharing including:

1. Protection of privacy and confidentiality: Shared data must not include any personal identifiers and must have been collected with informed consent, including consent to share data after adequate anonymization/de-identification.
2. Re-identification after anonymization/de-identification must not be attempted, without legal orders.
3. In addition, care must be taken to ensure that the data resource is not used to ostracize communities; ethnic, religious, geographical or any other.
4. Appropriate ethical approval(s) need to be obtained by the data-submitter prior to data submission

Source: pharmabiz.com

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PHARMA INDIA

2. India & USA: Inter-institutional agreement for cooperation in medicine

The Union Cabinet has approved the inter-institutional agreement between India and the USA for:

- regenerative medicine
- 3D bioprinting
- new technologies in medicine
- exchange of scientific ideas/information and technologies, and
- joint use of scientific infrastructure

With an aim to contribute towards the development of research and education through academic collaboration, the agreement will focus on the general areas of common interest that include:

1. Exchange of faculty members and students for training, study and research especially in the areas on 3D Bioprinting
2. Execution of joint research projects
3. Exchange of information and academic publications.

Source: pharmabiz.com

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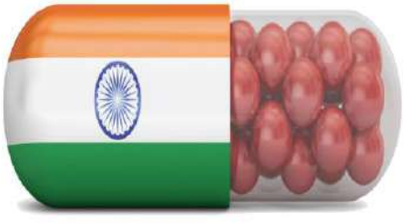
PHARMA INDIA

3. Indian pharma: 207 ANDA and 55 tentative approvals from US FDA in FH19



The growing presence of the Indian research-based pharmaceutical companies in international market during the last couple of years can be seen from rising Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (FDA).

Of the total 476 ANDA approval by the US FDA in the first half ending in June 2019, 207 of these ANDAs (>43%) were grabbed by Indian pharma companies and their subsidiaries. Also, of total 102 tentative approvals by USFDA, Indian companies received 55 tentative approvals.

US FDA approved a total of 813 final ANDAs and 194 tentative approvals during the year 2018 and Indian companies had received 290 final and 77 tentative approvals.

Source: pharmabiz.com

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PHARMA INDIA

4. Pharma players to step up regulatory compliance: Fitch group

India Ratings & Research
A Fitch Group Company

The US focused Indian pharmaceutical players would be required to step up regulatory compliance in Financial Years 2020 to 2030 as they invest in complex generic drugs, specialized and innovative scenario, according to India Ratings and Research (Fitch Group).

From the second half of 2017, industry witnessed the resolution of key manufacturing facilities of large manufacturers under warning letters and import alerts with an average period of 24 to 36 months after regulatory restriction. While this is encouraging, a reduction in resolution times and limited repeat observations would indicate regulatory discipline re-tuning to the industry. Input quality risk stemming from high dependence on Chinese players has been an emerging concern in 2018-2019, leading to product recalls initiated by major players.

This is high time that Indian pharmaceutical companies stepped up their regulatory compliance and build up their reputation as reliable suppliers.

Source: biospectrumindia.com

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REGULATORY ROUND-UP

1. Postmarket safety reporting guidance for combination products

The US Food and Drug Administration (FDA) has finalized the guidance document that explains postmarket safety reporting (PMSR) requirements for combination products. The guidance document will assist the applicants to better comply with important product postmarketing safety reporting requirements and provide timely, comprehensive safety information about combination products at established intervals.

This guidance document comes after FDA twice pushed back compliance dates for the safety reporting requirements for constituent parts. In April 2019, the agency said it does not intend to enforce the below mentioned requirement documents until 31 July 2020 for combination product applicants using the FDA Adverse Event Reporting System (FAERS) and Electronic Medical Device Reporting System (eMDR) to report Individual Case Safety Reports (ICSRs).

- 21 CFR 4.102(c) and (d) (constituent part-based PMSR requirements),
- 4.104(b)(1) and (b)(2) (submission process for constituent part-based ICSRs), and
- 4.105(b) (recordkeeping requirements)

The guidance also includes two hypothetical examples of postmarket safety reporting considerations for combination products. The first example follows a product marketed under a new drug application comprised of an injectable drug in a sterile pre-filled syringe and the second involves a drug-eluting stent marketed under a premarket approval application.

Source: raps.org

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REGULATORY ROUND-UP

2. Medical device premarket cybersecurity: TGA finalizes guidance

TGA Health Safety Regulation

Australia's Therapeutic Goods Administration (TGA) has finalized the guidance document on premarket requirements on medical device cybersecurity. The 53-page final guidance provides the details regarding premarket cybersecurity requirements for manufacturers and sponsors of medical devices and *in vitro* diagnostic devices.

In line with the other members of the International Medical Device Regulators Forum (IMDRF), TGA is also pushing for the total product lifecycle (TPLC) approach to risk and quality management with new information on TPLC expectations.

The IMDRF regulators will discuss the cybersecurity element via their respective draft and final guidances. The draft guidance on premarket cybersecurity was first issued by FDA's Center for Devices and Radiological Health. The guidance documents from Health Canada and TGA have come into effect, but FDA's documents are yet to be finalized.

Source: raps.org

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REGULATORY ROUND-UP

3. Technical specifications for submitting NGS data on antivirals

The US Food and Drug Administration (FDA) published a technical specifications document to help sponsors submit next generation nucleotide sequence (NGS) analysis procedures and data for the development of antiviral drugs in support of resistance assessments.

The FDA outlines the list of acceptable NGS platforms and details regarding the information and how that needs to be submitted to the FDA's Division of Antiviral Products. According to the guidance document, "Submissions of sequence data must include a thorough description of the analysis pipeline used to analyze the sequencing dataset and the raw sequence information so that the Division can conduct an independent analysis of the data".

The FDA further adds that two approaches can be used for NGS analyses of data in order to support the development of antiviral drug products:

1. mapping of short reads to a references sequence or
2. de novo assembly of short reads.

The document also features a frequency table example and explains the file type and submission procedures.

Source: raps.org

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REGULATORY ROUND-UP

4. Real-world data (RWD) and real-world evidence (RWE): FDA discusses

To discuss the use of real-world data (RWD) and real-world evidence (RWE) in the premarket and postmarket settings, key personnel from the Industry, academia and US Food and Drug Administration (FDA) gathered in July 2019. This would provide the FDA a guidance to evaluate the potential use of RWE to support label changes (i.e., addition/modification of an indication, comparative effectiveness or safety information). The FDA has also issued draft guidance on the types of RWD and RWE information that might be submitted. Several examples (as shown below) of when RWE has informed effectiveness determinations were also discussed.

DRUG	INDICATION	STATUS	DATA
Lutathera (Lutetium 177 dotatate)	GEP-NET Gastropanc, Neuroendo tumors	Approved 2017	Open label clinical trial Analysis of 360 patients in an investigator sponsored, open, single arm, single institution study of 1214 patients
Voraxaze (Glucarpidase)	Treatment of MTX toxicity	Approved 2012	Approval based on open-label, NIH compassionate use protocol
Uridine Triacetate	Treatment of 5 FU overdose	Approved 2015	Two single arm, open label expanded access trial of 135 patients compared to case history control
Defitelio (Defibrotide sodium)	Severe hepatic veno-occlusive disorder	Approved 2016	Two prospective clinical trials enrolling 179 patients and an expanded access study with 351 patients
Blincyto (Blinatumomab)	Treatment of acute lymphoblastic leukemia	Approved 2014	Single arm trial Reference group weighted analysis of patient level data on chart review of 694 patients at EU and US study sites
Carbaglu (Carglumic acid)	Treatment of NAGS deficiency	Approved 2010	Retrospective, non-random, un-blinded case series of 23 patients compared to historical control group
Myozyme (Alglucosidase Alfa)	Treatment of Pompe disease	Approved 2004	Open-label, non-randomized study of 18 patients compared to historical control group of 62 untreated patients
Refludan (Lepirudin)	Anti-coagulation in heparin-induced thrombocytopenia	Approved 1998	Two non-randomized, open-label multicenter trials using historical control comparator group from HIT registry

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Pfizer acquires Therachon

Pfizer has completed the acquisition of privately held clinical-stage biotechnology company Therachon Holding AG for $340 million.

The terms of the transaction for the acquisition included $340 million upfront payment from Pfizer with an additional $470 million in additional payments contingent on the achievement of key milestones in the development and commercialization of TA-46, an investigational medicine for the treatment of achondroplasia.

Therachon
achieving potential

Achondroplasia is a genetic condition and the most common form of short-limb dwarfism with no treatment approved.

Plans to advance the development of TA-46, which has the potential to be a first-in-class therapy for the treatment of achondroplasia.

The transaction is not expected to impact Pfizer's current 2019 adjusted financial guidance.

Source: europeanpharmaceuticalreview.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. AbbVie acquires STING pathway-focused Mavupharma

AbbVie has acquired the oncology drug discovery company Mavupharma. The financial terms of the transaction were not disclosed.

AbbVie's vision is to advance breakthrough areas of science leading to a strong pipeline of innovative cancer treatments and has a very strong oncology drug pipeline, including early and late stages of clinical development: Rova-T, Venclexta and Imbruvica.

Mavupharma focuses on the discovery and development of novel approaches to target the STING (STimulator of INterferon Genes) pathway. Signaling linked to this pathway is known to play an important role in generating an immune response against tumors.

Mavupharma's only current clinical candidate is MAVU-104 - a small molecule inhibitor of ENPP1, a phosphodiesterase that negatively regulates the STING pathway.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Cipla to acquire stake in digital therapeutics startup Wellthy

Goldencross Pharma, a wholly-owned subsidiary of Cipla, is in an agreement to acquire the Mumbai-based firm Wellthy Therapeutics for a cash consideration of Rs 10.5 crore.

Under this deal, both the partners plan to provide combination of pharmacotherapy and digital therapeutics for improved patient outcomes in diabetology and cardiology. A multi-lingual clinically-validated digital disease management platform will be made available to patients living with diabetes or cardiovascular diseases.

The platform brings together behavioral science, real-world clinical evidence and artificial intelligence to provide real-time monitoring, coaching and advice to patients, and virtual clinical assistance to doctors.

By pairing Cipla's pharmacotherapy strengths with the digital approach to health care taken by Wellthy Therapeutics, the drug firm will add to its diversified portfolio in the cardio-metabolic area to provide holistic care to patients from awareness, diagnosis and compliance to well-being.

Source: economictimes.indiatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. AbbVie to acquire Allergan in multibillion-dollar merger

The Dublin-based botox-maker Allergan is to be acquired by the US pharma company AbbVie. As per the cash-and-stock transaction, Allergan is valued at $63 billion (£49.6 billion). The takeover will create the world's fifth-largest drug company, with estimated $48 billion revenue in 2019.

AbbVie itself has been under pressure to offset losses incurred by biosimilar competition to its arthritis treatment Humira (adalimumab).

Near $20 billion brought in by Humira in 2018 represented about 60% of the Abbvie's global sales. However, the patents for the drug for Abbvie expired in Europe in late 2018, and four competitor products are already on the market. Its US patent expires in 2023. Acquiring Allergan, with an annual revenue of $16 billion, goes a long way towards plugging this hole in its balance sheet.

Source: chemistryworld.com

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DRUGS: APPROVALS AND LAUNCHES

1. Amgen, Allergan launch first US biosimilar of Herceptin and Avastin

Amgen and Allergan have launched biosimilars of both Herceptin (trastuzumab) and Avastin (bevacizumab) in the US. Earlier this year, Roche estimated the arrival of biosimilars to Herceptin, Avastin and a third top drug, Rituxan (rituximab), in the second half of 2019.

Amgen and Allergan's biosimilars of Herceptin and Avastin are now the first cancer drugs to face biosimilar competition in the U.S. The lower-cost biosimilar versions will come cheaper than Roche's brand-name versions, with Amgen and Allergan setting the list price to each at 15% below that of the original biologics.

Roche expects competition to eventually weigh on sales. That impact has already been observed for Herceptin elsewhere. Sales fell by 16% last year after biosimilars launched in mid-2018 for the European and Japanese markets.

Source: pharmabiz.com

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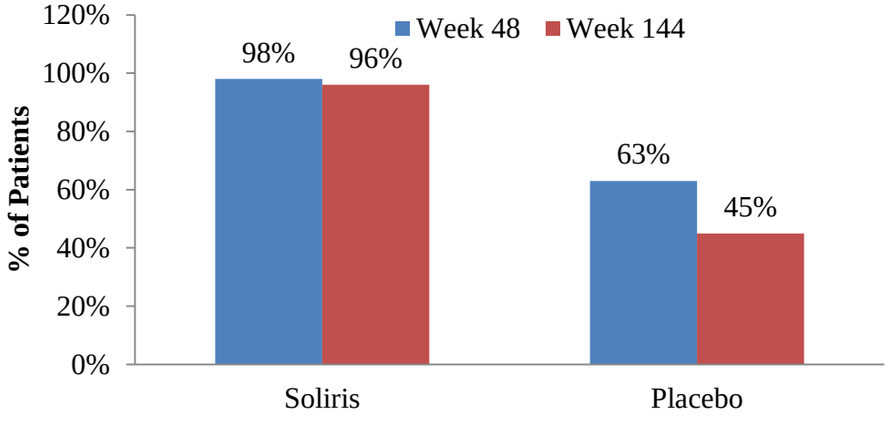
DRUGS: APPROVALS AND LAUNCHES

2. FDA approves Alexion's Soliris as first treatment for CNS disease NMOSD

The US Food and Drug Administration (FDA) has approved Alexion Pharmaceuticals' Soliris (eculizumab), a first-in-class complement inhibitor. The drug has been approved for patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

NMOSD is an autoimmune disease that attacks the central nervous system (CNS), and causes irreversible damage to the brain, optical nerve and spinal cord. Complement activation due to the anti-AQP4 antibodies is one of the underlying pathologies.

Soliris met the primary endpoints of a Phase III, randomized, double-blind, placebo controlled study of 143 patients, which led to its approval. The endpoint was prolonging time to first adjudicated relapse or attack and reducing the risk of relapse.



This approval changes the landscape of therapy for patients with NMOSD.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

3. Cipla arm InvaGen pharma gets USFDA nod for pregabalin

InvaGen Pharmaceuticals, a subsidiary of drug major Cipla has received final approval from the US FDA for Pregabalin Capsules. InvaGen has received approval for the drug for strengths- 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg.

Cipla said the approved product is a generic therapeutic equivalent version of Pfizer's Lyrica.

Pregabalin capsules are indicated for:

1. management of neuropathic pain associated with diabetic peripheral neuropathy
2. management of postherpetic neuralgia
3. adjunctive therapy for the treatment of partial onset seizures in patients ≥17 years of age
4. management of fibromyalgia
5. management of neuropathic pain associated with spinal cord injury.

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

4. Teva's AirDuo Digihaler inhalation powder to treat asthma approved by FDA

TEVA PHARMACEUTICALS LTD

Teva Pharmaceutical Industries Ltd. announced the US Food and Drug Administration (FDA) approval for AirDuo Digihaler (fluticasone propionate 113 mcg and salmeterol 14 mcg) inhalation powder.

It is a combination therapy digital inhaler with built-in sensors connected to a companion mobile application, which provides the information on inhaler use to people with asthma.

AirDuo Digihaler is indicated for the treatment of asthma in patients aged ≥12 years. AirDuo Digihaler is not used to relieve sudden breathing problems and won't replace a rescue inhaler.

The approval of AirDuo Digihaler is based on the review of the supplemental new drug application (sNDA) submitted by Teva to the FDA. AirDuo Digihaler was approved in a low, medium and high dose (55/14 µg, 113/14 µg and 232/14 µg) administered twice daily.

AirDuo Digihaler contains the same active ingredients as Advair Diskus, which is also approved in low, medium and high doses: 100/50 µg, 250/50 µg and 500/50 µg.

Source: pharmaceutical-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Takeda's subcutaneous vedolizumab meets primary goal in phase 3 study

Takeda Pharmaceutical has reported that the VISIBLE 2 clinical trial of a subcutaneous (SC) formulation of vedolizumab met its primary endpoint in adults with moderately to severely active Crohn's disease (CD).

Vedolizumab is a gut-selective biologic developed as a humanized monoclonal antibody. The IV formulation of the drug has approvals in more than 60 countries to treat moderately to severely active ulcerative colitis and CD in certain patients.

The phase 3 trial of the SC formulation was intended to assess the safety and efficacy of vedolizumab 108mg SC as maintenance therapy in patients who had a clinical response at week six after two doses of open label, 300mg intravenous (IV) vedolizumab at weeks 0 and 2.

Participants were given SC vedolizumab from 6-weeks for every two weeks up to week 50. Clinical remission was observed in a statistically significant proportion of subjects, compared to placebo, at week 52. Safety analysis showed that adverse events reported during the trial were consistent with the known profile of the IV formulation, without any new signals.

Source: drugdevelopment-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. HIV vaccine: how close are we?

The researchers from the OHSU's Vaccine & Gene Therapy Institute and OHSU School of Medicine's department for molecular microbiology and immunology have demonstrated a promising vaccine that clears HIV-like virus from monkeys and is closer to human testing.

The researchers published a pair of papers in *Science Translational Medicine* journal providing the methodology the vaccine is based on. It uses a form of the common herpes virus cytomegalovirus, or CMV, which is live-attenuated, or weakened so CMV couldn't spread as easily. The new version still managed to eliminate SIV, the monkey version of HIV, in 59% of vaccinated rhesus macaques; results similar to earlier findings with the vaccine's original, non-attenuated version. Furthermore, the new version generated a long-lasting immunity as nine of 12 vaccinated monkeys could still fight off SIV infection post three years.

Having an attenuated version of the vaccine is the key to potentially use it in humans. No vaccines use non-attenuated live viruses due to safety concerns.

In addition, this new work demonstrates that those rhesus macaques protected against SIV by the vaccination are also protected against a second challenge years later. This robustness is very important when looking at the development of a vaccine against human HIV.

Source: technologynetworks.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Sandoz begins ROSALIA phase 1/3 study for denosumab in osteoporosis

Sandoz, a Novartis division and a global leader in biosimilars, announced that the first patient was enrolled in ROSALIA, an integrated phase 1/3 clinical study for its proposed biosimilar denosumab. The objective of the study is to confirm that the biosimilar denosumab matches the innovator denosumab in terms of pharmacokinetics, efficacy, safety, and immunogenicity in patients with postmenopausal osteoporosis.

Denosumab is indicated for treating a variety of conditions, such as

1. osteoporosis in postmenopausal women
2. increased risk of fractures in men
3. treatment-induced bone loss
4. to prevent bone complications in cancer metastasized to the bone
5. giant cell tumor of the bone.

The ROSALIA study will be conducted in postmenopausal patients (~520) with osteoporosis. Patients will be randomized to receive either biosimilar denosumab or the innovator denosumab for 52 weeks. Post which, the patients receiving innovator denosumab will be re-randomized to continue with a third dose or will be transitioned to biosimilar denosumab, until 78 weeks of treatment. The primary endpoints of ROSALIA study is the percentage change in lumbar spine bone mineral density.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Researchers develop 'Trojan horse' chemo drug delivery system

The researchers at the Northwestern University have developed a new drug delivery system that can disguise chemotherapy drugs as fat. Thinking the drugs are tasty fats, tumors invite the drug inside. Once there, the targeted drug activates, immediately suppressing tumor growth.

The system is an engineered long-chain fatty acid with two binding sites on each end for the drugs, which is hidden inside human serum albumin (HSA). The body's cellular receptors recognize the fats and proteins supplied by the HSA, and allow the fatty acid to enter the tumor cells. Then the drug starts getting metabolized and kills the tumor cells.

The study was published in *Journal of the American Chemical Society* and was funded by Elevance Renewable Sciences.

Source: pharmaceutical-technology.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Amgen wins patent block on Sanofi drug rival

Amgen has won a lawsuit to uphold a patent blocking Sanofi from marketing its injected cholesterol drug in Germany.

The Regional Court ruled that Sanofi's Praluent (alirocumab) infringes Amgen's patent directed to antibodies targeting PCSK9, which protects their same-class rival Repatha (evolocumab).

Amgen had filed a patent infringement complaint in 2016 shortly after marketing approval of Repatha.

Source: europeanpharmaceuticalreview.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Natco pharma gets interim relief in BMS patents case

The Delhi high court has given interim relief to Hyderabad-based Natco Pharma Ltd in a fresh patents battle with Bristol-Myers Squibb (BMS). The Delhi high court set aside an injunction petition filed by BMS seeking to protect its anti-coagulant Apixaban against Natco's generic version 'Apigat', which was launched in June 219. Per BMS, its product was granted a patent in 2011 and has patent protection till September 2022.

BMS had filed its claims for patent infringement at the Delhi high court, asserting its patents, and had secured an injunction.

After appeal from Natco against the ruling and got the injunction lifted and the case was sent back to a single judge bench asking it to pass a fresh verdict.

Source: livemint.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Suit: generic pharma companies used code to fix price increases

According to a 510-page federal lawsuit filed in Connecticut, representatives of some of the major generic drug manufacturers used code words to conspire with competitors to divide the market share and coordinate price increases.

The lawsuit says the representatives used phrases like "playing nice in the sandbox" and "fluff pricing".

According to the Attorney General, the goal was to artificially inflate prices, hinder competition and restrain trade.

Source: medicalxpress.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Reckitt Benckiser to pay $1.4bn to settle over opioid treatment sales

The UK conglomerate Reckitt Benckiser, maker of Durex and Lysol, will pay $1.4bn (£1.1bn; €1.2bn) to resolve civil litigation and criminal investigations launched by the US government over its marketing of Suboxone, an opioid addiction treatment.

The payment of $1.4bn is a record payout in litigation stemming from the US opioid epidemic. Also, this is one of the biggest settlements ever paid by a pharmaceutical company to the US government.

Reckitt Benckiser will pay $1.15bn to the federal government and $200m to states whose programs covered patients receiving Suboxone.

Source: wsj.com

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TECHNOLOGY /NDDS

1. Low-cost retinal scanner could help prevent blindness globally

A low-cost, portable optical coherence tomography (OCT) scanner has been developed by the Biomedical engineers at Duke University. This OCT scanner facilitates vision-saving technology to underserved regions throughout the U.S. and abroad.

The redesigned, 3D-printed spectrometer, scanner is 15X lighter and smaller than current commercial systems and is made from parts costing <1/10th the retail price of commercial systems, without any compromise on imaging quality.

The design of the new scanner takes the light on a circular path within a housing, which is usually made from 3D-printed plastic. Due to the circular spectrometer light path, any changes in the expansion/contractions are done symmetrically, which maintains the alignment of optical elements.

The weight of new OCT device is 4 pounds, and is expected to be sold at <$15,000.

Source: visionmonday.com

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TECHNOLOGY /NDDS

2. Penumbra launched JET 7 with XTRA FLEX mechanical stroke remover

The Penumbra JET 7 Reperfusion Catheter with XTRA FLEX technology is the latest advancement in the Penumbra System JET – ENGINE family of products, which was launched last September. Penumbra is releasing a new stroke thrombectomy aspiration system.

The system will be launched at the Society of NeuroInterventional Surgery 16th Annual Meeting in Miami. Penumbra ENGINE generates the vacuum and helps pull out the thrombi from inside the brain. The Penumbra JET 7 Reperfusion Catheter developed form the XTRA FLEX technology is designed to be compatible with the Penumbra ENGINE. This technology is targeted to be used on the proximal large vessel occlusions. It has a relatively wide 0.072″ lumen.

Source: businesswire.com

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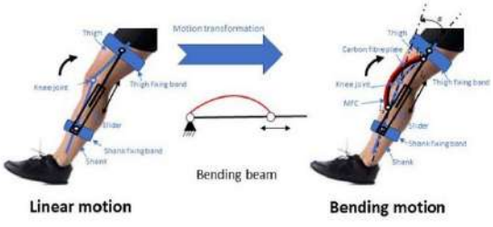
TECHNOLOGY /NDDS

3. Wearable device harvests energy for bending of the knee



Researchers from the Chinese University of Hong Kong have developed a device that can harvest energy from the human knee during walking, without a substantial increase in effort for wearers. The tests were performed in multiple users the power generation was measured with and without the device attached, which resulted from the walking speeds, consumption of oxygen and production of CO2.

The study results concluded that the new generator did not require additional effort by the wearer to produce electric power. The device which weighs <1 pound produces power which is just enough for GPS devices and health monitoring equipment.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. Human pancreas-on-a-chip identifies cause of cystic fibrosis

Scientists at the Cystic Fibrosis Research Center (Division of Pulmonary Medicine) have created a human pancreas on a chip that allows identification of the possible cause of a frequent and deadly complication of cystic fibrosis (CF) called CF-Related Diabetes, or CFRD.

Cystic fibrosis is a genetic lung disease caused by a mutation in the CFTR gene and the scientists want to evaluate if their device can help people with this disease. The study is published in the journal *Nature Communications*.

Next, the researchers will use the device in a pilot study to test Food and Drug (FDA)-approved drugs that modulate CFTR gene expression with an aim to determine how well different CFTR drugs can slow or reverse lab-simulated CFRD.

Source: technologynetworks.com

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