Lambda Research Newsletter

November 2017

Contact Us

Dr. Tausif Monif
President - Global operations
tausifmonif@lambda-cro.com

Dr. Mrinal Kammili
Ex. Director – Global Head, BD
mrinal@lambda-cro.com

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GLOBAL NEWS

1. Pharma and medtech industries prepare for hard Brexit

Drug makers and medical devices companies are preparing to protect the supply chain after crash out of Britain from the European Union (EU). According to the latest updates, some of the small service businessmen have already relocated to stay inside the bloc.

Brexit has fueled anxieties in the healthcare sector governed by the different complex regulatory agencies. Drug makers have already been affected from the European Medicines Agency's uproot from London.

Brexit also created various other big problems like potential need for retesting of UK-manufactured batches of medicines shipped to Europe and transfer of UK product licenses to European-based entities.

Britain has a very big pharmaceutical sector and medicinal products are also supplied to Europe and various other countries where shipments are governed by EU. This disorderly exit from EU in 2019 will affect the drug supplies in different countries governed by Britain.

Source: reuters.com

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GLOBAL NEWS

2. FDA approves Mvasi® as first biosimilar against cancer

The U.S. Food and Drug Administration (FDA) approved a very first biosimilar for the treatment of cancer. Mvasi (bevacizumab-awwb) is Amgen's first biosimilar of Avastin (bevacizumab) for the treatment of multiple types of cancers.

Bringing this new biosimilar to the market will provide a cost effect option for the treatment of cancer. The FDA approved Mvasi® for the treatment of adult patients with certain brain, colorectal, kidney, lung, and cervical cancers. Specifically, the approved indications include:

- Metastatic colorectal cancer, in combination with intravenous 5-fluorouracil-based chemotherapy as a first- or second-line treatment.
- Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrmidine-oxaliplatin-based chemotherapy as a second-line treatment.
- Non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel as a first line treatment.
- Glioblastoma with progressive disease following prior therapy, based on improvement in objective response rate.
- Metastatic renal cell carcinoma, in combination with interferon alfa.
- Cervical cancer that is persistent, recurrent, or metastatic, in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Mvasi® is not indicated for the adjuvant treatment of surgically resected colorectal cancer. This approval of FDA is based on the review of evidence that included extensive structural and functional characterization, preclinical trials data, and human pharmacokinetic and pharmacodynamics data.

Source: fda.gov

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GLOBAL NEWS

3. Dr. Reddy's recalls 500K heartburn tablets after FDA warning letter

Dr. Reddy's is still struggling with its manufactured products. Dr. Reddy's is recalling 569,000 store-brand famotidine tablets from the US market. This recall resulted after the failure of routine tests for impurities and degradation by the US Food and Drug Administration (FDA).

This medicine was sold at CVS pharmacies as CVS Pharmacy Acid Controller, and at Walmart. According to the FDA report, it was a Class 3 recall that means the drug was not likely to cause any injury to humans.

Dr. Reddy's also pulled 84,000 famotidine tablets produced for CVS last year, but now the company needs to pull the drug nationwide. In both the cases, company found an out-of-specification result during routine stability testing.

These ongoing manufacturing issues triggered a decline in the sales of Dr. Reddy's products in the US market.

Source: fiercepharma.com

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GLOBAL NEWS

4. Typbar-TCV could be the first typhoid vaccine for young children

Currently, no vaccine is available against typhoid for children younger than 2 years; a new vaccine by India's Bharat Biotech, Typbar-TCV could be the first vaccine for this age group. In a recent meeting, the World Health Organization's Strategic Advisory Group of Experts (SAGE) on Immunization recommended this capsular Vi-polysaccharide conjugate vaccine for infants and children over 6 months in typhoid endemic regions.

The decision of the expert panel was based on the basis of a Phase 2b trial conducted by the University of Oxford on 112 healthy adults, in UK, in 3 groups. In the trial, Typbar-TCV was compared with Sanofi's Typhim Vi and placebo.

Results of the Phase 2b trial are published in ***The Lancet***, which indicates that the vaccine halves the number of infections with the efficacy of the vaccine reaching upto 87% under different conditions. This vaccine could be given to children below two years of age providing long term immunity. This vaccine is already approved in India and the approval process is underway in several other countries.

So far only 2 types of typhoid vaccines have been approved by the World Health Organization (WHO). One is Sanofi's Typhim Vi and the other is GlaxoSmithKline's Typherix, but these vaccines could not be administered in children under 6 years of age.

Source: fiercepharma.com

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PHARMA INDIA

1. Intas launches new biosimilar for Bevacizumab in India with 60% less prices

Intas Pharmaceutical has launched the new biosimilar for Bevacizumab in India. Bevacizumab is an anticancer drug for the treatment of various types of cancer like colorectal cancer, lung cancer and cervical cancer. Bevacizumab can be used for the treatment of certain forms of brain tumors.

Currently, Bevacizumab is sold under the name Avastin® by Roche pharma. The price offered by Intas Pharmaceutical for 400mg is Rs 39,995, which is 60% lower as compared to the innovator company.

Bevacizumab is one of the blockbuster molecules of Roche Pharma with sales of $7 billion annually. But due to cost of the drug, it currently serves only 5% of the patients.

Intas will share the market of the drug with some other companies like Zydus Cadila, Hetero and Reliance Life sciences.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

2. Piperazine as a new treatment option for Chikungunya

The Scientists of IIT-Roorkee found that piperazine, which is a commonly used drug for deworming has anti-viral properties and could be effective for the treatment of Chikungunya.

According to the researchers, piperazine is effective in preventing the spreading and replication of Chikungunya virus in the lab. Currently, no treatment option is available for the treatment of Chikungunya. Available methods are only for reliving symptoms associated with the infection.

Currently, drug testing is in the pre-clinical phase and testing is ongoing in the animals. Researchers are planning to start clinical trials.

The study was published in the ***Journal of Antiviral Research,*** which explains the potential of the drug and mechanism of action. Piperazine binds to the hydrophobic pockets of capsid protein of Chikungunya virus and prevents spread of the virus.

Source: indiatoday.intoday.in

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PHARMA INDIA

3. Price cartelization of drugs in US resulted in lawsuit over 5 Indian companies

The state of Connecticut has filed a lawsuit against 5 Indian companies for price cartelization of drugs in the US. A list of 12 generic manufacturers were released which are alleged to be involved in the price cartelization of drugs; 5 are Indian companies.

These 5 companies include Zydus Cadila Pharmaceuticals, Sun Pharmaceuticals, Emcure Pharmaceuticals, Dr Reddy's Laboratories, and Glenmark Pharmaceuticals. These companies are sued by 45 states of US for fixing price on nearly 15 drugs.

This lawsuit has been initiated by the state of Connecticut. Some major companies such as Teva, Sandoz and Activis are also involved in the list of these 12 companies. This lawsuit also includes the name of some individuals like Rajiv Malik, President of Mylan, and Satish Mehta, MD of Emcure Pharma.

Multiple conspiracies are included in the lawsuit of these 45 states for restrained trade, artificially inflated prices and to maintained prices and reduced competition. According to the agencies, prices of the generics should be less than that of the innovator drug due to less developing cost and research.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

4. For marketing approval in India, global trials must include Indians

To ensure the safety and efficacy of drugs in the Indian patients, the Drugs Controller General of India (DCGI) has made it mandatory for the pharmaceutical companies to conduct clinical trials on the Indian population. This decision was taken by keeping public safety in mind.

The decision was taken in a technical committee meeting. In this meeting it was decide that if any company is intending to market its new drug in the Indian market which is being developed out of India; they have to include Indian patients for the clinical trial.

If the global clinical trial is already approved in any International Council for Harmonization (ICH) country like US, Europe and Japan, then the proposal will be reviewed by the Indian regulatory agency on priority without refereeing to any subject committee. For any specific reason which should be recorded in writing, this can be subjected to the committee.

This move will be beneficial for the Indian clinical research organisations and hospitals. These organisations are responsible for conducting clinical trials in humans.

Source: health.economictimes.indiatimes.com

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REGULATORY ROUND-UP

1. FDA releases new ICH Guidance for preparing CTD

The US Food and Drug Administration (FDA) introduced a new guidance which is a part of a series from the International Council of Harmonization (ICH) for preparing a Common Technical Document (CTD) for applications submitted to the FDA.

This common format for the document will reduce the time and resources required for registration. These recommendations provide:

- CTD and the electronic common technical document (eCTD) for Modules 2 through 5, along with the directions for hierarchy of headings, document pagination and segregation and formatting
- separate tables describing the recommended granularity for paper and eCTD v3.2.2 submissions, and for paper and eCTD v4 submissions

Guidelines are developed by M4Q CTD and M8 eCTD Implementation Working Groups of ICH and subject to consultation by the regulatory parties.

Source: raps.org

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REGULATORY ROUND-UP

2. FDA introduces product specific guidances for the development of generic drugs

For the successful development and manufacturing of generic drugs, the product of applicant should be pharmaceutically equivalent to its reference listed drug (RLD). The generic product should have the same active ingredient, strength, dosage form and route of administration as that of the RLD.

There should be no statiistical difference between the RLD and the generic's extent of absorption and should be therapeutically equivalent. The generic should have the same safety and efficacy as that of its RLD.

Different types of evidences can be used to establish bioequivalence of the pharmaceutical products as mentioned in 21 CFR 320.24. Bioequivalence of the drug can be explained by in vivo or in vitro testing, or both. Method of selection is based on the type of study.

To facilitate and to assist the generic drug makers, FDA has published few product specific guidances. These guidances show the expectations and development process of the products. These guidances are published in an incremental manner and listed in an alphabetic manner according to the RLD used.

Source: fda.gov

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REGULATORY ROUND-UP

3. EMA draft guidelines for RSV treatment options

The European Medicines Agency (EMA) introduces its new guidelines for the treatment of respiratory syncytial virus (RSV). These guidelines will help pharmaceutical companies to develop new medicines, direct-acting antiviral agents, monoclonal antibodies and vaccines for the treatment of RSV.

RSV is a common respiratory virus that causes mild, cold-like symptoms. RSV can be serious in infants and older adults. Currently, no specific treatment option is available for the treatment of RSV, only several medications are under development.

Draft guidelines of EMA focus on the assessment of safety and efficacy of different vaccines and medications. These guidelines also mention the criteria for the treatment of RSV in newborns, infants and older children. A part of the guideline also mentions the use of vaccines in pregnant women.

The remaining sections describe the study design and methods to assess the efficacy of the vaccines in different scenarios, and selections of appropriate dose regimens of the medicines. This draft also provides the considerations on non-clinical investigations for efficacy and safety.

Source: raps.org

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REGULATORY ROUND-UP

4. FDA releases new guidances for drug developers on drug-drug interactions

The US Food and Drug Administration (FDA) released two new draft guidances for the drug developers to investigate new drug's potential for drug-drug interactions (DDIs). These new guidances by FDA will replace the draft guidances of 2012. FDA has designed DDI studies to provide meaningful information for the management of risks in the patients taking more than one medicine.

These new guidances of FDA reflect the current thinking of FDA and will also help to align with other International regulatory agencies, mainly with the European Medicines Agency and Japan's Pharmaceutical and Medical Devices Agency.

Clinical Drug Interaction Studies
This is a 32 page draft guidance document for the recommendations on timing of clinical DDI studies, design and conduct of these studies.
The draft guidance says "After conducting in vitro drug metabolism and drug transporter studies, sponsors should determine the need for and timing of clinical DDI studies with respect to other studies in their clinical development program."

In Vitro Metabolism- and Transporter-Mediated DDI Studies
This is a 47 page draft guidance document focused on the *in vitro* approaches of investigating interaction potential. The draft explains the metabolism-mediated drug interactions, transporter-mediated drug interactions, DDI potential of metabolites and labeling recommendations.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. AbbVie collaborates with Bristol-Myers Squibb to evaluate therapeutic regimen in advanced solid tumors

AbbVie collaborates with Bristol-Myers Squibb to conduct clinical trials for the evaluation of a new investigational antibody drug conjugate ABBV-399 and Opdivo (nivolumab) for the treatment of c-Met overexpressing non-small cell lung cancer (NSCLC).

Currently, Phase 1b study for the evaluation of the potential of combination is underway. In the trial, Opdivo, which is designed to alleviate immune suppression, will be combined with ABBV-399.

Clinical trials will be conducted to determine the tolerability and potential efficacy of the combination for the treatment of advanced c-Met overexpressing NSCLC patients who failed one prior line of chemotherapy.

Opdivo is Bristol-Myers Squibb's immunotherapy molecule, which acts as a programmed death-1 (PD-1) immune checkpoint inhibitor. Opdivo is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response.

Source: worldpharmanews.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Johnson & Johnson collaborates with the U.S. Department of Health and Human Services to develop vaccine against influenza

Janssen Research & Development LLC (Janssen) and the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) collaborate to develop a new influenza vaccine.

This collaboration will bring together the scientific capabilities of Janssen with the world-class expertise of Biomedical Advanced Research and Development Authority (BARDA), a component of ASPR.

This agreement is created under the U.S. Government's Other Transaction Authority (OTA), Janssen and BARDA. Under this agreement, all the agencies will invest equally to help Janssen for the investigation of influenza medicines and vaccines.

Assets of Janssen include JNJ-5806 (formerly AL-794) which is a potent inhibitor of influenza A and B viruses including strains. This molecule aims to protect against all influenza strains.

Source: worldpharmanews.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Alembic Pharma acquires Orit Laboratories LLC

Alembic Pharmaceuticals has completed the acquisition of the US based generic drug developer Orit Laboratories LLC. This acquisition also includes the real estates owned by Okner Realty LLC. Proximare Inc. acted as a strategic advisor for Orit and Okner. Financial details for the transaction were not disclosed.

After this acquisition, Alembic Pharmaceuticals will have a total of 69 ANDA approvals from the US Food and Drug Administration (FDA).

Currently, Orbit has 7 approved ANDAs with 4 ANDAs pending approval. Orbit is mainly focused on the development and filing oral solid and liquid products. This acquisition will be the first cross border transaction of Alembic Pharma.

Source: pharmabiz.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Lupin acquires Symbiomix Therapeutics for $150 million

Lupin has acquired an US based women's health company, Symbiomix Therapeutics, for $150 million. Under this deal, Lupin will pay an upfront amount of $50 million to Symbiomix Therapeutics, and the rest in next five years.

Symbiomix Therapeutics is mainly focused on developing drugs for women healthcare. The US drug regulator had recently approved the lead compound of Symbiomix Therapeutics, Solosec® (secnidazole) oral granules for the treatment of bacterial vaginosis (BV). This product will help Lupin to strengthen its women health business.

Solosec® is the first and only oral treatment option approved for BV and expected to enter the market in 2018. This acquisition is in line with Lupin's product Methergine.

Source: businesstoday.in

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DRUGS: APPROVALS AND LAUNCHES

1. EC approves Xermelo® for the treatment of carcinoid syndrome diarrhea

IPSEN
Innovation for patient care

Ipsen pharmaceutical gets the European Commission's (EC) approval for Xermelo® (telotristat ethyl) 250 mg three times a day (t.i.d) for the treatment of carcinoid syndrome diarrhea. The drug is approved in combination with somatostatin analogue (SSA) therapy.

This approval allows Ipsen to market the Xermelo® in all 28 countries of European Union. Approval of the drug is based on the results of 2 randomized Phase 3 trials, TELESTAR and TELECAST.

TELESTAR trial was a 12-week double-blind, placebo-controlled, randomized, multicenter Phase 3 Pivotal Trial to show the efficacy and safety of telotristat ethyl 250 mg t.i.d. The primary end point of the study was to measure the mean change in bowel movements (BM), which was found to be -0.81 for telotristat ethyl 250mg ($p<0.001$) against placebo.

TELECAST was similar to TELESTAR trial conducted in patients with carcinoid syndrome. The percent change from baseline in u5-HIAA excretion at Week 12 was +97.7% in the placebo group versus -33.2% in the telotristat ethyl 250 mg t.i.d group.

Source: regulatoryaffairs.pharmaceutical-business-review.com

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DRUGS: APPROVALS AND LAUNCHES

2. EC approves Gazyvaro® of Roche for the treatment of advanced follicular lymphoma

The European Commission (EC) has approved Roche Pharma's Gazyvaro® (obinutuzumab) in combination with chemotherapy for the treatment of advanced follicular lymphoma. Gazyvaro® is an engineered monoclonal antibody designed to attack and destroy targeted B-cells.

Gazyvaro® attaches to CD20 protein present on certain B cells not on stem cells or plasma cells, and destroy targeted B-cells directly or along with the body's immune system.

The approval was given on the basis of Phase 3 Gallium study. In this study, Gazyvaro® showed progression-free survival (PFS) over MabThera® (rituximab). This Phase 3 study demonstrated that Gazyvaro® is effective in decreasing the risk of disease progression or death.

Primary end point of the study was to check PFS in the patients of follicular lymphoma, whereas the secondary end point was to access PFS assessed by PFS in the overall study population, response rate, overall survival, and safety.

Source: regulatoryaffairs.pharmaceutical-business-review.com

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DRUGS: APPROVALS AND LAUNCHES

3. Janssen's Symtuza® receives approval from EC for the treatment of HIV-1

The European Commission (EC) has approved Janssen's HIV-1 treatment drug Symtuza®. Symtuza® is a once daily darunavir-based single-tablet regimen (STR). Symtuza® once daily is indicated for the treatment of HIV-1 in adults and adolescents aged 12 andolder with a body weight of at least 40 kg.

Symtuza® is a fixed dose combination (FDC) of darunavir, cobicistat, emtricitabine and tenofovir alafenamide (D/C/F/TAF). This FDC is a combination of already approved drugs.

Approval of the drug was based on the results from a bioequivalence study, which compared Symtuza® with the combined administration of the separate agents; darunavir at 800mg, cobicistat at 150mg and emtricitabine / tenofovir alafenamide (FTC / TAF) at a 200 mg/10 mg fixed-dose combination.

This study indicated that once-daily STR is bioequivalent to the combined administration of the separate agents and is well tolerated as that of the monotherapy.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

4. Mylan receives US FDA approval for generic glatiramer acetate

The US Food and Drug Administration has approved the generic version of Mylan's Copaxone® (glatiramer acetate) for the treatment of multiple sclerosis (MS).

The US FDA has approved the injections of Copaxone® in 2 different versions for the treatment of MS relapse:
- 40 mg/mL three-times-a-week
- 20 mg/mL once-daily

Mylan has invested an amount of $10 million over many years to bring this medicine into the market. Mylan is also offering a patient support programme, which will focus on access to the therapy and adherence to the regimen.

Mylan's Abbreviated New Drug Application (ANDA) includes the data which demonstrated that Copaxone® has the same active ingredient, dosage form, route of administration and strength as that of the innovator drug.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Novartis's Xolair® shows effectiveness even after 12 weeks treatment interruption

Novartis announces the latest results of the Optima trial of Xolair® (omalizumab) including patients with chronic spontaneous urticaria (CSU). During the trial, 90% of the patients showed positive results for Xolair® after the interruption of treatment.

Findings of the trial were presented at the 26th European Academy of Dermatology and Venereology (EADV) Congress in Geneva, Switzerland.

CSU is a distressing skin condition which appears spontaneously with persistent hives and painful deep swelling of the skin for ≥6 weeks. Xolair® is the first approved therapy for the treatment of CSU patients, who cannot be treated with H1 antihistamine.

In Optima trial, 314 patients of CSU were treated with Xolair® 150 mg or 300 mg in which H1 antihistamines were not effective. The patients who responded well to the initial treatment underwent a pause. If symptoms reappeared, the patients were retreated and complete control was achieved in 90% of the patients within 3 months of the treatment.

Source: pharmpro.com

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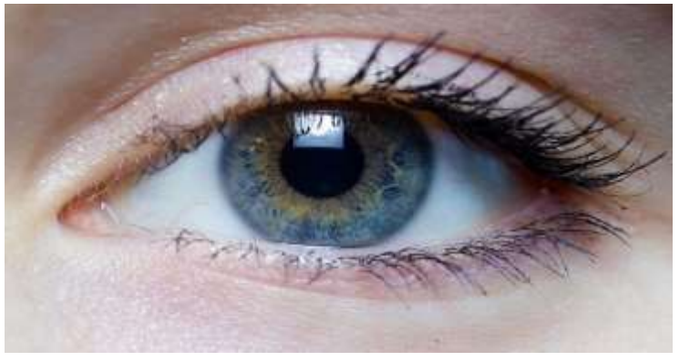
DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. New drug of Apellis Pharmaceuticals to prevent progression of dry AMD



Researchers from the Centre for Eye Research Australia (CERA) have developed a new compound APL-2 to slow down the progression of dry age-related macular degeneration (AMD) or geographic atrophy (GA). The study is sponsored by Apellis Pharmaceuticals.

Dry AMD is an eye disease associated with the death of retinal cells slowly over many years resulting in irreversible vision loss. A Phase 2 trial was conducted on 246 patients across 40 sites in the world.

In this Phase 2 trial, an injection of APL-2 given either monthly or every other month for 12 months resulted in the reduction of lesion growth of 29% and 20%, respectively.

Greater effect was noticed in another six month study in which a reduction of 33% with every other month administration was noticed. Based on these positive results, Apellis plans to proceed with Phase 3 studies.

Source: medicalxpress.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Anti-diabetic drug to act as an anti-obesity drug

Danish pharmaceutical company Novo Nordisk has developed a new anti-diabetic drug Semaglutide, which can be used as an anti-obesity drug. Semaglutide is chemically very similar to GLP-1 hormone, which acts on the appetite control system in the hypothalamus of the brain and reduces hunger and food cravings.

The research has been published in the journal ***Diabetes, Obesity and Metabolism***. According to this research, the drug which targets the appetite control system can bring out significant weight loss.

In the trial, Semaglutide was given to 28 people for 12 weeks with a body mass index (BMI) range of 30 to 45 kg/m^2. During the study, researchers noticed that the amount of food consumption was 24% lower with Semaglutide.

The complete trial was conducted by the University of Leeds and funded by Novo Nordisk.

Source: leeds.ac.uk

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. BTSA1 kills cancer cells without harming healthy cells

Scientists from the Albert Einstein College of Medicine have developed a small molecule BAX Trigger Site Activator 1 (BTSA1) that directly triggers suicide in the cancer cells without harming healthy cells.

The complete research was published in the journal ***Cancer Cell***. The published study shows how BTSA1 acts on acute myeloid leukemia (AML) cells.

In the study, researchers show that BTSA1 promptly induces apoptosis in AML cells resulting in suicide of cancer cells. BTSA1 acts on executioner protein in cells known as BAX. When the molecule gets activated, BAX proteins fight with the mitochondria of the cancerous cells and result in holes in the cancerous cell which leads to cell death.

Researchers explain that when BTSA1 was tested on blood samples of high risk patients, the molecule triggered apoptosis in AML cell without any effect on the healthy cells. At present, the molecule is tested on the animal model only and shows no signs of toxicity in the healthy tissues.

Source: medicalnewstoday.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. CEL-SCI receives European Patent for Multikine for the treatment of head and neck cancer

CEL-SCI Corporation has received the European patent from the European Patent Office for their new lead investigational immunotherapy agent Multikine (leukocyte interleukin, Injection) for the treatment of head and neck cancer. The product is currently under development in a Phase 3 pivotal trial for head and neck cancer.

The patent is entitled as “A Method for Modulating HLA Class II Tumor Cell Surface Expression with a Cytokine Mixture”.

This patent addresses the mechanism of action of the molecule to make tumors more visible to immune system. Multikine enable the immune system to recognize and attack tumor cell by complete this.

Source: biospace.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Patrys Limited receives United States Patent for PAT-LM1 for cancer treatment

Patrys Limited has received the United States Patent for its anti-cancer pre-clinical candidate PAT-LM1.

The patent is entitled as “LM-1 antibodies, functional fragments, LM-1 target antigen, and methods for making and using same”. This patent is granted for the use of PAT-LM1 in the treatment of colon cancer metastasis.

Currently, eight patents are granted for the PAT-LM1 families in three different countries including the United States, Europe and the United Kingdom. Application of Patrys for Europe is pending.

Patrys has an ongoing program for the out-licensing of PAT-LM1 and granting this patent strengthens the IP portfolio for business development.

Source: biospace.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. GB Sciences Inc. receives global patent for nanotechnology based formulation to relieve neuropathic pain

GB Sciences Inc. has received a global worldwide intellectual property license for their innovative solution based on nanotechnology for neuropathic pain. This formulation is developed and patented by the researchers of the University of Cadiz and the Mental Health Networking Biomedical Research Centre.

This research has shown that this formulation of cannabinoid shows controlled liberation of the drug and provides neuropathic pain relief in rats for a period of eleven days after oral administration of a single dose. A part of the research was published in ***Nanomedicine: Nanotechnology, Biology and Medicine***.

Under this agreement, researchers will work along with the company to innovate formulations based on polymer nanoparticles with active ingredients developed by GB sciences for the treatment of chronic pain.

In this novel formulation, researchers used nanoparticles to capsule the main active ingredient in a polymer matrix composite.

Source: news-medical.net

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Soleno Therapeutics receives US patent for DCCR for the treatment of hyperphagia in PWS

Soleno Therapeutics, Inc. has received a new patent from the U.S. Patent and Trademark Office for the use of pharmaceutical formulations of diazoxide. This diazoxide formulation can be used for the treatment of hyperphagia in patients suffering with Prader-Willi syndrome (PWS).

This patent covers the use of Diazoxide Choline Controlled Release Tablet (DCCR) for the treatment of hyperphagia which is considered as highest priority unmet needs in PWS.

Soleno is expected to start its Phase 3 trial for DCCR by the end of 2017. The study is expected to take 9-12 months for the completion.

DCCR is a novel controlled release formulation of diazoxide, administered once daily. Diazoxide oral suspension has been used for decades for few rare diseases.

Source: biospace.com

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Clinical Research NEWS letter
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TECHNOLOGY /NDDS

1. A surgical glue that can seal wounds in 60 seconds

Researchers of Harvard Medical School have developed an elastic, adhesive surgical glue which could seal wounds in the skin or in the organs without any staples or sutures. This gel is prepared from methacryloyl-substituted tropoelastin, which is a hybrid elastic protein.

The gel can be squirted onto internal and external wounds resulting in sealing of wounds and encourage healing. Currently trials are limited to animals and researchers are planning to start human trials.

This gel works on a simple mechanism that when this formulation comes in contact with tissue surfaces it solidifies into a gel like compound without running away. This formulation can heal wounds in half the time as compared to stitches or staples.

Recent results are from the trail conducted on rodents and research was published in the ***Journal of Science Translational Medicine***. Clinical trials are not yet started.

Source: sciencealert.com

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2. 'Body-on-a-chip' system for the testing of new drugs

Researchers from the Wake Forest Institute for Regenerative Medicine have developed engineered micro hearts, lungs and livers which can be used for the testing of new drugs.

According to researchers, by combining these micro-organs in a monitor system they can mimic the human body response for the medications. This chip is designed to reduce the burden of pharmaceutical companies during the development of new drugs.

The complete report was published in the Scientific Reports, published by ***Nature***.

The organ structures were prepared from the cell types found in human tissues by using 3D printing or various other methods. Heart and liver were selected for the system as the toxicity of these organs is the major reason behind recall of drugs.

The complete organoid system is placed in sealed monitor systems with nutrient filled liquid to keep organoid alive and to introduce drug into the system.

Source: phys.org

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3. Light activated nanoparticles to reduce antibiotic resistance

Researchers from the University of Colorado Boulder showed that light activated nanoparticles can boost the effectiveness of antibiotic treatments used to counter drug-resistant superbugs. These light activated nanoparticles are termed as quantum dots.

Researchers have re-potentiated the existing antibiotics for certain isolated infections by introducing quantum dots. These quantum dots can be deployed selectively and can be activated or deactivated at different specific wave lengths of light.

These quantum dots do not attack infecting bacteria directly, as they release superoxide, which interferes with the bacterial metabolism and cellular processes.

The findings were published in the journal ***Science Advances***. The research shows that dots can reduce the resistance of effective antibiotics without producing any adverse side effects.

Source: news-medical.net

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4. IPC launches mobile app for ADR reporting in India

The Indian Pharmacopoeia Commission (IPC), the National Co-ordinating Centre (NCC) for Pharmacovigilance Programme of India (PvPI) has introduced a new mobile app for Adverse Drugs Reaction (ADR) reporting in India. This app will help healthcare professionals and patients in ADR reporting.

This mobile app is named as “ADR PvPI” android app. This app is available online for the stakeholders. As this app is developed by keeping in mind about healthcare professionals and patients, concerned persons can upload ADR and lab reports in the app in a user-friendly manner.

ADR PvPI app is developed to have administrative control of data with IPC and NCC-PvPI. The persons are trained for the Pharmacovigilance (PV) monitoring and are placed in the various institutes across India.

Source: pharmabiz.com

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