

Lambda Research Newsletter

October 2020



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▶ GLOBAL NEWS

1. New candidate to treat inflammatory diseases



The researchers at the Christian Gruber at MedUni Vienna's Institute of Pharmacology has isolated a peptide (small protein molecule) from beetroot.

The peptide has inhibitory action on a particular enzyme prolyl oligopeptidase that is responsible for the breakdown of messenger molecules in the body. According to the particularly stable molecular structure and pharmacological properties the beetroot peptide may be a good candidate for development of a drug to treat certain inflammatory diseases, such as e.g. neurodegenerative and autoimmune diseases.

In future studies, this group of plant peptides called 'knottins', such as those found in beetroot could be potentially provide a drug candidate for treating these diseases.

Source: medicaldialogues.in



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2. Researchers solve mystery to treat neurological and blood pressure disorders

The researchers from the Swedish Defense Research Agency (FOI) and Umeå University have resolved 50-year-old mystery of potential consequences for treating neurological conditions and blood pressure disorders.

The cholinergic system is vital in all humans and animals, the function of the cholinergic system is to transport signals between the brain and various parts of the body, such as muscles.

The researchers have now instead focused on substances and mechanisms that restrict signaling at the source, the enzyme choline acetyltransferase, abbreviated ChAT. According their study, they hope to develop drugs that can temporarily block ChAT and thereby reduce nerve signaling in patients poisoned by nerve agents.

The researchers have described how ChAT manufactures its own inhibitor from the body's own substance coenzyme A and a group of chemicals called arylvinylpyridines.

Already from 60's it was discovered that arylvinylpyridinines affect ChAT but still we did not understand the mechanism and have not succeeded in further developing these into drugs.

The mechanism discovered is very unusual it is the first time it has been described in the research literature.

Source: news-medical.net



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3. Nanobodies effectively neutralize SARS-CoV-2 in cells



Single-domain antibodies known as nanobodies can be produced in bacteria or yeast and their stability gives the potential for aerosol delivery.

In two separate studies, Michael Schoof et al. and Yufei Xiang et al. has described in his studies the identification of nanobodies that efficiently neutralize SARS-CoV-2. Monoclonal antibodies that bind tightly to the SARS-CoV-2 spike protein and efficiently neutralize SARS-CoV-2 in cells, these show promise but must be produced in mammalian cells and need to be delivered intravenously.

Michael Schoof et al, nanobodies provide a unique potential prophylactic and therapeutic strategy to limit the continued toll of the COVID-19 pandemic.

Source: news-medical.net



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4. Researchers identify new therapeutic targets for Alzheimer's disease

The researchers at the Hong Kong University of Science and Technology (HKUST) have identified new therapeutic targets in endothelial cells and microglia for Alzheimer's disease (AD).

Accordingly to the team, the increased angiogenesis (the formation of new blood vessels from current ones) and immune system activation in a subpopulation of endothelial cells are associated with the pathogenesis of AD,

The researchers also identified novel targets for restoring neural homeostasis in AD patients. The team has also used their single-cell transcriptome analysis to study the mechanism by which the cytokine interleukin-33 (IL-33), an important protein for immune signaling, exerts beneficial actions, making it a possible AD therapeutic intervention.

The researchers found that IL-33 reduces AD-like pathology by stimulating the development of a specific subtype of microglia that helps clear amyloid-beta, a neurotoxic protein found in AD brains.

The team is also the first to capture data on the mechanisms by which microglia transform into an amyloid-beta-consuming phagocytic state, which is a major cellular mechanism for the removal of pathogens.

Source: science.ust.hk



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► PHARMA INDIA

1. Clinical trial for sputnik V vaccine in India



Dr Reddy's Laboratories Ltd and Russian Direct Investment Fund (RDIF) have received approval from the Drug Control General of India (DCGI) to conduct phase II and III clinical trial for Sputnik V vaccine in India. This will be a multicenter and randomized controlled study to evaluate safety and immunogenicity.

Sputnik V vaccine has developed by the Gamaleya National Research Institute of Epidemiology and Microbiology was registered by the Ministry of Health of Russia and became the world's first registered vaccine against COVID-19 based on the human adenoviral vectors platform.

Currently, Sputnik V is ongoing phase III clinical trial in Russia and the proposed number of subjects is 40,000.

In begging of the September 2020, Dr Reddy's and RDIF has collaborated to conduct clinical trials of Sputnik V vaccine and its distribution in India.

Source: pharmabiz.com



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► PHARMA INDIA

2. Gynecologic cancers are the most common in India



Cervical and ovarian cancers are the second most common gynecologic cancers in India. Gynecologic oncology is a specialized field of medicine that focuses on cancers of the female reproductive system consisting ovarian cancer, uterine cancer, vaginal cancer, cervical cancer, and vulvar cancer.

Some preventive action can be taken to keep away gynecologic cancers includes:

- Lifestyle modification
- Regular screening with pap smear once in every 3 years,
- HPV testing for cervical cancers once in every 5 years,
- Vaccination for cervical cancer to the girls between the age of 9 to 11 years but can be given anytime up to the age of 26 years
- Avoiding nulliparity to prevent endometrial cancers.

Now a days, there are several advances in the field of gynecologic oncology consisting surgery, chemotherapy or radiotherapy. These have changed the outcomes of women suffering from gynecologic cancers.

Women themselves are unaware of the early signs and symptoms or at times feel embarrassed to consult a doctor. This needs to be overcome and a more positive message of awareness should be shared in public for prevention, screening, treatment and care of gynecological cancers.

Source: pharmabiz.com



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▶ PHARMA INDIA

3. India develops OralScan handheld device for detecting oral cancer



Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST) Thiruvananthapuram has developed OralScan hand held imaging device for screening, detection and biopsy guidance of oral cancer.

OralScan is a Make-in-India funding from the scheme National Initiative for Developing and Harnessing Innovations (NIDHI) of Department of Science and Technology (DST).



It was designed and developed entirely in India and supported by the biotechnology ignition grant of Biotechnology Industry Research Assistance Council (BIRAC), INVENT (DST), and Kerala Start-Up Mission.

Kerala government plans to registry of cancer patients in the state as part of efforts to arrange its various initiatives against the disease.

In India oral cancer is a growing concern with more than 80,000 fresh cases reported each year. The disease has a high mortality rate because of the delay in detection.

OralScan will be marketed at a price of Rs. 5.9 lakhs, and it is onetime investment for hospitals and laboratories without any additional costs.

Source: indiatimes.com



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▶ PHARMA INDIA

4. ART: right diagnosis and treatment is a huge challenge in India

The assisted reproductive technology (ART) is hope to millions of people and Indians are rapidly adopting the treatments to fulfill their dreams of childbirth.

In India, the access of right diagnosis and treatment is a huge challenge. With the advancement of fertility treatment across the world, most conditions relating to infertility are curable.

According to the World Health Organization data, globally 48 million couples and 186 million individuals are infertile. The UN health body defines 'infertility' as a disease of male or female reproductive system defined by the failure to achieve pregnancy after 12 months.

Now a days, through ART, female and male infertility has become treatable. ART includes many procedures; the most prominent methods include:

- In Vitro Fertilisation (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Cryopreservation of gametes (egg or sperm) or embryos
- Preimplantation Genetic Testing (PGT)
- Gamete Intrafallopian Transfer (GIFT)
- Zygote Intrafallopian Transfer (ZIFT)
- Others

Source: pharmabiz.com



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▶ REGULATORY ROUND-UP

1. EMA guidance on scientific advice and protocol assistance



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency (EMA) has released guideline to address number of questions for users of the scientific advice or protocol assistance procedures.

The guidance provides an overview of the procedure related to scientific advice or protocol to applicants when preparing their requests. It also explains the scope and nature of scientific advice and protocol assistance.

It will enable Applicants to submit requests which are in line with Scientific Advice Working Party (SAWP) requirements, allowing efficient validation and evaluation.

The guidance also describes different steps of the procedure on the preparation of discussion meeting with the SAWP. EMA has also announced that drug developers will have to use the IRIS Regulatory & Scientific Information Management Platform to request scientific advice.

Source: regulis.com



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▶ REGULATORY ROUND-UP

2. UK MHRA to join the ACSS Consortium



Pharmaceutical companies that submit applications to some countries will benefit from having their products evaluated for marketing in those countries simultaneously with reduced evaluation times. Drug developers have worried about the potential effect of Brexit on patient access to new and critical medicines.



In response, the Medicines and Healthcare products Regulatory Agency have joined the Australia-Canada-Singapore-Switzerland (ACSS) regulatory consortium which will be rebranded to ACCESS.

The UK population is the involvement of MHRA will significantly increase the market accessible via the consortium. When the MHRA joins, ACCESS will cover a population of 145 million people.

ACCESS partners will work together and aligning high standards of scientific rigor and integrity with reduced regulatory duplication. The MHRA will become a full ACCESS member at the end of the transition period on 01st January 2021.

Source: regulis.com



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▶ REGULATORY ROUND-UP

3. IRIS platform for EMA



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Drug developers will have to use the European Medicines Agency's (EMA) IRIS Regulatory & Scientific Information Management Platform to request scientific advice from 19th October 2020. Drug developer can ask for scientific guideline from EMA regarding to the methods and study designs.

The IRIS platform is handling of product-related regulatory procedures more efficient and user-friendly and to ensure better data quality through integration with other EMA systems.

Currently, IRIS is used to apply for orphan designation, notification of parallel distribution, briefing meetings with EMA's Innovation Task Force, and to request Research Product Identifiers for new medicinal products.

EMA's move to the IRIS platform for scientific advice requests is part of their larger digital transformation movement.

Source: regulis.com



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▶ REGULATORY ROUND-UP

4. Latest updates to the MHRA transition period guidances



The Medicines and Healthcare products Regulatory Agency (MHRA) has published further guideline.

The following updated guidance on medical devices includes new information surrounding Northern Ireland

- Sourcing medicines for the Great Britain market from an approved country for import or Northern Ireland from 1st Jan 2021
- Importing investigational medicinal products into Great Britain from approved countries from 1st Jan 2021
- Acting as an Responsible Person from 1st Jan 2021
- Supplying medicines to Northern Ireland from 1st Jan 2021
- Importing a human medicine
- Procedures for UK Paediatric Investigation Plan (PIPs) from 1st Jan 2021

Further guidance and updates from the MHRA is planned over the coming weeks.

Source: regulis.com



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➤ MERGERS / ACQUISITIONS / COLLABORATIONS

1. Sanofi to buy Kiadis



SANOFI

Sanofi has entered agreement deal to buy Kiadis, for developing innovative 'off the shelf' natural killer (NK) cell based medicines to treat life-threatening diseases.

NK cells seek and identify malignant cancer cells and have broad application across various tumor types.



Kiadis-NK cell technology platform will have broad application against liquid and solid tumors that create synergies with Sanofi's emerging immuno-oncology pipeline, providing opportunities for pursue potential best-in-disease approaches.

Sanofi had also Kiadis' K-NK004 preclinical programme license for multiple myeloma before this deal and now also gains access to the firm's K-NK002.

According to the agreement, Sanofi will make a public offer to buy the entire share capital of Kiadis for 5.45 euros per share and representing an equity value of 308 million euros (subject to customary conditions).

Source: pharmatimes.com



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➤ MERGERS / ACQUISITIONS / COLLABORATIONS

2. Oxford BioDynamics partnership with Boca Biolistics



OXFORD BIODYNAMICS

Oxford BioDynamics enters strategic partnership with Boca Biolistics. According to the agreement, Oxford BioDynamics will receive blood samples from COVID-19 patients with clinical information on disease severity.

The samples will be support product development of Oxford BioDynamics' EpiSwitch prognostic immune-response test. Oxford BioDynamics requires the major samples as possible depicting the broadest possible range of severity levels expressed in COVID-19 patients. Boca Biolistics will procuring samples for Oxford BioDynamics from the US and the Caribbean.



BOCA BIOLISTICS
Reference Laboratory

Oxford BioDynamics is to develop a disease severity test using its EpiSwitch technology. Using this 3D structure of genomic, which contains more than one million molecular regulatory data point.

Source: pharmaTimes.com



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► MERGERS / ACQUISITIONS / COLLABORATIONS

3. Sanofi collaborated with MSD



Sanofi has collaborated with MSD to conduct phase II clinical trial for evaluating the safety, pharmacokinetics and preliminary efficacy of THOR-707 combined with or in sequenced administration with MSD's Keytruda (pembrolizumab) in patients with various cancers.



THOR-707 is an IL-2 therapeutic designed for the treatment of malignancies and could demonstrate improved pharmacology to allow for less frequent dosing.

Sanofi has already evaluated phase I trial to evaluate the safety and tolerability of the drug. It recommended phase II dose alone and in combination with anti-PD-1 and anti-EGFR antibodies.

This collaboration can increase and expand the effectiveness of KEYTRUDA and improve the outcomes for patients with cancer.

Source: pharmatimes.com



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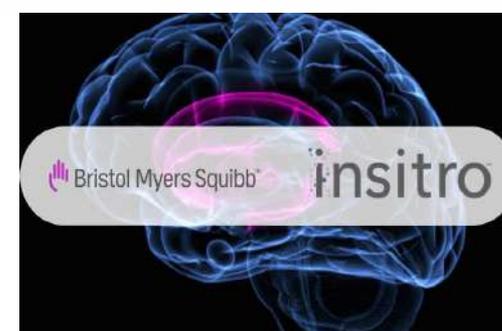
► MERGERS / ACQUISITIONS / COLLABORATIONS

4. BMS joined with insitro to develop drugs for ALS



Bristol Myers Squibb has signed agreement with machine learning specialist insitro for development of drugs for amyotrophic lateral sclerosis (ALS) and frontotemporal dementia.

Insitro is a novel platform to develop induced pluripotent stem cell-(iPSC) derived disease models for ALS and frontotemporal dementia. This platform applies on machine learning, human genetic and functional genomics to generate and optimise predictive in vitro models and aid therapeutic discovery and development.



BMS will be able to select a number of targets to advance through clinical development and will also be responsible for regulatory submissions and eventual commercial activities.

According to the agreement, Insitro will receive an upfront payment by BMS of \$50m and also insitro eligible to receive a further \$20m in near-term operational milestones, as well as over \$2bn in further milestones and sales royalties.

Source: pharmatimes.com



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▶ DRUGS: APPROVALS AND LAUNCHES

1. Lynparza received two new EU approvals



AstraZeneca and MSD's immunotherapy Lynparza (olaparib) has received two new approvals in the European Union. The first approval is for the first-line maintenance treatment with bevacizumab in patients with HRD-positive advanced ovarian cancer.



The European Commission approval is based on results from the PAOLA-1 phase III trial. In which Lynparza added to bevacizumab improved the median time patients live without disease progression by more than three years compared to bevacizumab alone.

In which Lynparza more than tripled median radiographic progression-free survival (rPFS) versus enzalutamide or abiraterone and 78% reduced the risk of disease progression or death.

The median overall survival was 20.1 months versus 14.4 months for mCRPC patients with BRCA 1/2 mutations.

Source: pharmatimes.com



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▶ DRUGS: APPROVALS AND LAUNCHES

2. EU approved AZ's Forxiga for heart failure



The European Commission has approved AstraZeneca's Forxiga (dapagliflozin) for the treatment of symptomatic heart failure with reduced ejection fraction (HFrEF).

Dapagliflozin is the SGLT2 inhibitor and it has been approved in this indication for the treatment of adult patients with and without diabetes. Its potential reach in the heart failure market.

Heart failure affects around 15 million people in the EU with at least half of those having a reduced ejection fraction. This occurs when the left ventricle muscle cannot contract adequately and therefore expels less oxygen-rich blood into the body.

AstraZeneca has received approval based on results from the DAPA-HF phase III trial that showed Forxiga reduced the risk of the composite outcome versus placebo by 26%.

Forxiga is already approved under the brand name Farxiga in the US for the treatment of patients with HFrEF and it is currently under review in Japan and several other countries.

Source: pharmatimes.com



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▶ DRUGS: APPROVALS AND LAUNCHES

3. GlaxoSmithKline's Zejula received EU approval



GlaxoSmithKline's Zejula (niraparib) has received the European Commission approval for the treatment as first-line monotherapy maintenance treatment for adults with advanced ovarian cancer.

The indication cover the drug's use for patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer.

The data from the PRIMA study showed significantly improved progression-free survival (PFS) for patients treated with Zejula. Fifty seven percent reduction in the risk of disease progression or death versus placebo and a thirty eight percent reduction in the risk of disease progression or death vs placebo in the overall population. In addition, there was a 60% reduction in risk of progression in those with BRCA mutation tumors.

Source: pharmatimes.com



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▶ DRUGS: APPROVALS AND LAUNCHES

4. Evgen received full approval for COVID-19 trial launch



Evgen Pharma has received full regulatory approval for STAR trial to treat acute respiratory distress syndrome (ARDS) in patients with suspected COVID-19.

The STAR study will investigate SFX-01 that can reduce the severity or prevent the onset of ARDS in suspected COVID-19 patients.

SFX-01 is designed to up-regulate the Nrf2 pathway, which is part of the natural human defense against inflammatory and oxidative stress, such as the inflammation that occurs during a severe viral infection.

In animal studies, the Nrf2 pathway has been shown to reduce the severity of ARDS and the progressive lung damage observed in both COVID-19 and pneumonia patients.

Source: pharmatimes.com



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▶ DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Adial Pharma provides update on phase III ONWARD trial



Adial Pharmaceuticals has provided an update on its ONWARD phase 3 pivotal trials. ONWARD AD04 is the lead candidate of Adial Pharmaceuticals, it is the therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain genotypes related to the serotonin transporter and receptor genes.

Worldwide, AUD is the leading cause of death among men and women. The current therapies have limited efficacy and significant side effects.

AD04 may represent a paradigm shift in treating this population. Among patients with the target genotype. The European market is expected to be similar in size.

Source: pharmabiz.com



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► DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Novartis conducted phase IV study for migraine



Novartis has conducted HER-MES first phase IV, randomized, double-blind, double-dummy, head-to-head study of Aimovig (erenumab) against topiramate for the treatment of episodic and chronic migraine.

Migraine is a distinct neurological disease. It involves recurrent attacks of moderate-to-severe head pain that is typically associated with nausea, vomiting and sensitivity to light, sound and odors.

The aim of this clinical trial is to determine the tolerability and efficacy of Aimovig 70 mg and 140 mg compared with topiramate, it is an anticonvulsant drug therapy commonly used as standard of care in migraine prevention, in the highest tolerated dose (50-100 mg daily).

The study had enrolled 777 adult patients suffering from = 4 MMDs and who were naïve to, not suitable for or had previously failed up to three prophylactic migraine treatments. The primary outcome was the Aimovig treatment discontinuation rate due to adverse events compared with topiramate during the double-blind treatment phase of the study. Overall Aimovig showed superior tolerability against topiramate, with a higher proportion of patients remaining on Aimovig than on topiramate.

The secondary endpoint of Aimovig compared with topiramate in terms of a 50% reduction in MMDs to baseline in the last three months of the 24-week.

A higher number of patients in the Aimovig treatment arm experienced a significant >50% reduction in MMDs compared with those on topiramate treatment arm. The safety profile was generally consistent with those seen in previous Aimovig clinical trials.

Source: pharmabiz.com





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▶ DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Boehringer announces positive results from SENSCIS-ON trial



Boehringer Ingelheim has conducted open-label extension trial to evaluate the the long-term safety of nintedanib in patients with systemic sclerosis (SSc-ILD) who completed the phase III SENSCIS trial. The online study was published as part of ACR Convergence 2020.

Systemic sclerosis is also known as scleroderma and it is a rare autoimmune disease characterized by thickening and scarring of connective tissue throughout the body.

Approximately, about 100,000 people in the US and 2.5 million worldwide affected with the disease. Nintedanib is a tyrosine kinase inhibitor that inhibit the signaling pathways that lead to pulmonary fibrosis. It is already approved in more than 80 countries for the treatment of patients living with idiopathic pulmonary fibrosis (IPF).

The result showed in this study that the safety profile of nintedanib in SENSCIS-ON was consistent with that reported over 52 weeks.

In this SENSCIS trial diarrhea is the most frequently reported adverse event. The analysis showed that 347 patients in the extension study who received nintedanib demonstrated a decrease in FVC over 52 weeks as did patients in the SENSCIS study.

Source: pharmabiz.com



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► DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Novartis presents positive results from phase III HAWK and HARRIER trials

In the EURETINA 2020 virtual congress, Novartis has announced results of two new post-hoc analyses of the phase III HAWK and HARRIER clinical trials in wet age-related macular degeneration (AMD).

The first analysis demonstrated that fewer Beovu (brolicizumab) patients had early persistent fluid, defined as the presence of intra-retinal fluid and sub-retinal fluid through week 12 of treatment compared with aflibercept patients. For patients who did have early persistent fluid those treated with Beovu achieved greater best-corrected visual acuity (BCVA) gains and greater reductions in central subfield thickness (CST) at week 96 versus those treated with aflibercept.

A second analysis showed Beovu was associated with better control of retinal fluid, as measured by achievement and maintenance of defined CST levels.

In the study, more Beovu patients than aflibercept patients achieved CST control (80% vs. 69% at week 96 at a defined CST threshold of 320 μm , respectively). Patients who stayed longer in a controlled CST state had better visual gains compared with those who remained in an uncontrolled CST state. CST is a key indicator of fluid in the retina, and drying the retina is a core aim of treatment for wet AMD.

Beovu is the first advanced humanized single-chain antibody fragment (scFv) it is approved for clinical use. Beovu is approved in more than 40 countries, including in the US, EU, UK, Japan, Canada and Australia, based on the results of the HAWK and HARRIER clinical trials.

Source: pharmabiz.com



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► PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Sanofi and Regeneron win EU patent



SANOFI

REGENERON

The European Patent Office (EPO) Technical Boards has ruled in Sanofi and Regeneron's favor regarding proprotein convertase subtilisin/Kexin type 9 antibodies, and invalidating certain claims of Amgen's European patent (EP 2 215 124).

They found as a matter of law that certain of Amgen's asserted patent claims for antibodies targeting PCSK9 are invalid based on lack of enablement.

Under the agreement in December 2019, Sanofi take over sole rights for Praluent outside the U.S. Regeneron has sole rights for Praluent inside the U.S. Each party is solely responsible for funding development and commercialization expenses in their respective territories.

Source: medicaldialogues.in



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► PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Kitov Pharma receives notice of allowance for a U.S. patent



Kitov Pharma Ltd. Has announced receipt of a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a patent application entitled “Combinations of IRS/STAT3 Dual Modulators and Anti-Cancer Agents for Treating Cancer”.

Kitov’s NT219 is a dual inhibitor, novel small molecule targeting IRS1/2 and STAT3, it is major drug resistance pathways in many hard-to-treat cancers.

The application covers the various combinations of NT219 with multiple 2nd and 3rd generation EGFR inhibitors approved in the U.S.

In in-vitro and preclinical results showing strong and statistically significant inhibition of tumor growth that encouraging results suggest a potentially promising therapeutic avenue for NT219 that Kitov intends to explore in future clinical trials.

Kitov recently initiated a Phase 1/2 trial evaluating NT219 as monotherapy treatment of advanced solid tumors, as well as in combination with cetuximab for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) or colorectal adenocarcinoma.

Source: globenewswire.com



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▶ PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. GSK vs. Teva patent infringement decision reversal



The U.S. Federal Circuit Court has reinstated a 2017 jury verdict against Teva Pharmaceutical Industries Ltd. regarding the company to pay GlaxoSmithKline Plc \$235.5 million in a 13-year-old induced patent infringement case.



The federal court has decided that there was substantial evidence that Teva induced its generic version of Coreg a beta-blocker intended to treat medical conditions covered under a GSK patent until 2015.

The history of this case is under Food and Drug Administration rules Teva began selling a generic version of Coreg for the treatment of first two conditions with a skinny label.

GSK take legal action against Teva after the Food and Drug Administration (FDA) compelled Teva in 2011 to add the third indication, congestive heart failure, to the label.

In 2017, jury ordered Teva to pay GSK \$234.1 million for lost profit with \$1.4 million in royalties. In 2018, stating that the evidence did not support the jury's finding. In the 2nd Oct, FDA labels and witness testimony did support the "induced infringement" judgment against Teva.

Source: pharmlive.com



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4. Titan settlement agreement with Molteni and Horizon



Titan Pharmaceuticals has announced its settlement of its debt obligations with Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A ("Molteni") and Horizon Credit LLC II ("Horizon"). The debt was secured with a lien on all assets of Titan.

Under the agreement, Molteni and Horizon agreed to the approximately \$5.2 million of outstanding indebtedness in exchange for the payment by Titan of a total of \$1.6 million in cash to Horizon and Molteni

According to the closing agreement, there will be no rights on Titan's remaining assets, including all the ProNeura® intellectual property.

Source: prnewswire.com



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▶ TECHNOLOGY /NDDS

1. New microfluidic device to test pancreatic cancer drugs



The researchers at the Purdue University have developed unique microfluidic device that can be used to test a cancer drug on multiple tumor cells. Using this technology new drug therapies can be discovered and can be more effectively in existing drug.

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In the new microfluidic device consist of collagen channels that acts as pancreatic duct on a very small scale. Within a mix of cancer cells, it can grow and proliferate and various therapies can be delivered into the channels.

Here no much more research done on what kind of interaction happens within tumors.

Source: medgadget.com



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▶ TECHNOLOGY /NDDS

2. Machine-learning tool to diagnosis stroke



The researchers at the Penn State and Houston Methodist Hospital have developed a tool to help doctors in rapidly diagnosing strokes. This technology uses a smartphone to record a patient's speech and facial movements such as slurred words or a drooping facial muscle. A machine-learning algorithm then processes these data and to identify a stroke may be occurred or not.

In diagnosing stroke the researchers have said that the system is as accurate as clinician and it can provide accurate result within minutes.

Rapidly diagnosis and treatment is very important for stroke patients to prevent long term damages. However some cases, the subtle signs can be missed by clinicians due to mild to moderate symptoms and treatment is delayed.

During a stroke there are millions of neurons dying in every minute, in severe stroke it is obvious to our providers from the moment the patient enters the emergency department, but in the majority of strokes diagnosis can be delayed by hours and by then a patient may not be eligible for the best possible treatments.

Source: medgadget.com



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▶ TECHNOLOGY /NDDS

3. Skin sensor to help ALS patients



The researchers at the MIT have developed new wearable sensor to detect small deformations of the skin. This sensor is low cost and much cheaper. It may be more effective than current assistive communication technologies for ALS patients.

The wearable device includes silicon film that contains four piezoelectric sensors that can detect deformation of the underlying skin and convert in to an electrical signal. The gentle facial expression such as smile, twitch could be registered as specific messages.

Source: medgadget.com



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4. New ultrasound device to test sickle cell disease



The researchers at the Colorado University have developed a new rapid test for sickle cell disease. In this test, the technology uses ultrasound to heat a protein sample and then measures how it dissolves over time to identify the protein responsible for sickle cell disease. This tiny device is less than the size of a quarter and provides a result in as little as one minute, the disease is caused by a variant of hemoglobin.

Using a Thermal shift Assay to analyze proteins in a sample disease is to heat a sample and measure protein solubility however, the assay can take a whole day to run and requires cumbersome and expensive equipment. This method requires specialized equipment. This method requires specialized equipment such as calorimeters, polymerase chain reaction machines and plate readers.

Acousto Thermal Shift Assay (ATSA) is the new device uses ultrasound waves to heat a sample and is similar, cheaper, faster and more sensitive conventional TSAs.

This method is 7 to 34 times more sensitive and can distinguish the sickle cell protein from normal protein compare to TSA.

Source: medgadget.com



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