Lambda Research Newsletter

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GLOBAL NEWS

1. Big Pharma introduces artificial intelligence supercomputers to speed drug discovery

Big pharma has developed modern artificial intelligence (AI) supercomputers to facilitate drug discovery process. Now, GSK signs a deal worth $43 million with Big Pharma for AI to improve the hit-and-miss business of finding new medicines.

Various other pharmaceuticals are exploring the potential of AI to help streamline including Merck & Co, Johnson & Johnson and Sanofi.

These modern supercomputers and machine learning systems are designed to predict the behavior of molecule and to understand how likely they are to develop a useful drug. This system will result in saving of time along with money that is spent on unnecessary tests. This AI system is already being used in various other high-tech areas such as driverless cars and facial recognition softwares.

This is not for the first time where drug makers have developed any method to boost research and development productivity. In early 2000s, introduction of "high throughput screening", was also an advancement to test millions of compounds.

Source: health.economictimes.indiatimes.com

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GLOBAL NEWS

2. Zimmer Biomet introduces X-PSI™ for total knee replacement surgery

Zimmer Biomet introduced X-PSI™ Knee System as world's first Conformité Européene (CE) marked surgical planning system. This is an X-ray-based patient specific instrument that allows for patient specific implant positioning. This X-PSI™ system allows surgeons to use X-ray images to generate three-dimensional anatomic models for the surgical development plan.

This technique will anchorage the standard of care preoperative X-ray imaging instead of most commonly used techniques Magnetic Resonance Imaging (MRI) and Computerized Tomography (CT) scans now a days.

X-PSI Knee System is the 4th patient specific guide of the company. Zimmer Biomet is offering its Personalized Solutions franchise and the new technique will be launched in five countries of the European Union.

MRI and CT-based planning software has useful utility in joint replacement surgery but introduction of X-PSI™ emphasis the use of X-ray imaging; resulting into comparably high implant placement accuracy.

Source: prnewswire.com

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GLOBAL NEWS

3. Sun pharma signs agreement with Samsung BioLogics for manufacturing of anti-psoriasis drug

Sun Pharma has signed an agreement with Samsung BioLogics for manufacturing Tildrakizumab, a psoriasis drug. The approximate value of the strategic long-term manufacturing agreement is USD 55.5 million.

Tildrakizumab is an investigational IL-23p19 inhibitor, which is being evaluated for the treatment of moderate to severe plaque psoriasis.

This agreement with Samsung BioLogics' was signed at headquarter in Incheon, South Korea. Now Samsung BioLogics will manufacture Tildrakizumab for Sun Pharma.

Tildrakizumab was accepted for review in March 2017 by the European Medicines Agency (EMA) and in May 2017 by the US Food and Drug Administration (FDA)

Source: health.economictimes.indiatimes.com

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GLOBAL NEWS

4. Introduction of new method for determining intracellular bioavailability

A group of researchers introduced a new method for quantifying intracellular bioavailability of a drug. This method could be used to predict exposure of small molecules to the target cells and also regarding the efficacy of the drug.

This research has been published in the journal of *Proceedings of the National Academy of Sciences of the United States of America (PNAS)*.

It's very important to consider various internal environmental factors that may influence the efficacy of the drug as most of the drug targets are located inside the cell. Presently, there is no method available for the detection of intracellular concentration of the drug.

The new method is based on measuring the concentration of unbound drug available to exert a therapeutic effect inside the cell.

This method is also being investigated to check its potential to predict drug efficacy in the body. Preliminary studies show that replacing the correction factors with a simple determination of local bioavailability in the cells seems to be possible. Legibly, intracellular bioavailability is on the way to becoming an important early instrument in pharmaceutical drug research.

Source: who.int

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PHARMA INDIA

1. India introduces new program for the development of pharmaceutical products

The Ministry of Science and Technology of India launched its $250-million program to promote the production of biological drugs in the country. This program will focus on the development of new vaccines, bio-therapeutics, diagnostics and medical devices. The program was approved by the Union Cabinet in May, 2017.

The Indian ministry has received a loan of about Rs. 800 crore from the World Bank for "Innovate in India" (i3) program. This will help India to capture around 5% global biopharma market which is around 3% at present. The government aims to improve access to affordable healthcare through the i3 program.

This flagship program is expected to boost the collaborations between academia and the biopharma industry of the country. This program is launched for encourage innovations and to offer young entrepreneurs an avenue to engage with the best in the industry. The program will be implanted by the Department of Biotechnology's (DBT's) Industry Research Assistance Council (BIRAC) in collaboration with the World Bank.

After this program, the global biopharmaceuticals market is expected to touch $278,232.9 million by 2020.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

2. India is the second largest supplier to the UN in the health sector

In the year of 2016, India was the 2nd largest supplier of health sector to the United Nation (UN) system with total sales over $800 million, including pharmaceuticals.

India has maintained its position of number two since 2012 and is in top 10 suppliers since 2000. Total sale in 2015 was $902 million. Supply has dropped from $1.3 billion and 7.3 per cent in 2015 to $1.1 billion and 6% of total UN procurement in 2016. But India is still at number two.

Other procurements from India include food, management services and medical equipment supplies.

Out of 10 major countries supplying the UN, 3 were developing countries including India, the United Arab Emirates and Turkey in 2016. These 3 countries form a total amount of around $2.58 billion, which is 14.6% of the total UN procurement.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

3. CDSCO and IPC collaborate to audit 5 AMCs in the country

Central Drugs Standard Control Organisaion (CDSCO) Western Zone collaborated with Indian Pharmacopoeia Commission (IPC) in order to review the functioning of Adverse Drug Monitoring Centres (AMCs) in Gujarat. Agencies have audited 5 medical institutions in Gujarat with assessment on aspects like standard operating procedures (SOPs) and causality assessment.

IPC took this exercise initiative to generate awareness in medical institutions regarding effective surveillance system for the detection of Adverse Drug Reactions (ADRs). IPC is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).

A nation-wide PvPI was initiated by CDSCO under the Union health ministry in July 2010. PvPI leads with 0.82 points as per quality completeness score of Individual Case Safety Reports (ICSR) as against the global average of 0.55 accounted on a quarterly basis for a total of 150 countries including India which contribute to the global PvP database.

NCC-PvPI is the center where all the ADRs including ICSR are reported from all over the country. This NCC-PvPI works in collaboration with the global ADR monitoring centre (WHO-UMC), Sweden to contribute to the global ADRs data base.

IPC has also signed a Memorandum of Understanding (MoU) with the National Accreditation Board for Hospitals and Healthcare providers (NABH) following which around 600 NABH accredited hospitals have also started reporting ADRs as part of their pharmacovigilance activities mandated by the government.

Source: pharmabiz.com

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PHARMA INDIA

4. PvPI reported 2.70 lakh adverse drug reactions across 250 centers

Adverse drug reaction (ADR) monitoring centers (AMCs) reported around 2.70 lakh ADRs under Pharmacovigilance Programme of India (PvPI) till June 2017. After the notice from Government on 8th March 2016, 70 pharma companies have set up pharmacovigilance (PV) cells in their organizations for the collection, processing and forwarding ADRs to licensing authorities.

Pharmaceutical companies can fulfill their responsibilities either by setting up in-house systems for pharmacovigilance or by entering into contractual arrangements with Contract Research Organizations (CROs). Various activities of PV department include:

- processing and reporting of ADRs
- periodic Safety Update Report (PSUR)
- Periodic Benefit Risk Evaluation Report (PBRER)
- periodic Adverse Drug Experience Report (PADER)
- product quality complaints management, medical inquiries management
- safety data exchange agreement management
- signal detection for risk-benefit evaluation
- risk management programs(RMP)
- literature monitoring for ADR case reports
- training of company employees on ADR reporting
- global compliance monitoring
- audits and inspections

All the ADRs from the different centers of the country are reported to National Co-ordination Centre (NCC-PvPI) which works in collaboration with the global ADR monitoring center (WHO-UMC), Sweden to contribute in the global ADRs data base.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. PUMA failed to meet EU expectations received just 3 approvals in 10 years

It's been a long 10 years of establishment of pediatric-use marketing authorization (PUMA) but according to biopharmaceutical companies and regulators across Europe, some pediatric therapeutic areas have seen progress but PUMA failed to meet its expectations.

PUMA is a dedicated marketing authorization of European Medicines Agency (EMA) for the indications and appropriate formulations of the medicines which are already authorized. PUMA usees those medicines which are no longer covered by patent and are exclusively developed for use in pediatrics.

PUMA mainly works to stimulate research of off-label use of existing drugs into authorized use for better safety and therapeutic drug profile. But till now only three PUMAs have been authorized.

According to German regulators, PUMA did not meet the expectations and the concept of PUMA is falling short. United Kingdom (UK) government described this concept as a failure. This may be due to the lack of sufficient incentives to promote the research in off-patent pediatric indications. PUMA is also facing pricing pressure from the established compounds.

Till now, no decision has been taken by any agency regarding PUMA.

Source: raps.org

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REGULATORY ROUND-UP

2. HTA's new gateway for parallel consultations on marketing authorizations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

To align the data sponsors need and to win approval and secure reimbursement, European regulators and health technology assessment (HTA) bodies have advanced their plans. This advancement will form a gateway through which sponsors can request parallel consultations with the state members of European Medicines Agency (EMA) and the HTAs.

The sponsors can gain a marketing authorization only to learn HTAs are unwilling to pay for the drug on the basis of the data that secured the EMA approval. Due to the need of this complete procedure, patients have to wait for a longer time for the availability of a new drug.

Now National HTAs have sought to remove some of the problems associated with these processes through the European Network for Health Technology Assessment (EUnetHTA).

After this collaboration, companies will hold face to face meeting with the 2 agencies. The meeting will discuss concerns with EMS or HTAs with the sponsor's trial design. EMA and EUnetHTA created a joint guidance and template document to help sponsors for accessing advice.

Source: raps.org

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REGULATORY ROUND-UP

3. AAM sues Maryland for over price gouging law

The Association for Accessible Medicines (AAM), sued Maryland over a new law according to which generic drug makers need to pay a fine if they rise prices more quickly and by too much.

The generic drug price gouging bill, HB 631 was planned by the Maryland Government to become a law in June, 2017. The Government did not sign the bill but expressed reservations about unintended consequences along with the legal and constitutional concerns.

According to AAM, the discriminatory law is an unconstitutional overreach passed in June 2017 scheduled to take effect in October 2017. This law grants Maryland unprecedented powers to regulate the national pharmaceutical market resulting in:

- violating the United States Constitution and
- posing harm to vulnerable patient communities

AAM explains that this law is illegal because the law violates the Commerce Clause of the US Constitution as it gives Maryland the power to regulate interstate commerce.

Source: raps.org

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REGULATORY ROUND-UP

4. US House of representatives passes bill to reauthorize FDA user fee programs

The US House of Representatives passed a bill to reauthorize the prescription drug, generic drug, medical device and biosimilar user fee programs till 2022.

On the house floor, several representatives discussed the issue of expensive medicines but none of the user fee program addressed the issue directly. Cost of no competition high-priced brand name drugs and generic drugs can be reduced by increasing the speed of review of generic drugs.

The present user fee program is going to expire on 20th September 2017. The US Food and Drug Administration (FDA) declares that if the bill is not signed by the US President before this expiration; the agency will have to send a layoff notice to around 5,000 employees.

According to Congressional Budget Office, FDA is going to collect an amount of approximately $9 billion ($8 billion for drugs, $1 billion for devices) between 2018 and 2022, based on the fee level set in the Senate bill.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Arrien Pharmaceuticals signs license agreement with US-based pharmaceutical for psoriasis drug ARN-6039

Arrien Pharmaceuticals signed a license agreement with an US-based pharmaceutical firm for the clinical agent ARN-6039. Drug ARN-6039 will be developed for the potential treatment of moderate to severe psoriasis along with some other autoimmune disorders.

Psoriasis is a common worldwide chronic autoimmune disorder affecting around 3% of the total population. This partnership for ARN-6039 at the Phase 1 stage of development validates Arrien's small molecule fragment-based discovery platform.

Intensified activity of TH17 (T helper 17) cells along with excess production of pro-inflammatory cytokines including IL-17 and IL-17A are major elements associated with the pathophysiology of psoriasis.

The company has completed the Phase 1 trial for the safety, tolerability and pharmacokinetics of ARN-6039 before signing this agreement.

The small molecule ARN-6039 is an inverse agonist of ROR-γt which is a transcription factor that regulates TH17 and the generation of IL-17 and IL-17A pro-inflammatory cytokines associated with psoriasis.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. DePuy Synthes acquires Surgical Solutions LLC to enable innovation in invasive spine surgery

DePuy Synthes Products, Inc. which is a part of Johnson & Johnson Medical Devices Companies acquired Innovative Surgical Solutions LLC, working as Sentio LLC, to enable innovation in invasive spine surgery. The strategy of the company behind this merger is to invest technology in the fastest growing segment. The financial terms and conditions of the acquisition are not disclosed.

Nerve localization is an important procedure for many spine surgeries. The procedure involves minimally invasive approach termed as lateral surgery in which temporary and permanent neurologic complications are reported. These complications include pain and weakness in hip or leg due to stretching or bruising of nerves near the surgical field.

The current technologies available in the market require the use of needle electrodes in the patient's arms or legs to locate motor nerves, which may cause complications associated with anesthesia. Sentio's platform uses adhesive smart-sensors which are applied on the skin. With this technology, doctors can do the complete procedure individually without the need for the presence of a neuromonitoring specialist and avoid complications associated with the available therapy.

Source: prnewswire.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Roche acquires mySugr to form digital diabetes management platform

In an agreement signed between Roche and mySugr, Roche would acquire all the shares of the company mySugr GmbH. mySugr is an leading mobile diabetes platform in the market and now will be a integral part of Roche's new patient-centered digital health services platform in diabetes care.

This acquisition will allow Roche to expand and to form a leading position in the area of diabetes management.

This agreement will offer accessible patient solutions within an open platform for better response to the unmet needs of people with diabetes. According to the company, this acquisition is aimed to support the patients with diabetes and provide them an ideal glucose target range for the betterment of their lives.

mySugr was introduced to solve problems associated with diabetes through smartphones. After the acquisition,mySugr is going to remain as a separate legal entity with an open platform for all diabetes devices and services.

Source: worldpharmanews.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Neovacs and Centurion signs agreement for IFNalpha Kinoid for the treatment of lupus

Neovacs has signed an agreement with Centurion Pharma for IFNalpha Kinoid for the treatment of lupus. Centurion Pharma is a company which mainly focuses on chronic disease treatments. The company has experience in the vaccines as well as in the specialty therapeutic care markets.

This agreement represents the strategy of Centurion Pharma for the identification of high-quality patners for the development and commercialization of it's advanced vaccine, IFNalpha Kinoid.

This agreement will provide an amount of €6m to Neovacs as an upfront payment for the agreement. Neovacs will also receive an additional amount as double digital royalty on net sales.

Centurion Pharma will try to negotiate with local health authorities to obtain an agreement for the marketing of IFNalpha Kinoid followered by successful completion of Neovacs' Phase 2b clinical trial for the treatment of lupus.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. FDA approves Endari for the treatment of sickle cell disease

The U.S. Food and Drug Administration (US FDA) has approved Endari (L-glutamine oral powder) for the treatment of sickle cell disease. Endari is the drug approved out of 20 drugs and has therapeutic applications in patients with sickle cell disease to reduce severe complications associated with the blood disorder.

Sickle cell disorder is an inherited blood disorder associated with abnormal shaped blood cells. The abnormal cells restrict the blood flow in the blood vessels resulting in inadequate oxygen supply to the body, leading to severe pain and organ damage.

A long-term (48-week) randomized Phase 3 trial conducted in 230 patients aged 5 to 58 years old with sickle cell disease evaluated the efficacy and safety of Endari versus placebo. The patients treated with Endari experienced fewer visits to hospital as compared to placebo due to pain (median 3 vs. median 4), lesser hospitalization (median 6.5 days vs. median 11 days) and acute chest syndrome (8.6 percent vs. 23.1 percent).

Presently Endarii has received Orphan Drug designation for its use in rare diseases.

Source: fda.gov

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DRUGS: APPROVALS AND LAUNCHES

2. Zydus Cadila gets USFDA approval for marketing anti-obesity drug Phentermine Hydrochloride

The U.S. Food and Drug Administration (USFDA) has approved phentermine hydrochloride orally disintegrating tablets of Zydus Cadila for the treatment of obesity in the American market.

The company received marketing approval of the drug with 3 different strengths of 15, 30 and 37.5 mg.

The drug will be manufactured at the Moraiya unit in Ahmadabad, Gujarat, India. This drug is used together with diet and exercise to treat obese people, who are at a high risk for high blood pressure, high cholesterol or diabetes.

Currently, the company has more than 120 approvals and filed over 300 abbreviated new drug applications (ANDAs).

Source: health.economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. Sandoz received approval by European Commission for Erelzi® (Etanercept)

Sandoz, a Novartis division, has received approval by the European Commission (EC) for Erelzi® (etanercept) for the treatment of multiple inflammatory diseases. Erelzi® is now approved for:

- rheumatoid arthritis
- axial spondyloarthritis
  - ankylosing spondylitis and non-radiographic axial spondyloarthritis plaque psoriasis
  - psoriatic arthritis
  - juvenile idiopathic arthritis
  - pediatric plaque psoriasis

The product Erelzi® is available as a pre-filled syringe and an auto-injector pen, SensoReady, which is designed for the safety of the patient, comfort and convenience.

The approval by EC is based on the data generated by preclinical and clinical studies including pharmacokinetic data. In the trial, Sandoz demonstrated that its product Erelzi® matches the reference product with regards to safety, efficacy, and quality.

Source: biosimilardevelopment.com

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DRUGS: APPROVALS AND LAUNCHES

4. Novartis's Zykadia™ (ceritinib) approved by European Commission for ALK-positive NSCLC

The European Commission (EC) approved Novartis's Zykadia™ (ceritinib) for the treatment of advanced non-small cell lung cancer (NSCLC) in Europe. Zykadia™ is used as a first-line treatment for advanced NSCLC in anaplastic lymphoma kinase (ALK) positive patients.

Zykadia™ is an inhibitor of ALK, and administered orally. ALK is a gene that can combine with others to form an abnormal fusion protein, which supports the development and growth of certain tumors in cancer.

Zykadia™ is also approved by the Committee for Medicinal Products for Human Use (CHMP) in May, 2017. This EC approval is applicable for all 28 EU member states as well as Iceland, Lichtenstein, and Norway. Currently, the drug is approved in >70 countries globally.

Approval as the first-line treatment is based on the results from an open-label, randomized, multicenter, global, Phase 3 ASCEND-4 trial. ASCEND-4 was conducted to evaluate the safety and efficacy of Zykadia compared with standard chemotherapy in adult patients with stage IIIB or IV ALK-positive advanced NSCLC in whom no prior therapy was given.

Patients, in whom Zykadia™ was given as a first-line, had a median progression-free survival of 16.6 months. Overall intracranial response rate (OIRR) in patients with measurable brain metastases at baseline and at least one post-baseline assessment was 72.7% for patients treated with Zykadia where as 27.3% for patients treated with chemotherapy.

Source: pharmaceutical-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Progenza of Regeneus Ltd showed positive results for Phase 1

Regeneus Ltd drug Progenza showed positive results for Phase 1 for the treatment of osteoarthritis (OA). This Phase 1 trial showed that a single injection of Progenza into the knee of either dose (3.9 million cells or 6.7 million cells) in patients appeared safe and was well-tolerated.

In the Phase 1 study, the drug showed positive results for:

- primary safety endpoints
- significant reduction in knee pain and
- improvement in cartilage volume

No serious adverse events were noted and the drug was welltolerated. No data was found with concern in blood tests, ECG's, physical examinations, or other safety measurements.

MRI examination of knee joint structure showed significant improvement in lateral tibial cartilage volume for patients treated with Progenza.

This study confirms the safe use of Progenza when administered as an intra-articular injection. The beneficial effect of the drug on the knee structure suggests that this may be a potential drug for disease modification.

Source: sciencedaily.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Tailor-made cancer vaccine proves safe in clinical trials

Tailor-made vaccine showed positive results for two experimental treatments for skin cancer. These vaccines target particular tumors of patients of skin cancer. Vaccines also targets immune response to tumour cells.

These are the first vaccines which are tested on humans directed at neoantigens molecules resulting from DNA mutation. Neoantigens are not present in the healthy human being which makes it an ideal target for cancer therapy. NeoVax prevents cancer from recurring in melanoma skin cancer patients after surgical removal of cells. The NeoVax vaccine contained up to 20 neoantigens derived from patient tumours.

The two small sized studies showed positive results, and now, a large scale trial will be conducted for the vaccine. The results were published in the Journal *Nature*, 2017.

Vaccine-induced polyfunctional $CD4^+$ and $CD8^+$ T cells targeted 58 (60%) and 15 (16%) of the 97 unique neoantigens in treated patients.

Source: health.economictimes.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. US FDA endorses new gene-altering cancer treatment

The U.S. Food and drug administration (US FDA) approved the first gene altering cancer cell treatment for fighting cancers. This treatment is going to be the first gene therapy for the treatment of cancer. In the treatment patients' own cells will be reintroduced to fight cancer that activates the immune system to shut down the disease.

For this technique, a separate treatment will be created for each patient in that cells of the patients are removed at approved medical centers, frozen, and shipped to a Novartis plant for thawing and processing, frozen again and shipped back to the treatment center for the treatment of the patients.

Only a single dose of the product brought long remissions and possibly cures in the patients facing death due to failure of all treatment options. Side effects associated include raging fever, crashing blood pressure, lung congestion.

The trial was conducted on 63 patients who received the treatment from April 2015 to August 2016.

Source: health.economictimes.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Scientist developed first B-cell antibodies in lab

For the first time, scientists developed human antibodies in the laboratory. By the use of this technique, scientists can develop vaccines for various infectious diseases. In the natural process. B cells recognize the pathogen and produce antibodies against that pathogen. Now the researchers of Harvard University and Massachusetts Institute of Technology (MIT) in the US are trying to replicate this phenomenon in the laboratory. The scientists are using B cells isolated from patients' blood samples.

The scientists also mentioned that there is one specific antigen signal that is required to start proliferation and development of antibodies in the plasma cells.

The second signal can be provided by short DNA fragments called CpG oligonucleotides responsible for the activation of protein inside B cells named toll-like receptor 9 (TLR9). The patients treated with CpG oligonucleotides stimulate activation of B cells to produce antibodies. In each case, researchers were able to produce high-affinity antibodies in a very short duration.

The research was published in The Journal of *Experimental Medicine*.

This approach will help researchers to develop therapeutic antibodies for the treatment of infectious diseases.

Source: health.economictimes.indiatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Narcan nasal spray patent of Opiant is listed in US FDA orange book

Narcan nasal spray is an emergency opioid overdose treatment by Opiant Pharmaceuticals. Now, the US firm announced that the patent that covers the delivery and use of the 4 mg version of the product has been listed in the FDA Orange Book.

This listing means the other companies who are interested for the approval of its generic have to inform Opiant and its partner Adapt Pharma Limited of their intention.

The latest patent has the potential to be valuable for some of Opiant's additional programs. Opiant now have five Orange Book-listed patents for Narcan which are associated with the solid intellectual property position of the company and enhanced product exclusivity.

Naloxone is the active pharmaceutical ingredient (API) in the Narcan nasal spray. This is a generic opioid antagonist that reverses the central nervous system and respiratory system depression associated with opioids. Various injectable preparations of the product are available in the US market.

Source: in-pharmatechnologist.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. InDex Pharmaceuticals AB gets European patent for the use of cobitolimod in inflammatory disease

The European Patent Office issued a new patent to InDex Pharmaceuticals for the use of cobitolimod in the treatment of inflammatory diseases.

The patent is entitled as “The compounds and methods for reducing the recruitment or migration of polymorphonuclear cells”.

The patent was filled in 2009 and has exclusivity until October 2029. There is a possibility of up to 5 years of extension after the marketing approval.

This patent along with the previous patent is a part of the company’s strategy to establish a broad and strong portfolio of intellectual property rights to protect their commercially important discoveries.

Source: biospace.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. GlycoMimetics to receive patent for GMI-1271 by European Patent Office

The European Patent Office has issued an "intention to grant" letter to GlycoMimetics, Inc. for the drug candidate GMI-1271. The patent is titled as "E-Selectin Antagonist Compounds, Compositions, and Methods of Use."

GlycoMimetic's already has a patent and is now expanding the patent for various other indications including cancers.

The main objective of GlycoMimetic behind these efforts is to secure additional U.S. and foreign patents. After this new approval, the company will have the patent protection in Europe and in US till 2032.

The researchers explain that the European Patent Office's issuance of patent rights covering GMI-1271 underscores the progress they have made in protecting their intellectual property and innovative pipeline.

Source: biospace.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Cytori (CYTX) receives patent for cell therapy in the treatment of Scleroderma

Cytori Therapeutics, Inc. receives patent for the use of Habeo™ Cell Therapy for the treatment of scleroderma. Scleroderma is a symptom of a group of diseases that involve the abnormal growth of connective tissue, which supports the skin and internal organs mainly. The patent was issued on 5th July 2017 by European Patent Office (EPO), which will last till 2034.

The patent claims for the use of Adipose-Derived Regenerative Cells (ADRCs), including Cytori's Habeo™ Cell Therapy for the treatment of:

- Scleroderma
- Raynaud's phenomenon or
- Suppression of pain from Raynaud's Phenomenon

Habeo™ Cell Therapy is also patented for the use in vascular diseases and to treat ischemic wounds.

The main focus of this therapy is to target scleroderma and Raynaud's phenomenon, and research is also going on for various other therapeutic areas.

Source: biospace.com

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TECHNOLOGY /NDDS

1. New Neo-Islet technology is developed for treatment of insulin-dependent diabetes

Scientists of SymbioCellTech (SCT) developed a new technology that combines Mesenchymal Stem Cells (MSCs) with culture-expanded pancreatic islet cells to form three-dimensional cellular clusters, which is termed as Neo-Islets. This combination provided durabale blood sugar control.

The study published in the journal of *Stem Cells Translation Medicine* explains that a single dose of Neo-Islets administered into the abdominal cavity provides durable blood sugar control in insulin-dependent diabetes patients.

Type 1 diabetes is associated with an auto-immune disorder in which the cells of our own body destroy the islets cells resulting in the inability of pancreatic cells to produce insulin. For this treatment islet cells transplantation is done into the liver cells; however, it requires permanent use of potentially-toxic immunosupression drugs, it cannot be scaled up to treat the large number of patients that would benefit from this therapy and it is expensive.

To overcome all the problems associated with cell transplant and the need of taking immunosuppressant, this new technology has been introduced. In the published research, scientists have mentioned how to implant Neo-Islets into diabetic patients and how it will help the patients. Currently, only preclinical studies are conducted and now SCT is preparing for a phase 1/2 clinical trial in patients with type I diabetes.

Source: news-medical.net

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TECHNOLOGY /NDDS

2. New AI system to predict IVF success

Scientists have developed a new method to detect which in vitro fertilization (IVF) embryo is going to develop into a healthy baby. Researchers developed an artificial intelligence (AI) system to identify healthy embryos using images of 482 bovine embryos during their development.

Presently, embryologists are appointed to choose those fertilized eggs which are more likely to result in a pregnancy. The process involves checking of fertilized eggs with the naked eyes manually.

This system will help to detect the poor developed embryo more accurately in the earlier stage of development which is not possible with the naked eye. Presently, this system is tested on embryos of cows and resulted in thea detection of healthy embryos.

These systems will also lead to the reduction of human errors associated with more cycles of IVF. Researchers found that results of this technique were much more consistent as compared to the human embryologists.

Source: health.economictimes.indiatimes.com

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TECHNOLOGY /NDDS

3. Zirconia-doped ceria nanoparticles for the treatment of sepsis

Korean scientists in a study reported that zirconia-doped ceria nanoparticles act as effective scavengers for oxygen radicals. This mechanism enhanced the survival rate in sepsis model. In sepsis, cells are swamped with reactive oxygen radicals generated by aberrant response of immune system in a response to localized reaction.

The study was published in the journal *Angewandte Chemie*.

As day by day resistance to antibiotics is increasing, to overcome that, scientists developed a new alternative method for the inflammatory pathway of sepsis. In the body, cerum ion shows quick conversion to satisfy oxygen radicals forming superoxide anion, hydroxyl radical anion, or even hydrogen peroxide but in living cells this can happen only if it fulfills 2 conditions:

- size and nature of the particles
  - nanometer-sized particles are coated by a hydrophilic shell of poly(ethylene glycol)-connected phospholipids to make them soluble so that they can enter the cell and remain there
- accessibility of cerium ion responsible for quenching ($Ce(3^+)$) are coated on the surface of the nanoparticles

In the study, scientists found that a certain amount of zirconium ions in the structure help this conversion, because the $Zr(4^+)$ ions control the $Ce(3^+)$-to-$Ce(4^+)$ ratio as well as the rate of conversion between the two oxidation states.

These nanoparticles accumulate in the organ where immune response occurr and eradicate reactive oxygen species. This study reveals that these nanoparticles could be a new option for the treatment of sepsis.

Source: news-medical.net

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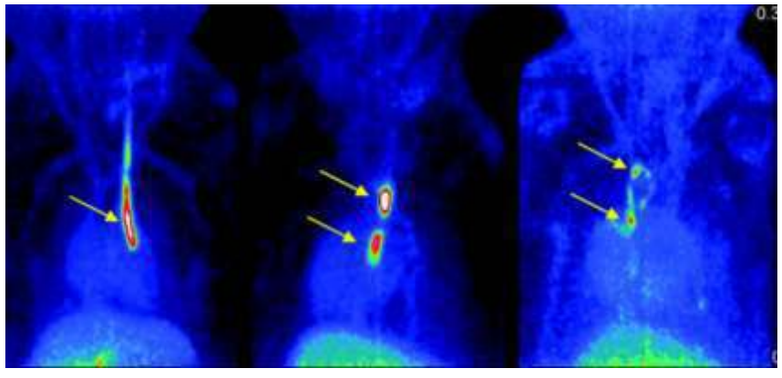
TECHNOLOGY /NDDS

4. Positron emission tomography for detection of blood clots



In a preclinical study, German researchers showed that targeting GPIIb/IIIa receptors with a fluorine-18 (18F) labeled ligand is a promising approach for diagnostic imaging of blood clots/ thrombus. GPIIb/IIIa is the key receptor involved in platelet clumping.

Presently available diagnostic techniques for the detection of blood clots rely on different modalities depending on the vascular territory, and do not address the critical molecular components.

This complete study was published in *The Journal of Nuclear Medicine's (JNM)* in July 2017.

Researchers in the preclinical study developed a novel small molecule tracer termed as 18F-GP1 for positron emission tomography (PET) imaging. This 18F-GP1 has high affinity to bind GPIIb/IIIa receptors. 18F-GP1 accumulates at the site of blood clot and removes the clot. Efficacy of 18F-GP1 is not affected by anticoagulants.

The present study is only a preliminary study on monkeys. This 18F-GP1 will not only provide accurate anatomic localization but will also predict the risk of clot growth. But according to researchers these drugs can lead to severe and life threatening bleeding, so balancing is required.

Source: news-medical.net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