Lambda Research Newsletter

August 2019

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Research Accelerated

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Clinical Research NEWSletter

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GLOBAL NEWS

1. Risk management platform addresses pharma's cybersecurity challenges

The BluePrint Protect software, developed by Intraprise Health, is designed to provide solutions for cybersecurity challenges faced by pharmaceutical companies.

The new devised platform uses Intraprise Health's third-party knowledge base through its 'Third-Party Assessment Cloud' and enables the user to automate third-party risk management processes. This system allows a pharmaceutical company's security team and its third parties to collaborate and communicate in real-time for security purposes.

There is always a need of a centralized, scalable security platform in the health care sector so that there is an effective collaboration amongst all stakeholders to visualize the risks in a meaningful manner. Intraprise Health's BluePrint Protect software is a such first-ever health care-focused workflow automation and visualization platform. This software is especially designed for third-party risk management.

The use of a security risk management platform in the pharmaceutical industry is particularly helpful for pharma companies and third parties for the security of the large volumes of consumer, provider, and pharmaceutical data. These data are personally identifiable, hence, there is a need for fool-proof security.

Source: pharmatechnologist.com

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GLOBAL NEWS

2. Topical drug delivery market growth to reach $123bn by 2024

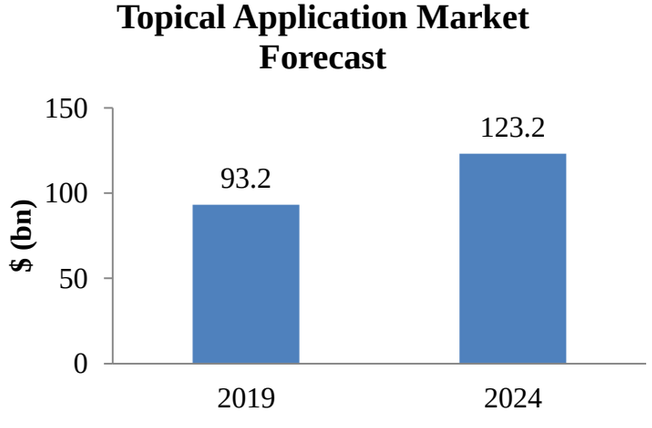
A market research trend has forecasted a 5.7% year-over year growth for the global market of drug products administered by topical application. Medicines indicated for ophthalmic, dermal, vaginal, rectal and nasal administration comes under the topical application category.

It is expected that North America will produce the highest revenues within the market during the forecast period. In addition, emerging markets such as China and India are expected to offer potential growth opportunities.

The highest annual growth rate in topical application products is expected in Japan, which could be due to the rising elderly population and increasing use of generic drugs.

The market is currently worth $93.2bn (€83.94bn) and according to the research report, it is projected to reach $123.2bn by 2024.

The major factors contributing to this growth are the high prevalence of skin diseases and diabetes, as well as increasing incidences of eye diseases and burn injuries.



Source: pharmatechnologist.com

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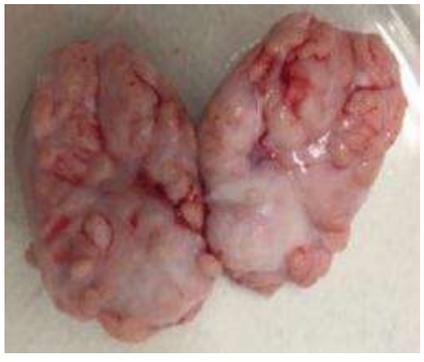
GLOBAL NEWS

3. R&D for NASH: Researchers develop miniature livers



Recent advances in human stem cell culture have raised hopes that researchers can create miniature versions of human livers, known as organoids, which can be helpful for treatment options for liver diseases.

Researchers from Tokyo Medical and Dental University and Cincinnati Children's Hospital Medical Center recently developed one of the sets of organoids using cells from a patient with Wolman disease to differentiate the cells into hepatic epithelial cell types, and create organoids more representative of the mix of pro-fibrotic and infllammatory cell types found in the human liver.

The researchers have hypothesized that “Human liver organoids derived from patients with genetic lysosomal enzyme deficiency lead to an exaggerated steatohepatitis phenotype as seen in patients, followed by in vitro rescue with a clinically active compound via FXR agonism.” The researchers developed one of the sets of organoids using cells from someone with Wolman disease, enabling them to assess the efficacy of Intercept Pharmaceuticals’ Ocaliva in the indication.

Source: outsourcing-pharma.com

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GLOBAL NEWS

4. New bioprinting method to sculpt complex tissue shape

Researchers at the Laboratory of Applied Photonics Devices (LAPD), in EPFL's School of Engineering, working with colleagues from Utrecht University, have developed an optical technique that can sculpt any complex tissue shapes in a biocompatible hydrogel containing stem cells in a few seconds. Endothelial cells can then be added and the tissue can then be vascularized.

The research team has published an article in *Advanced Materials* to describe this high-resolution printing method called 'volumetric bioprinting'. The researchers projected a laser down a spinning tube filled with a stem-cell-laden hydrogel to create these tissues. The energy from the light was focused at specific locations to shape the tissue, which then solidify. A complex 3D shape is available suspended in the gel after just a few seconds. However, there is no affect on the stem cells in the hydrogel.

Source: news-medical.net

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PHARMA INDIA

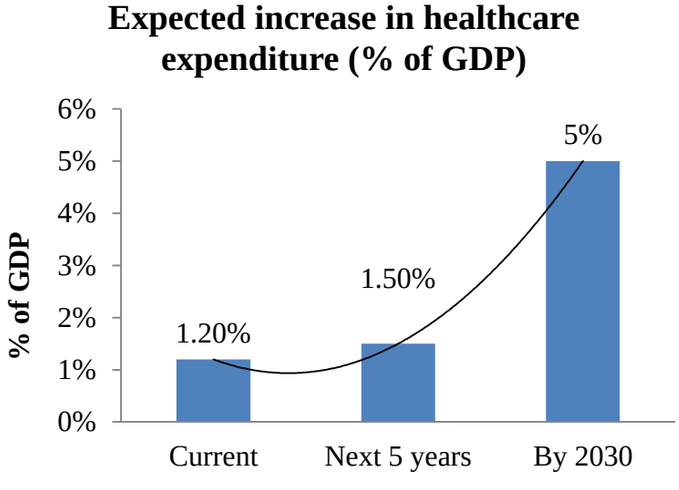
1. Indian pharma industry to achieve double-digit growth by 2030

It is expected that the Indian pharmaceutical industry may achieve a target of double-digit growth by the year 2030. A regulatory support from the Indian government such as increased budgetary allocations for healthcare and promotion of innovation would affect this.

The Indian government could also help the Indian pharmaceutical industry to achieve this target by simplifying regulatory approval processes, setting a coherent pricing policy framework, and creating a separate Ministry of Pharmaceuticals and dedicated zones for creation of medicines, are some of the ways that the government could help the industry achieve the ambitious target of becoming a USD 120-130 billion industry by 2030.

It is expected that the government should also aim to increase expenditure on healthcare from 1.2% from current to 2.5% of GDP by 2024, and to 5 per cent by 2030, for the industry to grow.

Source: economictimes.indiatimes.com



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PHARMA INDIA

2. IICT researchers discover new drug molecules from natural products

A team of researchers at the Indian Institute of Chemical Technology (IICT), Hyderabad, have discovered three new potential drug molecules.

The researchers have extracted these new molecules from natural products such as neem, fruits and herbs.

These molecules have the potential to be developed into drugs for curing the diseases related to brain, and cancers like pancreatic and breast cancers in patients.

The researchers have discovered the followed drug molecules:

Nimbolide from neem	• Nibolide has the potential to fight against pancreatic carcinoma.
Flavonoid	• Flavonoid is the most commonly occurring phytonutrient and abundant in fruits and vegetables. • Flavonoid contains oxygen as one of the atoms that could be replaced with nitrogen and change its properties: may be effective for brain cancers and other CNS related disorders.
Third molecule	• Extracted from herbs, used generally by Ayush practitioners as a taste enhancer for bitter herbal and Unani medicines. • This new molecule has the potential to cure breast cancer and other related disorders in cancer patients.

Source: pharmabiz.com

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PHARMA INDIA

3. India-US joint research grants on vaccine adjuvant development

The National Biopharma Mission (NBM), an Industry-Academia Collaborative Mission, is supporting the priority area of vaccine research and development in the Department of Biotechnology (DBT).

NBM is an Industry-Academia Collaborative Mission for Accelerating Early Development in Biopharmaceuticals, being implemented by the Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking of DBT aiming to create an ecosystem for innovative indigenous product development by researchers, startups and SMEs (Small and Medium Enterprises) to make Indian biotech industry globally competitive.

Indo US Vaccine Action Programme (VAP) is one of the oldest bilateral programmes that support a wide range of collaborative activities related to immunology, infectious disease biology and vaccine research between India and the USA. Under the VAP programme, the Department of Biotechnology in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID)-National Institutes of Health (NIH) invites proposals for the discovery, development, and/or preclinical testing of vaccine adjuvants. This joint DBT & NBM-BIRAC call will leverage the funding expertise of both the organizations.

Source: biospectrumindia.com

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PHARMA INDIA

4. Non-wearable sleep and breathing monitors for children

Raybaby, a health tech start-up, has developed a non-wearable sleep and breathing monitor for children. The company is now looking to enter the Indian market besides UK and Japan. Started in 2016, Raybaby has sold >2,000 non-wearable sleep and breathing monitors, mostly in the US market. According to the company, the device combines a radar sensor with an Artificial Intelligence (AI) powered platform, and is an accurate baby monitor.

Lumos Health is a market access programme focused on scaling technology start-ups in healthcare and life sciences. This programme is powered by Anthill Ventures & HCG. Incidentally, Raybaby was part of the shortlisted six start-ups under this programme.

The medical tech start-ups in India are definitely on the rise. The emerging trends in this space are for noncontact monitoring and early detection systems.

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. CDSCO to amend Form MD-11: Required to audit medical device facility

The Central Drugs Standard Control Organisation (CDSCO) is planning to amend the Form MD-11 under the Medical Devices (MD) Rules, 2017.

This Form facilitates the notified body or medical device officer to carry out effective audit for the medical device facility. The proposal to amend Form MD-11 was deliberated at the Drug Technical Advisory Board (DTAB) meeting held recently in Delhi.

Form MD-11 currently specifies that the central licensing authority (CLA) or state licensing authority (SLA) should serially number and duly stamp the pages of the audit or inspection book [as per clause (B)(i)].

The pages, except the first and the last pages shall include the name and designation of the auditor or medical device officer. Therefore, it would be appropriate that (B)(i) may be amended to serially number the pages of the audit or inspection book.

Source: pharmabiz.com

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REGULATORY ROUND-UP

2. DCGI guidance document on formulation development as per WHO guidelines

The Drug Controller General of India (DCGI) drafted a report in accordance with the World Health Organization guidelines regarding the development of guidelines on pharmaceutical development for Indian companies. According to the committee members, the WHO guidelines were quite similar to the practical situations in India.

As per Form 29 of the D&C Rules, the pharmaceutical manufacturers need to produce all documents concerning procurement and possession of the raw materials used in the proposed formulations. Similarly, the facility for the purpose of product development has to be owned or outsourced to third party contract research organizations which should have a valid license in Form 29 issued by the competent licensing authority.

The draft guidelines further recommend the introduction of the concept of retest period for active pharmaceutical ingredients (APIs), introduction of the definition of 'generic product' in the D&C (Drugs and Cosmetics) Rules, and mentioning of the overages requirements/limits in Schedule V and in IP, in the monograph of each drug.

Source: pharmabiz.com

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REGULATORY ROUND-UP

3. Inclusion of dossier approval in D&C rules to grant manufacturing license

The Drug Technical Advisory Board (DTAB) warrants the inclusion of provision of dossier approval to grant manufacturing license for drugs and they have recommended the same to the Union Health Ministry to amend the Drugs and Cosmetics (D&C) Rules, 1945.

Furthermore, the DTAB has also recommended issuing appropriate guidelines for the applicability of these provisions for 1) modified release dosage forms, and 2) products involving complex or special manufacturing technology.

An amendment in the D&C Rules, 1945, was made earlier in April 2017 according to the DTAB, which mandated the submission of bio-availability or bio-equivalence studies for the grant of manufacturing license. The applicants are required to submit the results of bio-equivalence study while submitting the application for grant of manufacturing license of oral dosage form of drugs falling under the Bio-pharmaceutical Classification System (BCS) Category II/ IV.

Source: pharmabiz.com

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REGULATORY ROUND-UP

4. Data interoperability: FDA to roll out modernization plan

The US Food and Drug Administration (FDA) is modernizing the technology infrastructure and framework and is expected to roll out an action plan to define the same in the coming months.

In recent years, the FDA has made efforts for this modernization with the reorganization of the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research.

In the journey towards interoperability, the next steps are critically evaluating interoperable technologies, ensuring the availability, reliability and well-characterization of the data and matching the best solutions to the characteristics of a patient at the point of care. The US FDA plans to better engage the tech community to update how the agency interfaces with the stakeholder community.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Boehringer and MD Anderson partners on virtual R&D center

Boehringer Ingelheim (BI) and The University of Texas MD Anderson Cancer Center have partnered to create a joint Virtual Research and Development Center. The new initiative will allow data sharing and analysis between the companies with a focus on research in oncology.

The drug pipeline of BI will be combined with the drug development capabilities of MD Anderson under this partnership that will generate potential therapies for multiple cancers, such as gastrointestinal and lung cancers. The companies will look at various phases, such as research, development and / or clinical stages under this partnership.

The new Virtual Research and Development Center will initially work on Boehringer's KRAS pathway inhibitors and a TRAIL-R2 antibody system. This system has the potential to induce death of cancer cells.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Bayer agrees to acquire biotech BlueRock for $1bn

German multinational pharmaceutical company Bayer has signed an agreement to acquire US-based biotechnology company BlueRock Therapeutics.

Bayer and founding investor Versant Ventures BlueRock at the end of 2016 with a $225m Series A Financing as part of the Leaps by Bayer unit. Bayer thus owned a 40.8% stake in the biotech, which develops engineered cell therapies in the fields of neurology, cardiology and immunology using an induced pluripotent stem cell (iPSC) platform.

Bayer will now acquire the remaining 59.2% stake in the company by paying around $240m in cash upfront at the closing of the transaction and an additional $360m after achieving pre-defined development milestones.

Bayer will now own full rights to BlueRock's CELL+GENE platform, which encompasses its broad intellectual property portfolio and associated technology platform including proprietary iPSC technology, gene engineering and cell differentiation capabilities.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Mylan to merge with Pfizer's unit Upjohn

Mylan has signed a contract with Pfizer to combine the latter's off-patent branded and generic medicines division Upjohn. This agreement will lead to the formation of a new pharmaceutical company. The deal will involve Upjohn's spin-off from Pfizer and simultaneous merger with Mylan, a major generic drug player.

The stocks of Mylan will be converted into one share of the new company. The share of the shareholders of Mylan and Pfizer shareholder will be 43% and 57% for the combined company.

The estimated revenue generation of the new company is ~$20bn in 2020. The company portfolio includes generics, over-the-counter products, prescription medicines and biosimilars.

The portfolio of Upjohn includes several established brands such as Viagra, Lipitor and Celebrex.

Boards of directors of both companies have approved the transaction, which is subject to Mylan shareholder approval and customary closing conditions. The expected completion of the deal is in mid-2020. The new company will have a total outstanding debt of around $24.5bn at closing.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Sensyne Health and Bayer: collaborated on AI drug development

A UK-based clinical artificial intelligence (AI) technology firm Sensyne Health has partnered with Bayer, a German pharmaceutical company, to accelerate the development of new heart therapies. Sensyne Health will allow Bayer to use the former's AI platform in the clinical development of therapies for cardiovascular diseases under this initial two-year deal.

According to Sensyne Health, the real-world evidence from its clinical AI analysis can help in accelerating the process for drug discovery and development and enable better patient outcomes. Sensyne is expected to generate £5m in revenues for over two years under this agreement.

AI is increasingly becoming a part of the pharmaceutical industry as witnessed with multiple big pharmaceutical companies having signed deals to purchase the technology within past few months.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. FDA approves Roche's tumour-agnostic drug

The US Food and Drug Administration (FDA) has approved Rozlytrek (entrectinib), a small-molecule tyrosine receptor kinase (TRK) inhibitor, for the treatment of adults with ROS1-positive metastatic non-small cell lung cancer (NSCLC).

The FDA has approved the drug with two indications for prices at almost half of Bayer's similar drug. The drug was separately granted accelerated approval for the treatment of adults or children aged > 12 years with solid tumors that have a gene fusion of the neurotrophic tyrosine receptor kinase (NTRK).

Roche will be pricing the drug at $17,050 per month, significantly lower than Bayer's Viktrakvi (monthly cost: $32,800). The treatment with Rozlytrek demonstrated shrinking of tumors in 78% of ROS1- positive patients, and nearly half of NTRK gene fusion-positive patients in the Phase I and II clinical trials.

Source: pharmatechnologist.com

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DRUGS: APPROVALS AND LAUNCHES

2. Dr Reddy's launches bevacizumab biosimilar in India

Dr Reddy's Laboratories (DRL) has launched a biosimilar of Roche's Avastin (bevacizumab) in India. The drug is indicated for the treatment of various types of cancers. Versavo, DRL's biosimilar, is available in strengths of 100 mg and 400 mg single use vials.

The biosimilar product will help improve access to high quality therapy at an affordable cost, addressing the needs of patients with different cancers in India.

Avastin and its biosimilars had India sales of around Rs 223 crore MAT for the most recent twelve months ending in December 2018 according to Ipsos India Tandem Oncology Monitor.

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. Regeneron's pre-filled syringe for aflibercept approved by FDA

The US Food and Drug administration (FDA) has approved Regeneron's Eylea pre-filled syringe injection. The FDA had requested additional data on the product last year. The US FDA approved the chemistry manufacturing and controls (CMC) prior approval supplement (PAS) for the Eylea (aflibercept) injection pre-filled syringe.

The FDA had rejected Eylea and issued a complete response letter (CRL) to Regeneron regarding "ongoing labelling discussions" in August 2018. The FDA approved the supplemental biologics license application for Eylea, with a 12-week dosing schedule 4 days after issuance of CRL.

Furthermore, FDA had denied Regeneron's prior-approval supplement in October 2018, and had requested additional information regarding manufacturing and supply processes and the completion of a usability study evaluating a single injection of the pre-filled syringe in 30 patients.

The 2mg single-dose sterilized pre-filled syringe is expected to be available in the market by the end of 2019.

Source: biopharma-reporter.com

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DRUGS: APPROVALS AND LAUNCHES

4. Upadacitinib: New rheumatoid arthritis treatment

Rinvoq (upadacitinib) from AbbVie has received the US Food and Drug Administration (FDA) approval and is expected to be available in the US market by August 2019 for the treatment of adults with active rheumatoid arthritis. Rinvoq (upadacitinib) is a once-daily, oral, small molecule Janus kinase inhibitor (JKI). The drug was approved by the US (FDA) for the treatment of adults with rheumatoid arthritis (RA), with inadequate response to methotrexate.

The FDA approval was based on a Phase III program in 4,400 patients that evaluated the efficacy, safety, and tolerability of the drug (total of 5 studies: SELECT-EARLY, SELECT-MONOTHERAPY, SELECT-COMPARE, SELECT-NEXT and SELECT-BEYOND). RINVOQ (upadacitinib) met all primary and ranked secondary endpoints across a variety of patients with moderately to severely active rheumatoid arthritis.

- SELECT-EARLY: ACR50 at week 121: 52% with RINVOQ 15 mg vs. 28% with MTX (methotrexate)
- SELECT-MONOTHERAPY: ACR20 at week 141: 68% with RINVOQ 15 mg vs. 41% with continued MTX
- SELECT-COMPARE: ACR20 at week 121: 71% with RINVOQ 15 mg + MTX vs. 36% with placebo + MTX
- SELECT-NEXT: ACR20 at week 121: 64% with RINVOQ 15 mg + csDMARDs vs. 36% with placebo + csDMARDs (methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, gold salts)
- SELECT-BEYOND: ACR20 at week 121: 65% with RINVOQ 15 mg + csDMARDs vs. 28% with placebo + csDMARDs

The European Medicines Agency and regulatory agencies in Canada and Japan are currently reviewing Rinvoq for approval.

Source: pharmatechnologist.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Activated carbon: acts like a slow-release drug capsule

Researchers at the University of Illinois at Chicago (UIC) have tested activated carbon in combination with Acyclovir to determine if the mineral could trap viruses from infecting the eye.

The researchers have got positive results. They now evaluated if loading the porous carbon with acyclovir could synergistically enhance the activity of acyclovir.

A charcoal delivery system with drug encapsulated carbon known as DECON was developed. In their experiment, researchers noted that activated carbon not only absorbed acyclovir into its pores but also slowly released it over a period of time. This phenomenon could be helpful in protection against herpes infections.

Source: pharmatechnologist.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. ViiV Healthcare reports positive data on long-acting HIV treatment

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, reported positive results from its global Phase III ATLAS-2M study investigating a combination treatment of cabotegravir and rilpivirine. The study met its primary endpoint of non-inferiority, showing similar efficacy of cabotegravir and rilpivirine administered every eight weeks compared to a four-week administration.

"The ATLAS-2M study results mean that people living with HIV could maintain viral suppression with six total treatments per year, instead of a daily oral treatment, 365 times per year," said Kimberly Smith, head of global R&D at ViiV Healthcare.

The injection displayed virologic suppression rates similar to that of standard care, at 92.5% for the injection against the standard of care at 95%. In addition, patient satisfaction was higher with the long-acting treatment, with 86.4% preferring the results from its previous Phase III studies.

Source: pharmatechnologist.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Positive results from CONQUER study of galcanezumab

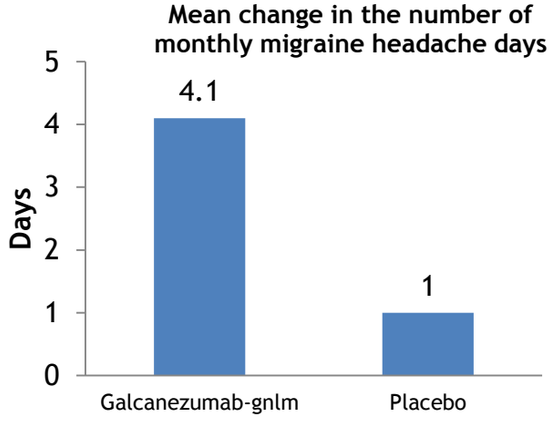
Eli Lilly and Company has reported positive results from the Phase III CONQUER study of Emgality (galcanezumab-gnlm) in patients who failed previous migraine preventive treatments.

The double-blind, global study was conducted in 12 countries and enrolled a total of 462 patients with chronic (n=193, 41.7%) or episodic migraine (n=269, 58.2%).

It evaluated the efficacy and safety of monoclonal antibody Emgality in the preventive treatment of chronic and episodic migraine in patients.

The study met its primary objective of demonstrating superiority of Emgality versus placebo in the overall mean change from baseline in the number of monthly migraine headache days across Months 1 through 3 (4.1 days vs. 1 day, P<0.0001).

Source: clinicaltrialsarena.com



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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Amgen and Allergan announce positive data for ABP 798

Amgen and Allergan have reported positive data from a comparative clinical trial of ABP 798 to treat patients with CD20-positive B-cell non-Hodgkin's lymphoma. The randomized, double-blind comparative JASMINE study evaluated the efficacy and safety of biosimilar candidate ABP 798 compared to Rituxan (rituximab) in lymphoma patients.

The JASMINE study enrolled a total of 256 adult patients randomized to receive either ABP 798 or rituximab at a dose of 375mg/m^2. ABP 798 was administered as an intravenous (IV) infusion once weekly for four weeks followed by dosing at weeks 12 and 20.

The trial's primary endpoint, overall response rate (ORR) at week 28, was found to be within the prespecified margin for ABP 798 compared to Rituxan. Overall, the study reported a clinical equivalence between the agents.

Amgen carried out the first study in patients with moderate-to-severe rheumatoid arthritis (RA). The latest trial of ABP 798 is the second of two studies aimed at supporting regulatory submissions for the drug candidate.

Source: clinicaltrialsarena.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Pharma players file suit in Canada challenging new rules to lower drug prices

A complaint has been filed by 5 pharmaceutical companies in a Canadian court that have challenged the constitutionality of new Canadian regulations that are intended to lower patented drug prices.

The complaint was filed by the Canadian arms of Merck & Co, Janssen Inc, Germany's Bayer AG and Boehringer Ingelheim, and France's Servier Inc in Quebec's Superior Court in Canada.

The Patented Medicine Prices Review Board (PMPRB) sets maximum drug prices in Canada. The new rules were announced earlier this month and are published in the official register and will become effective from July 1, 2020.

All five firms have said that the prices of medicines were always regulated by 10 provinces, not the federal government. According to the new regulations, PMPRB can set the drug price caps too.

Source: europeanpharmaceuticalreview.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Novo Nordisk vs. Mylan: Patent dispute over liraglutide drug in US

Novo Nordisk and Mylan are facing a legal battle after the latter filed a new drug application for a generic of Novo Nordisk's Victoza.

A lawsuit has been filed by Novo Nordisk against generic drug maker Mylan to stop it from marketing a generic version drug Victoza (liraglutide).

Novo Nordisk filed the suit at the US District Court for the District of Delaware claiming that an Abbreviated New Drug Application (ANDA) filed by Mylan with the US Food and Drug Administration (FDA) for the generic liraglutide is illegal.

Liraglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, approved in 2010 for adults, has recently gained an extended indication for adolescents aged 10 to 17.

Source: europeanpharmaceuticalreview.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Medicure announces settlement of patent infringement vs. Gland Pharma

Medicure International Inc., has reported the settlement of its ongoing patent infringement action against Gland Pharma Ltd. ("Gland") in the U.S.

Medicure had filed the patent infringement action against Gland alleging infringement of the patent no 6,770,660 (the '660 patent) in response to Gland's filing of abbreviated new drug application (ANDA) for marketing a generic version of AGGRASTAT® (tirofiban hydrochloride) injection before the expiration of the '660 patent.

Gland has acknowledged that the 'Patent No. 6,770,660 is valid, enforceable and infringed' under the settlement agreement.

As a result to the settlement, Medicure is entering into a license agreement with Gland and the anticipated launch of Gland's generic product on March 1, 2023. The '660 patent is listed in the FDA's orange book with an expiry date of May 1, 2023.

Source: prnewswire.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Lipocine's patent infringement lawsuit against Clarus therapeutics

Lipocaine Inc., a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, said in a statement that Lipocine's patent infringement lawsuit against Clarus's JATENZO® drug product relating to six of Lipocine's U.S. patents will be heard by the U.S. District Court of Delaware begining August 24, 2020.

Lipocine plans to seek a permanent injunction for Clarus's infringement.

TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men.

Source: prnewswire.com

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TECHNOLOGY /NDDS

1. Nanoscale silica bottles for drug delivery

According to researchers at the Georgia Institute of Technology, silica bottles filled with medicine and a temperature-sensitive material, can be used for targeted drug delivery for destroying cancer cells in the body. The study showed that nanoscale silica bottles, 500th of the diameter of a hair, could be used to deliver cancer drugs.

The researchers created silica-based hollow spheres of 200 nm size and each contained a small hole in the surface. Inside the spheres, fatty acids, near-infrared dye, and anticancer drugs are packed with an infrared laser. The laser is absorbed by the dye and is used to quickly melt the fatty acids in the sphere releasing the drug.

This innovative method can help in targeting tumors at particular sites in the body. The drugs are released only when the temperature is elevated thus avoiding side effects.

Source: pharmatechnologist.com

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TECHNOLOGY /NDDS

2. Flexible transistors for body-worn and implantable medical devices

Recently, engineers in a variety of institutions have been making great progress in the field of flexible electronics. A team of engineers at Tuft university has developed a transistor, which is made from linen thread, that enables to create electronic devices made entirely of thin threads.

This will allow for completely flexible devices made of thread that can be integrated into clothing, worn directly on the skin, or even used in electronic medical implants, including ones that can attach to a beating heart.

Researchers have combined thread-based sodium and ammonium ion sensors with an integrated circuit, which allows to measure biomarkers using a completely flexible device. The flexible transistors can be manufactured without requiring a clean room and using a relatively cheaper process.

“In laboratory experiments, we were able to show how our device could monitor changes in sodium and ammonium concentrations at multiple locations,” said a researcher at Tufts University School of Engineering and first author of the study.

Source: medgadget.com

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TECHNOLOGY /NDDS

3. New optical method for functional brain imaging

A new non-invasive brain imaging method has been developed to study the shape of the brain's surface and oxygenation of brain tissues. The new method has been developed by researchers from the University of Birmingham in the UK and Washington University School of Medicine. With this method, a deeper brain imaging with higher resolution can be performed as compared with available methods.

In future, brain mapping, ICU patient monitoring, and early diagnosis of a number of neurological conditions can be improved with this exciting discovery.

Functional neuroimaging provides valuable medical information of brain tissues and functional near-infrared spectroscopy (fNIRS), a non-invasive inexpensive technology helps to identify the brain surface and measure oxygenation.

In their new method, the researchers tested the potential of a new optical imaging system with 32 light sources and 30 light receivers to measure changes in the phase and intensity of light. The researchers have highlighted the theoretical calculations and simulations that describe the advantages of their approach.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. Optic nerve stimulation offers hope for visually impaired

Researchers from the Swiss Federal Institute of Technology Lausanne (EPFL) and Scuola Superiore Sant'Anna, Italy, have developed a new type of intraneural electrode called OpticSELINE to stimulate the optic nerve, which can bypasses the eyeball entirely and sends messages to the brain. This will pave the way for a new visual aid for daily living for the visually-impaired.

The researchers have published their findings of successful testing of the technology in rabbits in the journal *Nature Biomedical Engineering*. The scientists delivered electric current to the optic nerve via OpticSELINE and measured the brain's activity in the visual cortex in order to understand how effective these electrodes are at stimulating the various nerve fibers within the optic nerve.

"This limited number of electrodes is not sufficient to restore sight entirely. But these limited visual signals could be engineered to provide a visual aid for daily living," said Diego Ghezzi from EPFL.

Source: indiatimes.com

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WHAT'S NEW AT LAMBDA

1. Successful completion of USFDA inspections at 2 trial sites in Ahmedabad

The US Food and Drug Administration (US FDA) completed its inspection at two trial sites of Lambda Therapeutic Research Limited at Ahmedabad, Gujarat. The inspections were carried out from 29 July 2019 to 02 August 2019 at one site and from 05 Aug 2019 to 09 Aug 2019 at another site for a pharmacokinetic study of methotrexate. Overall, the inspections were successful with zero 483s.

2. Successful completion of surprise USFDA inspections at Toronto and Mumbai

The US Food and Drug Administration (US FDA) completed its surprise parallel inspection at 2 sites of Lambda Therapeutic Research Limited. The USFDA inspections took place at Lambda Therapeutic Research Limited's Toronto bioanalytical facility and Mumbai clinical facility. The inspections were carried out from 29 July 2019 to 02 August 2019. Both the facilities cleared the inspection with zero 483s.

3. Successful completion of USFDA inspection for Pharmacovigilance services

The US Food and Drug Administration (US FDA) completed its Pharmacovigilance inspection at one of Lambda's client sites at Raleigh City in North Carolina, USA. The inspection was carried out from 27 August 2019 to 29 August 2019. The inspection went off successfully without any observations.

The successful completion of these inspections yet again proves Lambda's high end quality and impeccable regulatory track record.

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WHAT'S NEW AT LAMBDA

4. Lambda to work on KnowledgeNET based eTMF

An electronic trial master file (eTMF) is a formalized means of organizing and storing documents in clinical trials. Lambda Clinical Trial team is now moving from paper based TMF to eTMF in order to maintain all the essential documents related to clinical trials in an electronic format. For this e-TMF, Lambda team is going to use KnowledgeNET as the platform, which is designed for handling clinical trial related documents in a coherent format electronically. This e-TMF software allows effective storage of the essential documents generated during the course of a clinical trial, which further enables ease of access for any purpose, e.g.: review, resolution of queries, regulatory/sponsor audit, etc.

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