Lambda Research Newsletter

October 2017

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Research Accelerated

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GLOBAL NEWS

1. MNCs dominate over domestic Indian peers with patented products

Currently, when pharmaceutical companies are trying to overcome the price cuts and regulatory issues, multinational companies (MNCs) are growing at a much faster rate as compared to its domestic peers due to better product mix.

Domestic pharmaceutical companies control almost 80% of the total Rs. 1 lakh crore Indian pharma markets. But due to the launch of specialized patented products in Indian market, MNCs are growing at a much faster rate as compared to the Indian companies.

In the month of August, the overall growth of Indian pharma companies was 1.4% whereas it was 6.2% for MNCs such as AstraZeneca, Janssen (division of Johnson & Johnson) and Boehringer Ingelheim.

MNCs have a small base as compared to Indian pharma companies but their patented products are helping to dominate over domestic companies. The core strength of Indian pharma market anti-infective segment registered a fall of 8% in August 2017, whereas anti-diabetics and cardiac disease drugs show double digit growth.

Source: health.economictimes.indiatimes.com

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GLOBAL NEWS

2. FDA to promote generic business for complex drugs

The US Food and Drug Administration (FDA) is now going to run a new program to make complex drugs more affordable. Under this program, the FDA is going to promote generics of these complex drugs.

Complex drugs are combination of drugs and devices, are very expensive and widely used. These complex drugs did not get any competitors even after patent expiry and the innovator kept their prices very high.

Creating copies and near copies of these drugs and their approval as generic is very difficult. Hence, now FDA will provide guidelines to the companies on how to win approval for such generics made for the benefit of the society.

Some of the complex drugs which require generics in the market include Advair inhaler and injected medicines, Forteo for osteoporosis, Copaxone to treat multiple sclerosis and Victoza for high blood sugar. The cost of these monthly medications without insurance is about $400 for Advair up to $5,200 for Copaxone.

Source: pharmpro.com

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GLOBAL NEWS

3. US FDA takes action against >500 websites selling medicine online

The US Food and Drug Administration (FDA) in partnership with international regulatory and law enforcement agencies took action against >500 websites selling medicines online. This action was taken as part of Operation Pangea X during the 10th annual International Internet Week of Action (IIWA).

These sites were selling potentially dangerous unapproved versions of the prescription drugs, including injectable epinephrine products, antibiotics and opioids, to the consumers.

Under this action, the USFDA sent 13 warning letters to the operators of 401 online websites. These websites were operated by different sophisticated criminal networks. The USFDA also seized around 100 website domains in Chicago, Miami and New York during the IIWA.

According to the FDA, these sites can also pose various risks other than health-related such as credit card fraud, identity theft and computer viruses etc. After this action, the FDA also provided information that customer can buy online drugs from “Be Safe Rx: Know Your Online Pharmacy”.

Source: pharmabiz.com

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GLOBAL NEWS

4. Bayer AG removes contraception implant from global market

Bayer AG, a German pharmaceutical manufacturer, has removed its 10 years old contraception implant Essure form all the markets other than USA. Bayer AG pulled this product out of the market due to the several lawsuits filed by the women of USA and France who suffered with severe side effects after the installation of the device.

Thousands of complaints were filed against the product for its side effects like extreme pain, post-implant miscarriage, thinning hair, puncturing of organs, cramping, bloating, fatigue, dizziness and depression. In some cases, the patients were left with no other options other than hysterectomy for removal of the device.

The product was already suspended temporarily by the Brazil's National Health Surveillance Agency, ANVISA in February 2016, and was subsequently banned in July 2016. It was pulled off from the markets of The Netherlands and Finland in May and from Canada in June, 2017.

The US Food and Drug Administration (FDA) reported around 15,000 side effects of Essure from November 2002 to December 2016. After these side effects, Bayer AG was ordered by the agency to conduct continuous testing of the product and mention its side effects on the packaging.

Source: Casassus B et al. Lancet. 2017;390(10102):1576

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PHARMA INDIA

1. Slow growth rate of Indian pharma market in August after GST

Indian pharma market shows a sluggish growth rate of 2.4% in the month of August after a month of goods and services tax (GST) implementation. This sluggish rate shows the deep impact of GST on the Indian pharma market. Although the sales in August recovered slightly compared to the month of July.

This slump is expected to continue for a couple of months. According to a survey, chemists and stockists stated that there is no improvement in the supply chain after the implication of GST. Softwares of stockitists are now updated whereas the process is still ongoing for the chemists.

With a growth rate of 2.4%, pharma sales for the month of August is around Rs. 10,317 crores with the maximum growth rate of 15.7% for Zydus Cadila, followed by 11.1% for Mankind and 8.9% for Lupin. Market is pulled down by -8% by anti-infectives whereas dermatology medicines showed a growth rate of 12.7%. Gastro-intestinal drugs showed a growth rate of 2.4% along with 10.6% for anti-diabetic drugs.

Impact of GST was high in the first month due to some issues like difficulties in software updation with stockist' billing being hampered to a large extent.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

2. Domestic stent makers to capture a greater share of India's coronary stent market

Domestic stent makers of India are trying to capture a greater share of the coronary stent market in India after the prices of devices were slashed by the Indian government. According to some multinational companies, this move has made it unviable to supply the latest generation model, and in this situation their local competitors are coming out as winners.

A positive increase in the sales of domestic manufacturers can be seen in the last six months. This increase is mainly due to the reduction in prices of the stunts increasing its affordability.

Major device manufacturers of India like Sahajanand Medical Technologies (SMT), Translumina Therapeutics and Meril Life Sciences captured about 30% of the total stent market, about 1,500 crores last year. In this year, 60% of the stent market is expected to be captured by the domestic firms, about 1,200 crores due to slashed prices.

Till now, it is not clear how these price caps will affect the multinational firms' sales like Abbott, Medtronic and Boston Scientific, which were holding 60% of the stent market until last year.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

3. Class-action lawsuits against Indian pharma companies on the rise

Recently, the number of class action lawsuits filed against Indian pharma companies are rising continuously. These companies are alleged for the pay-for-delay conspiracies as well.

American federal securities filed dozens of lawsuits for alleged violation against some big generic companies of India. These lawsuits are either individually or in a group comprising drug companies also from some other countries.

Some companies have settled the matter by negotiations while some class action law suits are still ongoing. The number of these lawsuits has been increasing after 2014.

Sun Pharmaceutical Industries and Dr Reddy's Laboratories are on the top of the list with several class action lawsuits. Other than these 2 companies, various other companies like Aurobindo Pharma Limited, Lupin and erstwhile Ranbaxy, which was merged with Sun Pharmaceutical Industries are also facing the same problems with the lawsuits.

Source: business-standard.com

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PHARMA INDIA

4. Government notified all companies to supply all knee implants

To pre-empt any shortages in the supply/availability of knee implants, the Government of India has notified all the implant makers and importers to continue their supply in similar manner for next 6 months as it was before slashing the prices.

This move by the government is to prevent any kind of shortage in the knee implants after the decision of National Pharmaceutical Pricing Authority (NPPA) for reducing the prices of knee implants. In the month of August, the NPPA reduced the prices of knee implants between Rs 54,000-77,000 based on the materials used for manufacturing.

This government notification resulted due to the application of various stent maker companies for the discontinuation of some stents due to slashed prices.

In last few weeks, NPPA has given permission to Abbott Healthcare for the discontinuation of dissolvable stent 'Absorb' and its metallic drug eluting stent 'XIENCE Alpine'. It is possible that in some time those companies selling knee implants will also request to withdraw some of their brands from India.

Source: health.economictimes.indiatimes.com

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REGULATORY ROUND-UP

1. New FDA guidelines on safety of interoperable devices

The US Food and Drug Administration (FDA) finalized a guidance document for interoperable devices. These guidelines explain recommendations on how a medical device can be used with other devices and information system securely.

These guidelines are meant to help manufacturers and FDA staff to identify considerations, which will allow them to connect and use data of one electronic system in the other.

These guidelines are mainly meant for the safe use of one device when used with another device as data generated by one device can vary with the other due to different parameters and units in data exchange system. This guidance of FDA recommends appropriate functional, performance, and interface requirements for connecting one data system devices with others.

Importance of transparency, recommending that designers and manufacturers provide information on a device's performance and interface characteristics, was also stressed so that one device can be used safely with the other. According to the FDA, agency and industry may need up to 60 days to perform activities to operationalize the policies within the guidance.

Source: raps.org

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REGULATORY ROUND-UP

2. Brexit can permanently damage capabilities of EMA

In a recent survey by the European Medicines Agency (EMA), it was found that only 6% of staff is ready to relocate into 19 different cities after leaving London. This shows that Brexit may lead to permanent damage to the European regulatory system.

This survey was done by EMA to check how likely the staff is interested to relocate into different cities. A sharp difference was found for the retention rates, which suggest that this will have major impact on EMA's ability to retain enough staff for proper functioning.

Retention rate for 8 countries was below 30%, and only 6% staff was likely to relocate. In 11 other countries, the relocation rate was about 60%. This warning was based on the assessment of EMA.

According to the assessment carried out by EMA, 462 full time employs will be required for the proper functioning of drug safety monitoring and other work. EMA thinks the system would fully recover within five years.

Source: fiercebiotech.com

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REGULATORY ROUND-UP

3. FDA introduces new statistical approaches for evaluating similarity for Biosimilars

The US Food and Drug Administration (FDA) released another set of guidelines for biosimilars evaluation. This draft of guidelines contains information which a sponsor should obtain regarding the structural, physiochemical and functional attribute of a reference product.

This 15 pages draft contains recommendations for evaluating analytical similarities of the biosimilars. These guidelines also stated that for the approval of biosimilar, it should be directly compared with the U.S. licensed reference product. The final analytical similarity report, which should be submitted as part of a biosimilar application containing analytical similarity assessment plan, should be developed in four stages as recommended by the FDA and contains:

- Differences in age of the lots produced at testing;
- Multiple testing results;
- Assay performance;
- Differences in attributes that will be considered acceptable.

The FDA also provided three tiers for acceptance criteria of biosimilars: ***Tier 1*** is for equivalence testing, ***Tier 2*** is the use of quality ranges, and ***Tier 3*** is an approach that uses visual comparisons. Other than the risk ranking, some other factors are also provided by FDA for further assessing the attribute and types of attributes or assays.

Source: raps.org

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REGULATORY ROUND-UP

4. FDA issues new guidance for combination product classification

The US Food and Drug Administration (FDA) issued the final guidance for classifying combination products as drugs, biologics or medical devices. These guidelines are combination of two 2011 draft guidelines which were drafted for the classification of a product under either device or drug.

Combination products are the combinations of 2 different FDA approved products. Classification of a combination product can affect the product development because classification will determine whether the sponsor needs to submit a new drug application (NDA), or biologics license application (BLA) or a 510(k) or premarket approval (PMA) application.

The final guidance was updated by the FDA for clarity and also includes a revised discussion of the agency's interpretation of the term "chemical action" as it relates to the definition of a medical device.

A discussion on reevaluating prior classification determinations is removed by the FDA, which was given in the draft classification guidance in response to comments from the industry.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Mundipharma acquires global rights for CAP7.1 of CellAct for the treatment of biliary tract cancer

Mundipharma acquires the worldwide development, commercialization and production rights to CAP7.1 from CellAct for the treatment of biliary tract cancer. The cost of this acquisition is more than $250m.

CAP7.1 is a new etoposide pro-drug acting particularly on the tumorous cells. Pro-drug gets converted into active metabolite in the gastrointestinal tract in presence of some enzymes. The drug is mainly focused on the release of higher doses of drug at the site of action for good safety and tolerability.

CAP7.1 was invented by the teaching hospital Charité - Universitätsmedizin Berlin, in Germany. The drug is indicated for the treatment of biliary tract cancer for which no second line agent is currently available.

The Phase 3 trial will be conducted by EDO pharma. EDO pharma will also be responsible for reformulation of treatment and manufacturing scale up. Under this deal, CellAct and Charité – Universitätsmedizin Berlin will receive sales-related income as royalty.

CAP7.1 showed positive results in a Phase 2 trial with a disease control rate of 56%. Results of the Phase 2 study were published in the *Journal of Clinical Oncology*.

Source: health.economictimes.indiatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Takeda collaborates with Shattuck Labs to develop immunotherapies based cancer treatments

Takeda Pharmaceutical collaborates with Shattuck Labs for the study and development of check point fusion proteins having potential to be used as advanced immunotherapy of breast cancer. In a single construction, this fusion protein is capable of restoring and improving immune system function.

Under this deal:

- Takeda will obtain development and marketing rights
- Shattuck Lab will use its Agonist Redirected Checkpoint (ARC) platform to form fusion proteins by combining two binding domains

ARC molecule of Shattuck Labs can block checkpoint molecules and simultaneously stimulate TNF superfamily co-stimulatory receptors present on the innate cells as well as on T-cells. These are the main targets for controlling immune system which gets disregulated in cancer.

Companies will conduct 2 pre-clinical and 4 discovery stage programmes under this collaboration, which will be funded by Takeda.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. SillaJen Bio Therapeutics collaborates with NCI to develop new colorectal cancer treatment

SillaJen Bio Therapeutics has entered into a cooperative research agreement with the National Cancer Institute (NCI) for the development of a new combination therapy for the treatment of colorectal cancer (CRC).

Under this agreement, SillaJen Bio Therapeutics and NCI will work together to study the new combination containing pexastimogene devacirepvec (Pexa-Vec), with anti-PDL1 and anti-CTLA4 antibodies.

For the evaluation, NCI is going to conduct an early Phase clinical trial in the patients of advanced-stage colorectal cancer. The patients will be recruited and treated at NCI. The Protocol will be developed by NIC and SillaJen jointly and the trial will be handled by NCI.

This deal will provide access to SillaJen to develop Pexa-Vec with NCI's scientific and clinical expertise.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. AstraZeneca to develop mRNA treatments for respiratory diseases in collaboration with MedImmune and Ethris

AstraZeneca has entered into 5 years strategic research collaboration with its global biologics research and development unit MedImmune, and German biotech Ethris for the development of therapy for respiratory diseases.

This new respiratory therapy is a stabilised non-immunogenic modified messenger ribonucleic acid (mRNA) therapy for the treatment of respiratory diseases. Under this collaboration:

- Ethris will receive €25m upfront along with research funding and is also eligible for future research and development milestones, including sales related royalties upon commercialization
- AstraZeneca and MedImmune will have worldwide licenses after completion of the research plan.

This mRNA treatment will deliver genetic instructions to the cell for the target cell to generate selected proteins for the prevention of disease. This technology can be implicated on the lungs where it allows replacing, inhibiting or augmentation of proteins, which cause respiratory diseases.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. Symbiomix Therapeutics receives FDA approval for Solosec

The US Food and Drug Administration (FDA) has approved Symbiomix Therapeutics' drug Solosec (secnidazole) for the treatment of bacterial vaginosis (BV) in adult women. Solosec contains 2g oral granules of secnidazol.

Solosec is a next generation 5-nitroimidazole antibiotic with enhanced pharmacokinetic properties. A single dose of the drug is efficacious and well tolerated.

The drug was approved by the US FDA based on data from two pivotal trials and an open-label safety study in BV. These trials showed that a single oral dose of 2g granules of secnidazol is effective for the treatment of BV.

No severe adverse events (AE) were associated with the drug. AE's associated with Solosec were mild to moderate. The US FDA provided fast track designation to Solosec along with at least 10 years of U.S. market exclusivity.

Source: drugs.com

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DRUGS: APPROVALS AND LAUNCHES

2. Canada receives three new generics from Mylan for the treatment of HIV

Mylan has launched three new generic anti-retroviral (ARV) drugs for the treatment of human immunodeficiency virus (HIV) in Canada. Drugs were approved by Health Canada.

Treatment includes:

- emtricitabine / tenofovir disoproxil fumarate at 200mg / 300mg indicated for the treatment of adult patients with HIV-1 infection along with some other ARV drug. FDC is alternative to Truvada.
- efavirenz / emtricitabine / tenofovir disoproxil fumarate at 600mg, 200mg and 300mg is indicated alone or in combination with some other ARV drug for the treatment of HIV-1 infection in adults. This FDC is an alternative to Atripla.
- tenofovir disoproxil at 300mg, for the treatment of HIV-1 infection in patients aged 12 and older in combination with some other ARV drug. FDC is a generic alternative to Viread.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

3. Duzallo receives FDA approval for the treatment of hyperuricemia

The US Food and Drug Administration (FDA) has approved Duzallo of Ironwood Pharmaceuticals, Inc. for the treatment of hyperuricemia associated with gout. The drug is effective in patients with gout in which appropriate doses of allopurinol alone was not able to achieve the target serum uric acid (sUA) level.

Duzallo is the fixed dose combination (FDC) of allopurinol and lesinurad. It is not approved for the treatment of asymptomatic hyperuricemia. This FDC can address both overproduction and underexcretion of serum uric acid which are the main causes of hyperuricemia.

Approval of Duzallo is based on a pharmacokinetic study that evaluated the bioequivalence of the fixed-dose combination of lesinurad and allopurinol compared to co-administration of individual lesinurad and allopurinol tablets. The efficacy and safety of the FDC were demonstrated in two pivotal Phase 3 clinical trials, CLEAR 1 (n=402) and CLEAR 2 (n=410).

Results of the studies showed that the FDC nearly doubled the number of patients who achieved target sUA levels of <6mg/dL at month 6 as compared to allopurinol alone. The FDC reduced the mean sUA to <6mg/dL in the 1st month and maintained through month 12.

Source: drugs.com, rheumatologyadvisor.com

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DRUGS: APPROVALS AND LAUNCHES

4. FDA approves Besponsa for the treatment of B-cell precursor ALL

Besponsa (inotuzumab ozogamicin) of Pfizer has been approved by the US Food and Drug Administration for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL) in adult patients.

Besponsa is a combination of a monoclonal antibody and a drug targeting CD22 antigen on the skin surface. Relapsed or refractory B-cell ALL is a rare disease which may lead to death within a few months, if not treated. Besponsa binds to the CD22 antigen on B-cells and causes cell death.

Approval of the Besponsa is based on a randomized, open-label, international, multi-center Phase 3 INO-VATE ALL trial. The trial was conducted to check the safety and efficacy of the drug on 326 patients with prior history of other medication. The study was published in the *New England Journal of Medicine (NEJM)*.

The rate of complete remission was significantly higher in the Besponsa group as compared to the standard-therapy group (80.7% vs. 29.4%, P<0.001).

Source: pharmaceutical-technology.com, Kantarjian HM et al. N Engl J Med. 2016;375(8):740-53

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Mirogabalin shows positive result in diabetic neuropathic pain

Mirogabalin of Daiichi Sankyo Company Limited showed positive results in the Phase 3 REDUCER trial for the treatment of diabetic neuropathic pain.

REDUCER was an Asian, Phase 3, multicenter, randomized, double-blind, placebo-controlled trail including 750 patients, aged 20 years or older, for 14 weeks in patients with diabetic peripheral neuropathic pain. The trial was followed by a 52-week open-label extension period.

The Phase 3 trial was conducted to evaluate the efficacy of mirogabalin by comparing with placebo. The trial was conducted in approximately 200 centers in Japan, Taiwan, South Korea and Malaysia.

Patients were randomized in the ration of 2:1:1:1 for mirogabalin 15 mg once-daily, mirogabalin 10 mg twice-daily, mirogabalin 15 mg twice-daily or placebo. Mirogabalin showed statistically significant reduction in diabetic neuropathic pain as compared to placebo. No significant safety concern was found with Mirogabalin.

Source: daiichisankyo.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. AstraZeneca's Bevespi Aerosphere® shows significant improvement in lung function in patients with COPD

BEVESPI AEROSPHERE™ (glycopyrrolate/formoterol fumarate) Inhalation Aerosol

AstraZeneca

Bevespi Aerosphere® (glycopyrronium and formoterol fumarate 14.4/9.6 µg) of AstraZeneca shows positive results in a Phase 3, PINNACLE 4 trial.

Bevespi Aerosphere® shows statistical significance over monotherapy of glycopyrronium in combination with formoterol fumarate and placebo.

The drug was administered by pressurized metered-dose inhaler (pMDI) twice daily to the patients suffering with moderate to severe chronic obstructive pulmonary disease (COPD). Based on the data from PINNACLE 4 trial, AstraZeneca will file a regulatory application for Bevespi Aerosphere® in Japan and China, in 2018.

PINNACLE 4 was a randomized, double-blind, 24-week, placebo-controlled, parallel-group, multicentre trial conducted on 1,756 patients across Asia, Europe and the US to check the safety and efficacy of Bevespi Aerosphere® in patients with COPD.

Bevespi Aerosphere® is a fixed-dose combination of glycopyrronium, a long-acting muscarinic antagonist along with formoterol fumarate, a long-acting beta-2 adrenergic agonist.

Source: worldpharmanews.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Dupilumab shows positive results in Phase 3 trial for the treatment of Atopic Dermatitis

Dupixent® (dupilumab) of Regeneron Pharmaceuticals, Inc. and Sanofi showed positive results in a Phase 3 CAFÉ study on adults with moderate to severe atopic dermatitis (AD). The patients in the trial were intolerant or inadequately controlled with cyclosporine A (CSA).

In the CAFÉ trial, Dupixent® showed significant improvement in the treatment of skin clearing, itching, and patient reported quality of life measures. The primary end point of the study was to achieve 75% or greater improvement in the affected area.

The study was a randomized 3 armed study including 325 patients for 16 weeks with either Dupixent® 300 mg weekly with topical corticosteroids (TCS), Dupixent® 300 mg every two weeks with TCS or placebo with TCS. In trial:

- 59% patients showed improvement with Dupixent weekly with TCS,
- 63% patients showed improvement with Dupixent every two weeks with TCS, and
- 30% patients showed improvement with placebo with TCS (P<0.0001)

The mean percentage change with weekly Dupixent with TCS was 78% where as 80% for once every two weeks whereas 47% for placebo plus TCS (P<0.0001).

Source: pharmpro.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Joint venture of Novartis and MMV launches patients trial for KAF156 against multidrug resistant malaria

Novartis and Medicines for Malaria Venture (MMV) have launched a patients' trial for evaluating the safety and efficacy of KAF156. KAF156 is a next generation antimalarial compound having the potential of treating drug resistant strains of malarial parasites.

The trial will be conducted using the combination of KAF156 and an improved formulation of lumefantrine at different centers in Africa and Asia.

KAF156 is a member of the novel class of antimalarial drugs -imidazolopiperazines. The proof of concept was shown in Phase 2a trial, which showed that the compound is fast acting and potent across the different stages of infection.

Now, a Phase 2b trial will test multiple doses of KAF156 in combination with lumefantrine. The trial will include feasibility studies of single dose in adults, adolescents and children. Novartis is developing the drug with scientific and financial support from MMV.

Source: worldpharmanews.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Scholar Rock receives patent for latent myostatin acting inhibitors for the treatment of neuromuscular diseases

The U.S. Patent and Trademark Office (USPTO) has granted a broad spectrum patent to Scholar Rock for covering any monoclonal antibody acting on the latent myostatin and prevent its proteolytic activation.

US patent 9,758,576 is granted to Scholar Rock for a broad protection of SRK-015. SRK-015 is a selective and local inhibitor for the activation of latent myostatin. The entire class of therapeutic antibodies acts by the same mechanism of action.

All these antibodies have therapeutic potential for the treatment of neuromuscular diseases and various other diseases associated with the nervous system. SRK-015 is developed by the company for the improvement of muscular strength along with the function in patients suffering with spinal muscular atrophy (SMA) and other disorders.

These monoclonal antibodies selectively inhibit signal of myostatin by blocking the proteolytic activation of the latent precursor. SRK-015 is the only candidate of this class and work by a different mechanism of action, with exclusivity through May 2034.

Source: biospace.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Tonix Pharma receives European patent for Cyclobenzaprine for the treatment of PTSD

Tonix pharmaceuticals received a European patent for Tonmya® (Cyclobenzaprine) for the treatment of Post-Traumatic Stress Disorder (PTSD).

Patent protects for the Tonmya® include patent for "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This Patent Will Provide Intellectual Property Protection until 2030. This patent may be further extended based on market authorisation.

Tonmya® is already designated as a Breakthrough Therapy for the treatment of PTSD by the U.S. Food and Drug Administration (FDA) and presently in a Phase 3 trial. This patent protects the use of cyclobenzaprine for the treatment of PTSD.

Tonmya® is a sublingual preparation of cyclobenzaprine that allows transmucosal absorption of the drug and bypasses first pass liver metabolism.

Various other forms of cyclobenzaprine are approved for the relief of muscle spasm associated with acute, painful musculoskeletal conditions. But Tonmya® has a different route of administration and pharmacokinetic profile as compared to other preparations.

Source: biospace.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Indivior UK Limited purchases DURECT'S patent for risperidone for $17.5 million

Indivior UK Limited signs an agreement with DURECT Corporation for the purchase of patent for risperidone for $17.5 million. Under this patent agreement, DURECT has assigned some US patent rights to Indivior. This patent agreement will provide intellectual property protection for RBP-7000. RBP-7000 is an investigational risperidone for once monthly injection in schizophrenia.

Indivior is going to submit a new drug application (NDA) for RBP-7000 to the US Food and Drug Administration (FDA).

According to this patent agreement, Indivior paid a non-refundable payment of $12.5 million to DURECT. Indivior will also pay a further $5 million to DURECT based on the regulatory milestones. This patent is extended through 2026.

Source: health.economictimes.indiatimes.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. USPTO approves patent for CG'806 of Aptose Biosciences and CrystalGenomics

The United States Patent and Trademark Office (USPTO) has granted the US Patent 9,758,508 to Aptose Biosciences and CrystalGenomics for CG'806.

The patent is for the pharmaceutical composition of CG'806 compound and methods for treating various diseases. This patent is granted for until the end of 2033.

Patent is entitled as "2, 3-Dihydro-isoindole-1-on derivative as BTK kinase suppressant, and pharmaceutical composition including same".

CG'806 is the first oral multi-targeted pan-FLT3/BTK inhibitor and has shown relevant impact on oncogenic targets.

Source: biospace.com

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TECHNOLOGY /NDDS

1. New injectable tissue patch can repair damaged heart

Researchers of University of Toronto Engineering have developed a tissue bandage, AngioChip for repairing damaged heart tissues. As for the repairing the tissues of heart damaged due to any kind of heart attack or any other medical condition, open heart surgery was required.

After the introduction of this new technique, a repair patch can be injected directly at the site of damage by a small size needle and no open heart surgery is required.

Researchers are using polymer scaffolds to develop 3D slices of human tissues in the lab. AngioChip is a small patch of heart tissue made from a person's own blood cells. After this patch is inserted, the heart cells even beat with a normal rhythm.

The scaffold is build from biocompatible and biodegradable polymer which naturally breaks down and leaves new tissues behind. Thisstudy showed significant results in rats but is yet to be conducted in humans.

Source: news-medical.net

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TECHNOLOGY /NDDS

2. Alzheimer's disease can be detected by novel eye test

For the detection of Alzheimer's disease, researchers in the US have developed a new method based on the detection of beta-amyloid protein. This test includes a noninvasive scan of eye retina.

Beta-amyloid proteins are amino acids which are main components associated with the formation of amyloid plaques in the brain during Alzheimer's disease. This research reveals that in the patients of Alzheimer's disease, retinal plaque is 4.7-fold high as compared to the normal person.

Usually, detection of neurotoxic beta-amyloid protein is done by positron emission tomography, or PET scans and by analyzing cerebrospinal fluid which is a very costly, invasive and inconvenient method.

This new scan uses an autofluorescence imaging system containing a specialized ophthalmic camera and sophisticated image processing software. This test can detect retinal plaque clusters, which are the most toxic form of beta-amyloid, non-invasively.

Source: health.economictimes.indiatimes.com

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TECHNOLOGY /NDDS

3. New method to detect protein biomarkers

Researchers at the Harvard University and Boston Children's Hospital have developed a new method, nanoswitch-linked immunosorbent assay (NLISA), for the detection of protein biomarkers. This new method is a cheap, sensitive, and highly accurate method for protein biomarker detection.

This technique can be used to revolutionize diagnostics, disease monitoring and can be used to prevent the spread of infectious diseases.

NLISA acts by screening DNA strands which changes shape in the presence of any protein biomarkers. When small DNA proteins bind to the target, they pull the DNA and change the shape of the DNA.

This technology is used for the detection of prostate-specific antigen (PSA). This test can also detect strains of Dengue in less than an hour.

Source: medgadget.com

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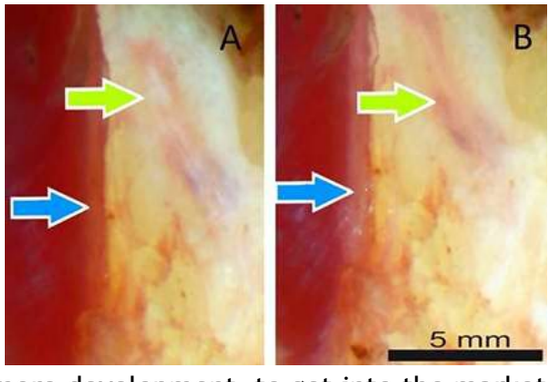
TECHNOLOGY /NDDS

4. New collimated polarized light imaging tool for detection of nerves during surgery

A team of researchers from The Netherlands have developed a collimated polarized light imaging (CPLi) based optical tool to spot nerves within tissues. This tool can prevent nerves from injury during surgeries of various sensitive and delicate parts.



This latest technology is based on the use of CPLi. By rotating CPLi light, nerve tissues can be spotted. This tool is capable of spotting 100% nerve tissues which was about 77% previously.

The tool is not yet ready to be launched in the market and needs some more development to get into the market.

The complete study is published in the journal of *Biomedical Optics Express* as "Evaluation of collimated polarized light imaging for real-time intraoperative selective nerve identification in the human hand".

Source: medgadget.com, Chin KWTK et al, Biomedical optics express. 2017;8(9):4123-34

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