Lambda Research Newsletter

March 2018

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Clinical Research NEWSletter

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GLOBAL NEWS

1. FDA issues new guidance for unpublished clinical trial data

As per the US Food and Drug Administration Amendments Act 2007 (FDAAA), clinical trial results should be reported within a year after its completion.

An online tracker named 'Trial Tracker' has been developed by the Alltrials campaign group to increase public accountability as well as to help researchers to ensure that they report all their clinical trials. This tool might be the first tool which openly track compliance to transparency reporting across all the trials.

The US FDA will impose a fine on the pharmaceutical companies for not reporting clinical data. The fine will be $10,000 a day if results are not reported within 30 days' of notice.

The USFDA had announced two strategies to improve transparency in reporting clinical trial results in January 2018, however, the Trial Tracker claims that there is still some absence of formal sanctions from the FDA.

TrialsTracker is the first tool and website to openly track the details of trials conducted under FDAAA 2007 that have missed deadlines for reporting their results.

Source: pharmaceutical-technology.com

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GLOBAL NEWS

2. Triple pill may more effectively reduce blood pressure

A new 'Triple Pill' containing a combination of low doses of three anti-hypertensive drugs may be safe, and helpful in reducing blood pressure more effectively.

Hypertension can lead to an increased risk of developing heart attacks, strokes, kidney problems and even death. Sometimes it requires more than one medication to achieve suitable reductions in blood pressure, making the patients uncomfortable. Hence, many products with combination of drugs are available targeting hypertension.

The new Triple Pill contains three anti-hypertensive drugs telmisartan (20 mg), amlodipine (2.5 mg) and chlorthalidone (12.5 mg). These drugs act via different mechanisms, and reduce the blood pressure by relaxing blood vessels, so that the heart does not need to pump as hard to send blood throughout the body.

The TRIUMPH study conducted in 700 patients showed that a significantly higher proportion of patients receiving the Triple Pill achieved their target blood pressure at six months as compared to the usual care. The results of this study were presented at the American College of Cardiology's 67th Annual Scientific Session 2018.

Source: health.economictimes.indiatimes.com

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GLOBAL NEWS

3. Republic Of Benin jails 7 Pharma executives in Fake Drug trial

Seven pharmaceutical executives were jailed by a court in Benin for four years for selling illegal drugs following a trial initiated in West Africa's campaign against fake drugs.

These seven pharmaceutical executives were declared for the sale, display, ownership and trade of fake drugs. They were working for wholesale distribution companies, of which 5 companies including GAPOB, Ubipharm, CAME, Ubephar and Promo Pharma dominate the sector in Benin.

Also, they were punished by imposing a fine of 100 million CFA francs ($190,000, 150,000 euros), a lawyer for civil plaintiffs told AFP after the trial, detailing the sum as token. Dozens of people were arrested and tonnes of fake drugs collected.

Source: channelstv.com

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GLOBAL NEWS

4. Glenmark to divest orthopedic brand portfolio

Mumbai headquartered leading drug-maker Glenmark Pharmaceuticals is looking to sell its portfolio of brands in the orthopedic segment to raise funds in a bid to reduce its debt and invest funds in its US business.

According to Indiainfoline.com, Glenmark's domestic business forms 30% of its total sales. The company reported a gross debt of Rs 4,638 crores and a net debt of Rs 3,603 crores as of December 31, 2017 and in Q2FY18 had said that it aims to reduce debt annually by Rs 300 crores.

Glenmark is looking to raise around Rs 800 crores to Rs 900 crores as part of this proposed non-core divestment exercise. Reducing debt has been a stated intent of the company and the funds will also be useful for its US business in activities like conducting clinical trials.

Many domestic as well as overseas strategic suitors have expressed interest in the portfolio

Source: health.economictimes.indiatimes.com

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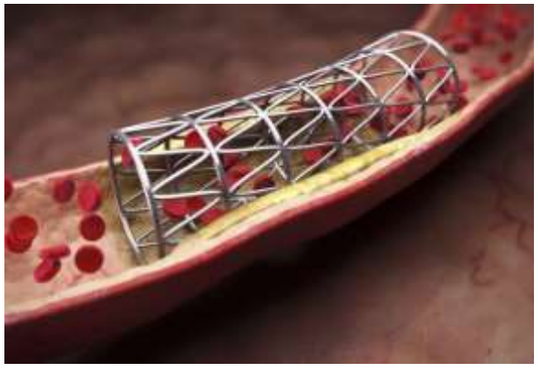
PHARMA INDIA

1. NPPA will not stop coronary stent withdrawal from India Market

The National Pharmaceutical Pricing Authority (NPPA) - Drug price regulator (New Delhi), has announced it will not stop the manufacturers of coronary stents to withdraw stents from the Indian market. However, the companies have to inform the NPPA 6 months in advance as per the Drugs Prices Control Order (DPCO), 2013.



The official memorandum of NPPA states that it will not disallow any company who has filed an application for withdrawal of their stents from the Indian market. However, the stent manufacturers have to follow the ceiling process of stents until the date of its discontinuation as per the DPCO, 2013. The NPPA, however, has suggested the companies to consider options for price revision before deciding to withdraw their products from the market.

The Indian government has revised ceiling prices of bare metal stents (BMS) and drug eluting stents (DES). The government has increased the prices of BMS from Rs 7,400 to Rs 7,660 and decreased the prices of DES from Rs 30,180 to Rs 27,890.

Last year in April, Abbott and Medtronic had sent their applications to NPPA for removal of their stents from India, but NPPA did not accept their applications and ordered them to continue supplying the stents in Indian markets.

Source: pharmatutor.org

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PHARMA INDIA

2. Net profit of 30 Indian pharma majors reduces by 38% in 9 months

Due to the US FDA activities against leading companies, challenging pricing environment of US generic drugs, cuts in prices and strong competition, 30 major Indian pharmaceutical companies have faced some difficulties during the first nine months ending in December 2017.

Their net profit reduced from Rs. 19,833 crore to Rs. 12,313 crore (37.9%) from the corresponding period of last year.

Sun Pharmaceuticals, Lupin, Dr Reddy's Laboratories, Glenmark Pharmaceuticals, Alkem Laboratories, Torrent Pharma, Biocon, Strides Shasun and Vivimed Laboratories are affected with decline in their net profit by >25%.

Furthermore, Divi's Laboratories and J B Chemicals & Pharmaceuticals registered reduction in profit by 23.4% and 19%, respectively. Ajanta Pharma, Pfizer, Granules India, Aarti Drugs, FDC and Wockhardt also failed to improve their profits.

Among the 30 companies, Cipla, Jubilant Life Sciences, Ipca Laboratories, GlaxoSmithKline Pharma (GSK) and Hikal posted double digit growth in net profits. Other companies like Aurobindo Pharma, Cadila Healthare, Alembic Pharmaceuticals, Laurus Laboratories, Nectar Lifescienes, Dishman Carbogen Amics and Syngene International clocked up a small growth in single digits during the first nine months of 2017-18.

Consequently, the overall performance for the year 2017-18 will be under tremendous pressure and may affect the share price movements.

Source: pharmabiz.com

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PHARMA INDIA

3. CDSCO publishes blue print of clinical trial rules 2018

To clearly define the features of an academic study, role of central licensing authority, trial protocol, biomedical and health research, the Center Drugs Standard Control Organization has published a blue print for clinical trial rules.

The new rules apply to all new drugs, investigational new drugs for human use, clinical trials, bioequivalence studies, bioavailability studies and Ethics Committees.

It will come into force after its final publication in the Official Gazette. This will be covered under Part XA and Schedule Y of the Drugs and Cosmetics Rules, 1945, and section 12 and 33 of the Drugs and Cosmetics Act, 1940. The new regulations clearly explain the features of an academic study, role of the central licensing authority, trial protocol, biomedical and health research.

The research which involves biomedical and health research will be made in compliance with the National Ethical Guidelines for Biomedical and Health Research involving human participants as specified by the Indian Council of Medical Research, and function as per the guidelines which are to be referred in Rule 15 by the Ethics Committee.

Source: cdsco.nic.in

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PHARMA INDIA

4. Unichem under NPPA observation for not approving price of drugs

As Unichem has not got the pricing of six anti-hypertensive drugs approved by the National Pharmaceutical Pricing Authority (NPPA), it is under observation of the NPPA. Also the decision has been handed over to the Drug Controller General of India (DCGI) on the therapeutic value of these drugs.

Considering these unusual events, the prices of 6 anti-hypertensives of Unichem will be in accordance to the prices in 2013. These drugs were intorduced into the market under brand names, 'Tritelsar 80 HS', 'Triolsar 20 HS', 'Triolsar 40 HS', 'Tritelsar 40', 'Tritelsar 40 HS' and 'Tritelsar 80' in 2013.

Last year, Ahmedabad-based Torrent Pharmaceuticals Ltd., purchased Unichem's India business for Rs 3,600 crore, but they stated they haven't received any such form from the NPPA. The combined value of the market for these six drugs was Rs 13.20 crore in February 2018.

Source: economictimes.indiatimes.com

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REGULATORY ROUND-UP

1. FDA publishes ICH Q&A guideline for drug substance manufacturing

The US FDA has cleared the recent version of the International Council of Harmonization's (ICH) guideline on the questions and answers for the development and manufacture of drug substances. This document was already approved by the ICH assembly in August 2017.

Q11 Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities), this questions and answers guideline is introduced to diversify on ICH's 2012 guideline on drug substance manufacturing. This questions and answers document provides additional simplification for drug substance manufacturing process by emphasizing the selection of combination as well as on justification of choosing starting materials.

This guideline, involves answers to 16 questions, which justifies and helps in the selection of starting materials. Furthermore, two decision trees are provided aimed at the assessment of a proposed starting material and to determine which steps in manufacturing have an effect on the drug substance's impurity profile.

Source: fda.gov

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REGULATORY ROUND-UP

2. MHRA introduces new guidelines for unification of data

The Medicines and Healthcare products Regulatory Agency (MHRA) has introduced a new guideline for the unification of data, which focuses on the protection of data that can fortify the patients' safety, and the quality of medical products.

The data integrity is regularly observed in form 483s of the US FDA, in its warning letters for pharmaceutical companies, and also in statements which are not complying with Good Manufacturing Practices (GMP) from the MHRA. This includes disposing or reentering of data in computerized systems.

This guidance undertakes the issues of paper based and electronic based data issues. The paper based data should be additionally verified. The data, which is collected in computerized system should be properly tackled while entering, transferring including its governance. These systems should be properly validated.

Further, this guidance should be read in association with the applicable regulations and the general guideline specific to each GxP, which is made in association with ICH Q9 considering the principles of these documents which may provide guidance and further information.

Source: gmp-compliance.org

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REGULATORY ROUND-UP

3. TGA is up to amend new advertising regulations

Australia's Therapeutic Goods Administration (TGA) notified that, they will make changes in the regulations related to the advertising of therapeutic goods this month, which would be executed in the upcoming two years.

Particularly, the changes will add punishment for advertisements that are not in compliance. Also, there will be minor changes in advertising code as well as in complaints handling system as of 1 July 2018, and there will be no requirement of pre-approval for certain advertisements from 1 July 2020.

The TGA will additionally develop a formal education program including guideline material which would guide the advertisers.

Source: tga.gov.au

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REGULATORY ROUND-UP

4. Stakeholders seek tweaks to draft guideline for Good ANDA Submission

The US FDA released draft guidelines for abbreviated new drug application (ANDA) on the basis of 2017's record to guide and reduce the number of cycles companies go through to win approvals.

The Association for Accessible Medicines (AAM) and IPEC-Americas are the industry groups that have sought clarity and added some information to some portions of the guideline.

Perrigo (over-the-counter drug maker) raised questions about how many guidelines will be declared for generic drugs. Perrigo noted that FDA lists 48 generic drug guidance documents, 17 of which are drafts, whereas in this draft on ANDA submissions, 35 guidance documents including drafts, are referenced in the document.

IPEC-Americas its members' concerns related to the need for a better understanding of expectations for atypical actives, saying it has requested that USP establish an expert panel on atypical actives.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Roche has acquired Flatiron Health for breakthrough cancer medicines

Roche has acquired Flatiron Health, a market leading company providing healthcare technology and services. Flatiron Health majorly works for oncology-specific electronic health record (EHR) software, along with the curation and development of real-world evidence for cancer research. The acquisition was made to fasten the development of breakthrough cancer medicines.

Flatiron Health has a large network of community oncology practices and academic medical centers across the US. It has designed a technology platform that facilitates understanding the individual patients' experience.

Flatiron Health is a leading technology company in oncology providing the technology and data analytics infrastructure required for research and development efforts in oncology. Flatiron is backed by Alphabet, a leader of oncology EHR software, and is focused in digital health analytics upstart in oncology that's attempting to use real world patient information and big data to spur better oncology R&D.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novartis extends alliance with Science 37 to advance virtual clinical program

Novartis has announced that they have expanded their alliance with Science 37, a leader in decentralized clinical trial technology and design, to begin 10 new clinical trials in the next three years. Their combined work will result in enhancing virtual and classical models with increasing degrees of decentralization towards a mostly "site-less" model.

Jointly, they have already started virtual trials for cluster headache, acne and nonalcoholic steatohepatitis (NASH).

This collaboration will improve digital technology, which allows patients to participate from their homes or local physician's office without coming to a central site of a large hospital. The trials are supposed to be started in the later part of this year in the US in the areas of dermatology, neuroscience and oncology. The trials will be using Science 37's proprietary Network Oriented Research Assistant (NORA®) technology – a technology that facilitates patients to take part using mobile devices and telemedicine services and also use customized enterprise software in some of the leading clinical development programs of Novartis.

Source: ehealthnews.eu

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Celgene acquires Juno Therapeutics to advance its cellular immunotherapy

Celgene Corporation has declared that it has completed the purchasing of Juno Therapeutics, Inc. The acquisition will result into the removal of listings of common stocks of Juno Therapeutics for trade on the NASDAQ Global Select Market.

By purchasing Juno, Celgene has become a prime leader in the cellular immunotherapy area via adding unusual technology and upgraded cellular production capacity to its large business portfolio and upcoming therapies which will answer to serious competitive needs in the field of hematology and oncology.

Celgene also acquires full rights to JCAR017 (lisocabtagene maraleucel; liso-cel), globally. This is potentially the best medication in the category of CD-19 targeted Chimeric Antigen Receptor Therapy (CART), which is currently in pivotal trials for conditions like relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL).

Source: ir.celgene.com

MERGERS /ACQUISITIONS /COLLABORATIONS

4. Theravance and Janssen jointly develop TD-1473 for gastrointestinal diseases

Theravance Biopharma Ireland limited and Janssen Biotech, a part of Johnson & Johnson, have collaborated for the development and marketing of TD-1473.

TD-1473 is a novel molecule for the treatment of inflammatory intestinal disease (IID). TD-1473 is an oral, highly potent, intestinal restricted, pan-Janus Kinase (JAK) inhibitor. This molecule is designed to specifically act on the inflammation site at intestinal wall, thereby, reducing its systemic exposure.

Theravance Biopharma plans to initiate a Phase 2b/3 study for the treatment of ulcerative colitis (UC) and a Phase 2 study for Crohn's disease (CD) in 2018.

Under the agreement, Theravance Biopharma will receive an upfront payment of $100 million for a total of $1 Billion in potential payments from Janssen Biotech.

Source: investor.theravance.com

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DRUGS: APPROVALS AND LAUNCHES

1. Lupin gets permission for generic Tamiflu from the USFDA

Lupin developed a new generic formulation oseltamivir phosphate (Tamiflu) oral suspension for the treatment of acute influenza. The dose of oseltamivir phosphate is 6 mg/mL. Lupin's oseltamivir phosphate was manufactured in New Delhi, India and got an approval from the United States Food and Drug Administration (USFDA). Lupin's product is a generic version of Hoffman-La Roche Inc's Tamiflu for oral suspension, 6 mg/mL.

Tamiflu is used for the treatment of an acute, non serious Influenza A and B in patients 2 weeks of age and older and in patients who have been symptomatic for no more than 48 hours, and also as prophylaxis for influenza A and B in patients 1 year and older.

In the US, the annual sale of Oseltamivir Phosphate was ~$358 million as per IQVIA MAT in October 2017.

Source: livemint.com

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DRUGS: APPROVALS AND LAUNCHES

2. FDA approves Amantadine ER for Parkinson's disease

Amantadine extended release tablet gets approval from the United State Food and Drug Administration (USFDA) for the treatment of Parkinson's disease and drug-induced extrapyramidal symptoms in adults.

Osmolex ER™ (amantadine) Extended-release Tablets

Osmolex ER tablet is a proprietary formulation – a combination of immediate release and extended release amantadine - using Osmotica's patented Osmodex technology.

Osmolex ER is a new treatment option for those patients suffering from Parkinson's disease and adults who have extrapyramidal reactions, or movement disorders, that are caused by certain medicines.

The drug is taken once in the morning. There are three dose strengths available 129 mg, 193 mg, and 258 mg tablets. The Initial dose is 129 mg and the maximum dose is 322 mg oral.

Source: medscape.com

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DRUGS: APPROVALS AND LAUNCHES

3. FDA approves apalutamide for prostate cancer

Erleada (apalutamide) is the first FDA approved treatment for non-metastatic, castration resistant prostate cancer.

Prostate cancer is the second common most cancer in men in the USA according to the national cancer institute in 2017. There were 161,360 men affected by prostate cancer and out of them 26,730 died.

The approval of apalutamide is based on the phase III SPARTAN trial in which apalutamide reduced the risk of metastasis or death by 72% in patients with nonmetastatic castration resistant prostate cancer. The median metastasis-free survival (MFS) was 40.5 months in the apalutamide arm versus 16.2 months in the placebo arm (HR, 0.28; 95% CI, 0.23-0.35; P<0.0001).

Source: onclive.com

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DRUGS: APPROVALS AND LAUNCHES

4. AstraZeneca launches a new combination of anti-diabetic drugs

Astrazeneca has developed a new combination Xigduo XR – a combination of metformin and dapagliflozin extended release tablets.

Dapagliflozin is a inhibitor of sodium-glucose cotransporter used in the management of type 2 Diabetes Mellitus, and is aided with diet and exercise for controlling the blood glucose levels in the body.

It is already approved in 61 countries including the US, the EU and Japan. The combination of metformin and dapagliflozin has a novel, convenient and extended release choice for Indian genotype for controlling 24-hour blood glucose levels. The doses of the drug are 10/500 mg and 10/1000 mg of Dapagliflozin and Metformin.

Xigduo XR displays many common side effects like obesity, higher insulin resistance, dyslipidemia.

Source: timesofindia.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Novo Nordisk's Semaglutide shows positive Phase III data

Novo Nordisk provides a positive result of oral semaglutide – a Glucagon like peptide-1 (GLP-1) analogue (insulin stimulator) for the treatment of diabetes in a Phase IIIa study - PIONEER 1.

The clinical trial compared the efficacy and safety of three doses of semaglutide 3 mg, 7 mg, and 14 mg with placebo in 703 patients for 26 weeks.

After statistical analysis, potential and superior results were observed for improvement in glycated hemoglobin (HbA_{1c}) level for all doses of semaglutide as compared with placebo.

The drug met its primary statistical endpoint, showing significant and superior improvements in HbA1c for all three doses compared to placebo. The 14 mg dose also showed significant and superior weight loss compared to placebo. If the company gets consistent result from other trials, it will seek approval from the regulatory agencies in 2019 and may possibly launch in 2020.

Source: biospace.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Improved cardiac function in COPD patients with lung hyperinflation with Novartis' Ultibro® Breezhaler®

Novartis has announced the publication of the CLAIM study that demonstrated that Ultibro® Breezhaler® significantly improved cardiac and lung function in COPD patients with lung hyperinflation, compared to placebo.

Ultibro® Breezhaler® includes the combination of indaceterol and glycopyrronium. The dose of the drug is 110/50 mcg once in a day.

CLAIM is the first study to investigate the effect of dual bronchodilation on cardiac function. Many people, who are suffering with COPD, are likely to have lung hyperinflation, increased risk of mortality, and cardiovascular comorbidities.

CLAIM was a randomized, double-blind, placebo-controlled, single center, two period cross over study for 14 days. It involved a total of 62 patients, of whom 57 completed both treatment periods. All patients had moderate-to-very severe COPD and confirmed lung hyperinflation (residual volume >135% predicted).

Ultibro® Breezhaler® 110/50 mcg is a once-daily dual bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD

Source: Novartis.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Otezla (apremilast) shows meaningful results in a Phase II study

Otezla (apremilast) has demonstrated meaningful results in a Phase II clinical trial in active ulcerative colitis. Aprimilast is an oral selective phosphodiestrase IV inhibitor. The doses of the drug are 30 and 40 mg twice a day (BID).

This randomized, placebo-controlled, multi-center, Phase II study enrolled 170 patients randomized to apremilast 40 or 30 mg BID or placebo for 12 weeks. The primary endpoint of the study was Total Mayo Score (TMS) and clinical remission at week 12. The results showed that a higher proportion of patients taking apremilast 30 mg BID achieved clinical remission versus placebo (nominally significant, $P<0.05$). The TMS of clinical remission was achieved in 21.8% of patients in the apremilast 40 mg (n=55) and 13.8 % in placebo (n=58) at 12 weeks. In 30 mg dose it was 31.6% (n=57); P-value nominally significant ($P<0.05$). The achievement of clinical remission shows meaningful improvements in active ulcerative colitis.

Viral upper respiratory tract infection, abdominal pain, back pain, and asthenia were the adverse events reported. For the treatment of ulcerative colitis, apremilast is not approved in any country. Apremilast was designated as an orphan drug for pediatric patients having ulcerative colitis by the US FDA in Jan. 2018.

Source: ir.celgene.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Positive Phase III results of ixekizumab in ankylosing spondylitis

Eli Lilly has declared positive result of Taltz (ixekizumab) in the treatment of ankylosing spondylitis in a Phase III study. The trial included a placebo arm and an active control arm (adalimumab) for comparison, and studied patients who had never received a biologic disease-modifying anti-rheumatic drug (bDMARD).

Ankylosing spondylitis is a type of spondyloarthritis, affecting joints in the body like pelvis, shoulders and hips.The symptoms of the disease are stiffness and loss of movement or impaired function of the joints.

Ixekizumab demonstrated a statistically significant improvement in the signs and symptoms of ankylosing spondylitis, as measured by the proportion of patients who achieved Assessment of Spondyloarthritis International Society 40 (ASAS40) response at 16 weeks, when compared to placebo. COAST-V is the first registration trial to use ASAS40 as the primary endpoint, compared to the standard endpoint of ASAS20. The adverse events were similar among the groups.

Ixekizumab is approved for the treatment of adults with active psoriatic arthritis. Taltz is also approved to treat adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Lilly plans to submit detailed data from this trial for disclosure at scientific meetings and in peer-reviewed journals later this year. The company plans to submit for regulatory approvals pending additional data from the ongoing Taltz development program later this year.

Source: prnewswire.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Patent for novel genome editing system

Benson Hill Biosystems was awarded the patent for its new CRISPR 3.0 Cms1 genome editing nucleases, by the U.S. Patent and Trademark office. The Patent No. is 9,896,696.

In addition, they expand the company's suite of genomics tools to accelerate crop performance improvements.

This genome editing system Edit, by Benson Hill, which is powered by CropOS™, allows companies across the agri-food value chain to tap natural genetic diversity as a powerful source of product differentiation and to improve health and bearable output of our food system.

This system unites analytical power of company's CropOS™ with its rich portfolio of diverse genome editing nucleases, which creates first comprehensive genome editing system. This is designed for optimization of plant characteristics such as flavor profiles, nutrient-density, and environmental sustainability with greater speed and precision than that was previously possible.

Source: news-medical.net

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Fertin Pharma A/S gets patent on one layered compressed nicotine gum

Fertin Pharma A/S – the market leading nicotine gum manufacturer, adds another landmark in the barrier of compressed nicotine gum with the already acquired large and complex patent portfolio on compressed two-layered nicotine gum.

The European Patent Office had licensed the new patent, which is believed to strengthen the competitive landscape in the segment of one-layered compressed nicotine gum. Fertin Pharma A/S has been issued many patents on this same technology in the last 10 years.

In addition to the newly issued European patent, Fertin Pharma A/S has also been issued a number of US as well as Indian patents, related to this technology.

Source: fertin.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Increased patent filings for UK Pharma and Biotech indicates investor confidence

The European Patent Office EPO in the last week issued a report which showed a considerable rise in patents filed by UK-based companies in 2017 in the pharmaceutical and biotechnology sectors, both from the UK and from other leading economies.

The EPO annual report, published in March 2018, shows a significant rise in patents filed by UK companies across both sectors in 2017 – with biotech up 25.3% and pharma up 15.7%. The UK was not the only region to report a rise in these sectors – the picture was reflected across the globe. The total number of patent filings at the EPO for biotech and pharma was up 14.5% and 8.1% respectively.

This year, medical technology topped the list of the ten leading fields of technology in 2017 with 13,090 applications. Pharmaceuticals ranked eighth with 6,330 applications, while biotechnology ranked ninth with 6,278 applications.

Source: biotechandmoney.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Sanofi sued over dengue vaccine

Dengue is a viral infectious disease caused by a virus and transmitted by mosquitoes. The symptoms of this disease are flu like. Philippines have the highest number of fatality rates of dengue infections, with 732 deaths in 2017.

The Public Attorney's Office (PAO) of the Philippines has filed a lawsuit against Sanofi demanding compensation for a 10 year old girl who died allegedly by a vaccine of dengue manufactured by Sanofi - Dengvaxia.

Sanofi stated that it was not any aware of any deaths related to the vaccination. The demanding compensation is $81,600.

Mosquito-borne dengue is the world's fastest-growing infectious disease, afflicting up to 100 million people worldwide, causing half a million life-threatening infections and killing about 20,000 people, mostly children, each year.

Source: in.reuters.com

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www.lambda-cro.com

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1. New technique for cervical cancer screening

BD SurePath Direct to Slide (DTS), is a unique Liquid Based Cytology (LBC) test intended to be used for screening and detection of cervical cancer, pre-cancerous lesions, atypical cells and all other cytological categories. It offers the availability of residual sample for conducting important additional follow-up tests without the need for repeat sampling.

Traditionally, conventional pap smear, a simple and quick test has been the mainstay of cervical cancer screening. However, this method has its limitations in preparation techniques and its ability to detect every abnormality, which makes it important to move towards a more efficient technique.

Cervical cancer is the second most common cancer in India among women aged between 15 and 44 years. The necessity of proactive and periodic screening stems from the fact that cervical cancer is a preventable and curable condition if detected in the asymptomatic stages. Unfortunately, in India, there continues to be a major gap in the awareness levels in women regarding screening, especially while still asymptomatic. This results in delayed diagnosis, making it critical to understand the advantages of screening and opting for appropriate testing methods.

Source: business-standard.com

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2. New device can diagnose risk of appendicitis in children

Scientists of Washington, including one of Indian origin, have made a new 'risk calculator' that can aid in diagnosing children with appendicitis and provide customized medical and surgical information.

The study has gathered information from ten pediatric emergency departments for developing a risk calculator from the Children's Hospitals and Clinics of Minnesota and HealthPartners Institute in the US. The scores were verified with the help of data from a single children's hospital.

The benefits of this device are that it is harmless, of low cost, with an ability to diagnose easily the risk of appendicitis when the patient presents with a symptom of pain in the abdomen. Also, it reduces the use of computed tomography (CT), via which there will be more proper use of ultrasound technique.

CT scans are expensive and children are exposed to radiation as well.

Source: hindustantimes.com

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3. Blood and urine tests to detect autism

Autism is a complex neuronal condition, with changes in the behavior, impairments in social interaction and development difficulties in language and communication skills. A researcher from the University of Warwick has developed a new technology for the diagnosis of autism spectrum disorder with blood and urine tests.

In blood plasma, proteins are damaged by the reactive oxygen species (ROS) and sugar molecule. In children who are affected by the autism spectrum disorder had higher levels of a protien dityrosine (oxidation marker) and sugar molecules. The researcher also identified the genetic mutation and transportation of amino acid in to neurons and other cells.

The Warwick team worked with collaborators from the University of Bologna in Italy, who recruited 38 children diagnosed with ASD along with a control group of 31 other children between the ages of five and 12. Blood and urine samples were taken from the children for analysis.

The Warwick team discovered chemical differences between the two groups. Working with a further collaborator at the University of Birmingham, the changes in multiple compounds were combined together using artificial intelligence algorithm techniques to develop a mathematical equation to distinguish between ASD and healthy controls. The outcome was a diagnostic test better than any method currently available.

Source: warwick.ac.uk

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TECHNOLOGY /NDDS

4. New smart contact lens for diabetes

A team of researchers has developed a new biosensing contact lens capable of detecting glucose levels in patients with diabetes. The new smart contact lens is capable of monitoring glucose levels in tears. This breakthrough has been jointly conducted by Professor Jang-Ung Park from the School of Materials Science and Engineering and Professor Franklin Bien from the School of Electrical and Computer Engineering at UNIST in collaboration with Professor Jung Heon Lee from the School of Advanced Materials Science and Engineering at Sungkyunkwan University.

According to the research team, this innovative smart lens with built-in pliable, transparent electronics can monitor glucose levels from tears in the eye. The device has not yet been tested in humans. However, the research team expects that the release of this device will offer diabetics a pain-free way to measure their glucose levels with the blink of an eye. Their findings have been published in *Science Advances*.

Source: sciencedaily.com

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