Lambda Research Newsletter

April 2017

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Clinical Research NEWSletter

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GLOBAL NEWS

1. US working on a system to encourage competition in the drug industry

The American President, Mr. Donald Trump, plans to introduce a new system in the pharmaceutical industry that would encourage competition and reduce drug prices. But details regarding how that system will work with the current drug and biopharma companies were not revealed.

The president wants to make the drugs more affordable while promoting innovation, and reducing the regulations. The President hopes that this plan will encourage the drug organizations to bring back operations and jobs to the US.

Previously, it was announced by Trump that they would try to reduce the US FDA regulations by 75-80%, though it was unclear as to how the prescription costs would be lowered.

Source: raps.org

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GLOBAL NEWS

2. EMA outlines GCP inspection plan for 2017

The European Medicines Agency (EMA) has published their 2017 work plan for GCP inspections. This new plan includes working collaboration with the US FDA, and to help decrease the chances of duplicative inspection.

Under this plan, the GCP working group of the EMA will develop new and revised guidelines on inspection procedures that can protect personal data and confidential information. These guidelines will be aligned to the new Clinical Trials Regulations.

This agenda will focus on the following objectives for 2017:

- Advance determination on the number of GCP inspections to be requested in 2017.
- Covering the broad range of product types, therapeutic areas/indications, target populations, sponsors/contract research organizations (CROs)/vendors, studies and sites.
- Proactive selection of the areas of importance for indications, populations, geographical locations of sites, recruitment rates, size of sponsors, size of CROs and tasks and other general trends.
- Diverse geographical regions to be chosen for inspection including countries that are outside the EU where a noted amount of clinical trial data gets generated.
- Ensuring available resources for GCP inspector to conduct routine and “for cause” GCP inspections.
- Revisions on GCP guidelines for advanced therapy medicinal products will be completed in 2017.
- Recommendations on the qualifications of inspectors validating trial compliance with GCPs will also be finalized in 2017.

The EMA will also take care to assist other countries to help develop GCP inspection roles, including Albania, Macedonia, Montenegro, Serbia, Turkey, Bosnia and Herzegovina and Kosovo.

Source: raps.org

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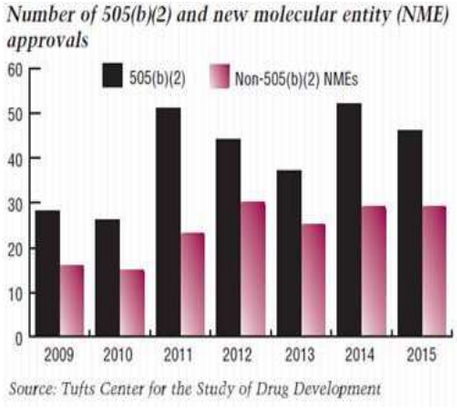
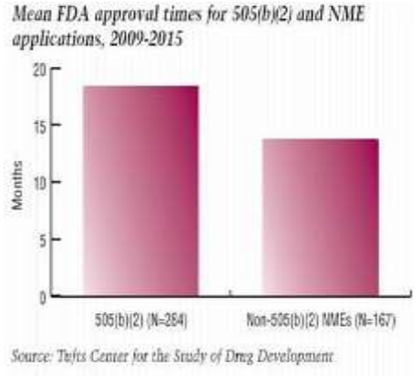
GLOBAL NEWS

3. 505(b)(2) approval pathway not facilitating shorter approval times in all cases

According to a study published by the Tufts Center for the Study of Drug Development, the streamlined 505(b)(2) approval process for new drug applications in the U.S. has not shortened approval times in all cases. Tufts researchers found that 63% of the 451 original new drug applications that were approved by the FDA through the 505(b)(2) pathway had mean approval times which were about five months longer than that for new molecular entities.





505(b)(2) pathway allows reducing the development time and decreasing costs; also companies can get 3 to 5 years of market exclusivity. The recent findings suggest that drug developers should not expect the 505(b)(2) applications to essentially lead to a shorter approval time or limited FDA requirements. Similarly as with any drug development program, it's vital to have an interaction proactively with the FDA in order to generate the data to bridge the 505(b)(2) program with the approved reference product. Following are the key findings from the Tufts CSDD study:

- 505(b)(2) applications accounted for 63% of 451 original NDAs approved by the FDA during 2009-15.
- Applications rely more on the data of the drugs approved previously, hence approval times qare expected to be shorter than the approval times of NME.
- Mean approval time for 505(b)(2) applications was about 5 months longer than that of NMEs.
- 50% of 505(b)(2) applications were approved in the 1st cycle during 2009-15, compared to 78% of all NME applications for 2014 and 85% for 2015.
- The percentage of 505(b)(2) drugs approved on the first review cycle was substantially lower than for all NMEs.

Source: thepharmaletter.com

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GLOBAL NEWS

4. Three new genes identified in RA pathogenesis

The researchers in the Rheumatology Unit of the Karolinska Institute have identified three new genes, ERBB2, TP53 and THOP1, to be associated with the pathogenesis of rheumatoid arthritis. The genes were identified with integration of RNA-sequencing data.

Researchers analyzed 377 genes from loci linked with RA through RNA-sequencing-based expression analysis. They performed the pathway analysis on 11 different genes with similar expression pattern in both treated and untreated patients with RA.

A total of 56 connector genes derived from pathway analysis were tested for differential expressions in the initial discovery cohort. These expressions were then validated in peripheral blood mononuclear cells from 73 patients with RA and 35 healthy controls.

The differential expressions found on ERBB2, TP53 and THOP1 genes were similar in both treated and untreated RA patients. An additional 9 genes were found with different expression in at least one group of patients while collecting the samples of healthy controls. Expression profiles of these three genes mentioned above were replicated in RNA-sequencing data in a separate collection of blood cell samples from healthy controls and untreated patients with RA.

Source: healio.com

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PHARMA INDIA

1. Up to 86% price reduction of cancer drugs in India

National Pharmaceutical Pricing Authority (NPPA) of India has reduced the prices of cancer medications as much as 86%, since March last year.

Iressa of AstraZeneca Pharma, India, is one of the drugs for which the price has been reduced from Rs. 29,259 to Rs. 3,977, a reduction of 86%. Dr Reddy's laboratories' Grafeel' price has also been brought under NPPA, price reduced by 41%.

Natco Pharma and Emcure pharmaceuticals are the other companies that have been affected by the price reduction.

The prices for the diabetes segment also have been reduced in the range of 42% to 10%. These include Glimy from Dr. Reddy's, Obimet from Abbott, Gluconorm from Lupin and Cetapin from Sanofi.

NPPA was set up in 1997 to monitor the prices of controlled and decontrolled drugs.

Source: business-standard.com

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PHARMA INDIA

2. Biocon and Mylan's trastuzumab biosimilar approved for three types of cancers

The Delhi High Court has permitted pharma biotech companies, Biocon and Mylan, to sell their copies of biosimilar drug trastuzumab for treating 3 types of cancer - metastatic breast cancer, early breast cancer and metastatic gastric cancer. Previously, the drug was allowed to be used only in metastatic breast cancer as granted by the Drug Controller General of India (DCGI).

Now, both the companies can use Roche's product data in their package inserts, which will allow them to generate revenue and take a firm foothold in the anticancer market.

The market of trastuzumab alone is about Rs 300 crores. Trastuzumab is sold under the brand names 'Herclon' and 'Biceltis' in India and worldwide as 'Herceptin'.

Reliance Life Sciences is also planning a similar appeal for their trastuzumab.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

3. VaxiFlu 4 of Zydus Cadila approved for launch in India

The Indian regulators have approved Zydus Cadila's VaxiFlu 4-a tetravalent inactivated influenza vaccine for seasonal flu. With this, Zydus Cadila will become the 1st pharma company in India and the 2nd in the world to market the tetravalent inactivated influenza vaccine. The vaccine protects against -H1N1, H3N2, Type B (Brisbane) and Type B (Phuket) viruses.

The vaccine has been developed at the Vaccine Technology Centre (VTC) in Ahmedabad. Previously, Vaxiflu S against H1N1 was also developed by this centre.

The estimated global market is about $4 billion for influenza vaccines.

Source: thepharmaletter.com

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REGULATORY ROUNDUP

1. US President signs orders for new US FDA regulations

The US president, Donald Trump, has signed an executive order seeking the formation of task forces to reduce the regulatory burdens on the American people. According to these orders, the US FDA regulations will be cut by 75% to 80%.

According to the order, each Regulatory Reform Task Force shall evaluate existing regulations and make recommendations regarding their repeal, replacement or modification, consistent with applicable law. At minimum, the Task Forces will attempt to identify the regulations, which:

- eliminate jobs, or inhibit the job creation
- are outdated, pointless, or ineffective
- impose prices that surpass the benefits
- create a serious irregularity or else, interfere with regulatory change initiatives and policies
- are not consistent with the necessities of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued in accordance to that provision
- derive from or follow the Executive Orders or other Presidential orders that have been along these lines cancelled or significantly changed.

Source: raps.org

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REGULATORY ROUNDUP

2. FDA warning for increased risk of serious pancreatitis with Allergan's Viberzi - eluxadoline

The US FDA has issued a warning on Allergan's Viberzi (eluxadoline) for an increased risk of serious pancreatitis in the patients without gall-bladder. The warning was given after two deaths among the patients who used Viberzi – a drug that is approved by the US FDA for the treatment of irritable bowel syndrome with diarrhea in adults.

FDA has received 120 reports of serious cases of pancreatitis or death, after the approval of the medicine. Out of the 68 patients who submitted their gallbladder status, 56 did not have a gallbladder and were treated with the approved dosage of Viberzi. Seventy-six patients were hospitalized, two of them died. These two patients did not have gallbladder.

Patients who died of pancreatitis had symptoms like severe abdominal pain, nausea, and vomiting after sixty minutes of taking a single dose of the drug. Some cases of them also involved sphincter of Oddi spasm or abdominal pain.

Source: raps.org

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REGULATORY ROUNDUP

3. European commission recommends changes to SmPC, Package Leaflets

The European Commission (EC) published a report narrating the recommendations for improvements in the information provided to the patients and the doctors for approved drugs. According to the report published by the EC, the EMA should update its guidelines to enhance the understanding and readability of package leaflets (PL) and summary of product characteristics (SmPC), to use the drugs safely in the EU.

Netherlands Institute for Health Services Research (NIVEL) and the University of Leeds conducted two studies PIL-S and PILS-BOX along with contributions from the EU-wide survey of stakeholders and member state and came up with this report.

Recommendations by the commission:

- The language utilized in the PL is unpredictable and the plan and the format are not generally easy to use. The elderly and those with low educated aptitudes are especially hindered, and mostly affect all patient groups.
- Guidelines ought to incorporate more points of interest on the standards of good information design, in which content and design are mutually considered. This would guarantee consistency with the legal necessity that the PL be 'clearly legible'. The report noticed that little text dimension, limit line dispersing and general length of the PL were the fundamental offenders.
- The regulations and QRD templates are "too restrictive" – recommends to be allowed to be changed for specific products.
- Information which is of limited relevance for patients should be deleted, which will facilitate improving the content and layout of the package insert.

Source: raps.org

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REGULATORY ROUNDUP

4. MHRA releases new guidance for common issues in clinical trial applications

The recent guidance was issued by the Medicines and Healthcare products Regulatory Agency (MHRA) UK, specifying the most common issues found in clinical trial applications with an end goal to help sponsors avoid unnecessary delay.

As indicated by the agency, more than 50% of about 1,000 clinical trial applications presented each year need more information before its review and approval.

As explained by the MHRA, currently, it reviews and assesses phase 1 applications within approximately 12 days and 22 days, which may be doubled or even tripled based on if further information is required from the sponsor. The agency is able to hold the 60-days statutory limit for evaluating the clinical trial applications despite these delays, however, it affects negatively both the sponsors and patients.

Fifteen percent of the clinical trial applications received by the MHRA are declined at the validation stage due to missing and insufficient information, and also, the most commonly recognized issue is lack of risk mitigation strategies.

MHRA takes note that the guidance should not be seen as a comprehensive checklist, and states that a portion of the issues recorded may not be relevant to all clinical trials.

As specified by the MHRA, the sponsors who do not comply with some of the issues, as mentioned in the guidance, might not necessarily get the GNA (grounds for non-acceptance) if they are justified scientifically for non-compliance with guidance.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. AstraZenecea and Sanofi alliance to develop respiratory syncytial virus antibody

AstraZeneca's global biologics research and development arm 'MedImmune' and the vaccines division of Sanofi 'Sanofi Pastuer' have collaborated to develop and commercialise MEDI8897 - a monoclonal antibody (mAb) for the prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV). The RSV is the most prevalent cause of LRTI among infants and young children.

At present, MEDI8897 is being evaluated in a phase 2b clinical trial in pre-term newborn children who are not eligible for the current standard of care solution and the only drug currently approved to prevent LRTI - palivizumab.

Under the deal of this worldwide agreement, Sanofi will make a direct payment of 120 million Euros to AstraZeneca and pay up to 495 million Euros ($521 million), action of sure development and sales-related milestones.

Source: worldpharmanews.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Takeda acquired Ariad pharmaceuticals

Takeda Pharmaceutical Company Limited has completely acquired Ariad Pharmaceuticals, Inc., for $24.00 in cash for each share. Ariad's investigational drug brigatinib, an ALK inhibitor in cancer therapeutic area, was one of the chief attractions for Takeda towards this acquisition.

Takeda expect brigatinib to be the best-in-class ALK inhibitor for non-small cell lung cancer. The company forecast its market potential to reach at peak annual sales of over $1 billion.

This acquisition will strengthen the priority oncology business of Takeda with Ariad's innovative targeted treatments and capabilities for research and development. More specifically, brigatinib is expected to boost Takeda's global solid tumor franchise.

Source: pharmpro.com

MERGERS /ACQUISITIONS /COLLABORATIONS

3. Boehringer Ingelheim and Weill Cornell Medicine collaborate to discover next generation COPD treatments

Boehringer Ingelheim has collaborated with the US medical research center - Weill Cornell Medicine, to find new treatment approaches for chronic obstructive pulmonary disease (COPD). The collaboration can set up an excellent example for the unique approach and focus on early innovation, to identify and develop novel medical treatments for patients with COPD.

This is the second collaboration, between the pair that could possibly halt or even reverse the progression of the disease process of COPD.

The collaboration will combine the unique understanding of chronic airway diseases from Weill Cornell Medicine's Department and expertise of Boehringer Ingelheim in the discovery and development of new therapies for respiratory diseases.

Source: health.economictimes.indiatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Glenmark and Evestra announce partnership for generic contraceptive product

A generic version of Merck & Co's contraceptive product will be developed and commercialized by a joint venture from Glenmark Pharmaceuticals and Evestra Inc.

Under this strategic partnership, Glenmark and Evestra will develop and market the generic version of, NuvaRing® - etonogestrel /ethinyl estradiol vaginal ring. The product is currently being developed, and Abbreviated New Drug Application (ANDA) is planned in 2019.

The exclusive commercializing and distribution rights of the product have been secured by Glenmark for the U.S. market, and with an option to commercialize two additional Evestra vaginal ring products.

Source: health.economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

1. QTERN® (Dapagliflozin and Saxagliptin) approved by FDA for T2DM

AstraZeneca

QTERN

The US FDA has granted approval for AstraZeneca's fixed-dose combination drug, Qtern (10 mg dapagliflozin and 5 mg saxagliptin), to treat adults with type 2 diabetes as an adjunct to diet and exercise.

This new drug is for improving the blood sugar levels in type 2 diabetes patients who have not been able to achieve glycemic control with dapagliflozin alone or who are already receiving treatment with both dapagliflozin and saxagliptin. Dapagliflozin is a SGLT-2 inhibitor and Saxagliptin is a DPP-4 inhibitor; Qtern is an OD tablet.

Qtern was approved by the FDA based on the data from a 24-week, phase 3, multicenter, randomized, double-blind, placebo-controlled trial, with 315 patients.

The combination is not meant to treat type 1 diabetes mellitus or diabetic ketoacidosis.

Source: businesswire.com

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DRUGS: APPROVALS AND LAUNCHES

2. Kisqali® of Novartis approved for HR+/HER2- Metastatic Breast Cancer

The US FDA has approved ribociclib (Kisqali), in combination with an aromatase inhibitor, as initial endocrine-based therapy treatment. Ribociclib, the cyclin-dependent kinase 4/6 (CDK4/6) inhibitor, is indicated for postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-), advanced or metastatic breast cancer.

Kisqali was approved based on the phase 3 trial (MONALEESA-2), that has shown efficacy of the treatment in improving progression-free survival (PFS) with the combination of ribociclib and letrozole, compared to letrozole alone. Also the combination in this study has reduced the risk of progression or death by 44% as compared to letrozole alone. The tumor burden risk was found reduced by at least 30% among more than half of the patients taking this combination.

Kisqali, from Novartis, offers once-daily administration of a 600 mg tablet for a 3-week period, followed by 1 week without treatment. It is to be taken in combination with any of the aromatase inhibitors for 4 weeks.

Source: fda.gov and novartis.com

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DRUGS: APPROVALS AND LAUNCHES

3. Siliq (brodalumab) approved for moderate-to-severe plaque psoriasis

Siliq (brodalumab), an injectable biologic, has been approved by the US FDA, for the treatment of the adults with moderate-to-severe plaque psoriasis. The approval comes with a warning about the risk of suicide. Siliq is used as a systemic treatment after the failure of other options.

Siliq has been evaluated for its safety and efficacy in 3 randomized, placebo-controlled clinical trials among 4373 adult patients with moderate-to-severe plaque psoriasis. Siliq was found effective when compared with placebo.

Suicidal events/ behavior were found among the patients treated with Siliq during clinical trials. But a causal association has not been established. However, the drug will receive a boxed warning and will only be available through a risk-evaluation mitigation-strategy programme, called the Siliq REMS Program due to the observed suicidal ideation and suicide events during the clinical trials.

Source: fda.gov

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DRUGS: APPROVALS AND LAUNCHES

4. US FDA approves the first drug to treat nocturia

Noctiva (desmopressin acetate) nasal spray, from Serenity Pharmaceuticals, has been approved by the USFDA to treat adults with nocturia who awaken at least twice per night to urinate, due to nocturnal polyuria.

Noctiva is the 1st US FDA approved drug to treat nocturnal polyuria. Noctiva should be administered as a metered nasal spray in either nostril, few minutes before bedtime. The drug in the inhaler decreases urine production and thereby reduces the need to urinate for several hours when patient is asleep.

Noctiva was approved on the basis of two randomized, placebo-controlled studies by showing significant reductions in the mean number of nocturic voids and reducing the number of night time voids among the patients.

Decreased sodium levels (hyponatremia) were found in the blood among the patients treated with Noctiva. Hence, a lower dose of Noctiva should be recommended as an initiating dose for the patients who are at risk of hyponatremia. Also, the medicine contains a boxed warning and a Medication Guide.

Health care providers should confirm the sodium level of the patient before starting Noctiva. Also, the level of sodium should be monitored within 1 week and approximately 1 month after initiating treatment, and thereafter at regular intervals.

Source: businesswire.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. AstraZeneca's Lynparza hit the goals in phase 3 trial for BRCA-mutated MBC

AstraZeneca's Lynparza met its primary endpoint in the phase 3 OLYMPIAD trial in BRCA-mutated metastatic breast cancer (MBC).

This was a randomized, multicenter (19 countries from across Europe, Asia, North America and South America) phase 3 trial carried out in 302 patients with HER2-negative MBC with BRCA1 or BRCA2 mutation.

Lynparza (olaparib) demonstrated statistically and clinically improved progression-free survival (PFS) as compared with other chemotherapeutic agents (capecitabine, vinorelbine or eribulin); the safety profile of Lynparza was at par with earlier studies.

Olaparib is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour DNA damage response (DDR) pathway deficiencies to preferentially kill cancer cells.

It is currently approved by EMEA as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. It is also approved in the US as monotherapy in patients with deleterious or suspected deleterious germline BRCA-mutated (as detected by an FDA- test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

Olaparib is currently being investigated in another international ongoing phase 3 study called OLYMPIA in patients with non-metastatic breast cancer.

Source: astrazeneca.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. GSK's once-daily Relvar™ Ellipta™ showed positive study results

GlaxoSmithKline and Innoviva announced the positive results from a non-inferiority lung function study, which showed that the treatment could be switched, from the twice-daily Seretide (fluticasone propionate /salmeterol) to the once daily Relvar Ellipta (fluticasone furoate/vilanterol, FF/VI) 100/25, for patients with well-controlled asthma without any effect on their lung function.

Once daily Relvar™ Ellipta™ met the study's primary endpoint with 95% confidence interval falling above the non-inferiority margin.

The safety profile of FF/VI was found consistent with other studies among the asthma patients.

The non-inferiority for once-daily Relvar™ Ellipta™ as compared to twice-daily Seretide on lung function can build the confidence that the once-daily treatment option with Relvar Ellipta will provide a choice for the physicians to prescribe for the patients who struggle taking a twice-daily treatment regimen.

Source: pharmpro.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Roche's pertuzumab shows improvement in early breast cancer patients

According to the results from the phase 3 APHINITY study, Roche's Perjeta regimen showed improvements in patients with an aggressive type of early breast cancer.

The study demonstrated that Perjeta regimen helped people live longer without their disease returning compared to Herceptin and chemotherapy alone.

The adjuvant treatment of Perjeta (pertuzumab), Herceptin (trastuzumab) and chemotherapy (the Perjeta-based regimen) combination showed reduction in the recurrence of invasive disease or death among the patients with HER2-positive early breast cancer (eBC) compared with Herceptin and chemotherapy alone.

Perjeta-based regimen has shown a consistent safety profile, similar with that seen in previous clinical trials.

The combination of Perjeta, Herceptin and chemotherapy is accredited as a neoadjuvant (before surgery) therapy for patients with HER2-positive eBC in more than 75 countries after approval by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Source: pharmpro.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Dupilumab showed positive phase 3 results in in atopic dermatitis

Sanofi and US biotech Regeneron Pharmaceuticals have announced positive phase 3 study (Chronos) results for Dupixent (dupilumab) in the treatment of atopic dermatitis. Atopic Dermatitis is a chronic inflammatory disease showing symptoms mostly appearing on the skin. It is the most common form of eczema.

The study results demonstrated a significant improvement in the clearance of skin lesions and overall disease severity with dupilumab as compared to corticosteroid alone therapy in adult patients with uncontrolled moderate-to-severe atopic dermatitis (AD) who received previous topical corticosteroids treatment.

The Biologics License Application for the drug got the priority review standing from the US FDA, in December a year ago, with a target action in March 29.

Dupixent was endorsed for the Europeon regulatory filing in late 2016, which is currently under evaluation by the European Medicines Agency with expected decision by this year.

Source: thepharmaletter.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Supernus settle patent litigation with Zydus on Trokendi XR®

Supernus® Pharmaceuticals
www.supernus.com

Zydus Cadila

Supernus Pharmaceuticals, Inc. has finalized the settlement deal with Zydus Pharmaceutical (USA), Inc. and Cadila Healthcare Limited (collectively, "Zydus") for ongoing patent litigation for Zydus' Abbreviated New Drug Application (ANDA) seeking marketing approval for Supernus' Trokendi XR® (extended-release topiramate) capsules. This settlement deal will allow Zydus to market the generic version of Trokendi XR® from January 2023, or before in certain situations.

Supernus Pharmaceuticals is developing and marketing products for central nervous system diseases; it has known antiepilectic products - Oxtellar XR® (extended-release oxcarbazepine) and Trokendi XR® (extended-release topiramate).

Trokendi XR possesses patent protection up to 2027.

Source: globenewswire.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. UK high court rules against AbbVie in Humira patent

The UK High Court has ruled in favour of Fujifilm Kyowa Kirin Biologics and Samsung Bioepis in terms of the validity of different dosing regimens of AbbVie's well-known and higher selling monoclonal antibody Humira (adalimumab) that is used in the treatment of rheumatoid arthritis, psoriasis and psoriatic arthritis.

The UK court ruling has been welcomed by the biosimilars' developers related to the patent for Humira indication, but the judgement is cautioned by the IP lawyer for not authorizing it outside the UK.

As argued by the AbbVie spokesman, Abbvie has already relinquished its UK patents that would expire after October 2018. The UK result is not applicable to the US case nor is it predictive of the outcome.

Fujifilms' FKB327 is a biosimilar to Humira and has successfully completed phase 3 trials in October 2016 and is expected in the market soon. Furthermore, European Medicines Agency has accepted to review Samsung Bioepis's version, SB5, in last July.

Source: biopharma-reporter.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Mylan enters into agreements with Genentech and Roche on Herceptin®

Mylan has got the global commercialization licenses for its Herceptin to market globally post a global settlement agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd on patents of Herceptin® (trastuzumab).

This deal will give a clear pathway to Mylan for commercializing Herceptin in different global markets. The licenses relate to all countries except for Japan, Brazil and Mexico.

As a part of the settlement, Mylan will withdraw its pending Inter Partes Review (IPR) challenges against two U.S. Genentech patents (patent numbers 6,407,213 and 6,331,415).

Mylan is co-developing six biosimilar products with Biocon for the global market. For the proposed biosimilar trastuzumab, Mylan has exclusive commercialization rights in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries, whereas Biocon has co-exclusive commercialization rights with Mylan in the rest of the world.

After this settlement and the current acknowledgment of Mylan's application for its proposed biological product trastuzumab with the US FDA, Mylan expects being possibly the first organization to launch a biosimilar to Herceptin in the U.S.

Source: prnewswire.com

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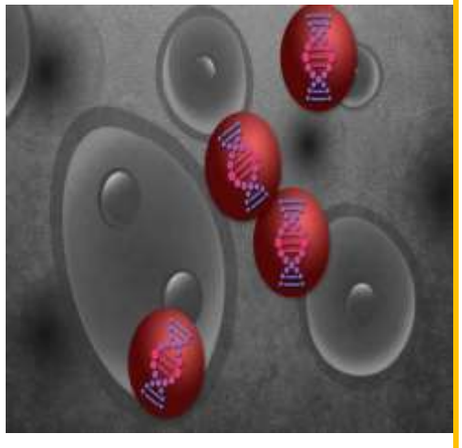
TECHNOLOGY/NDDS

1. Novel technology for rapid screening of promising nanoparticles for drugs



Nanoparticles are small, virus-sized elements prepared in the laboratory, and are widely used for biomedicines. The rapidly evolving nanoparticle technology offers hope for many diagnostic or therapeutic applications.

The researchers from the universities of Geneva (UNIGE) and Fribourg (UNIFR), Switzerland, have developed a quick screening method to identify the most promising nanoparticles, which can speed up the development of future treatments.

The compatibility of nanoparticles to the human body can be determined in less than a week by this new screening method, which earlier used to take several months of work.

Due to the vast utility of the nanoparticles (range: 1 to 100 nm) in medical applications, the new rapid screening technique was developed by the National Centres of Competence in Research (NCCR) "Bio-Inspired Materials" project. This method facilitates researchers to quickly select the most promising particles for biomedicines as well as in a cost-effective manner, eliminating the need for animal studies.

This discovery has been published in the journal *Nanoscale*. This technique may bring a quick, safe and more affordable development of nanotechnology applied to the drugs.

Source: news-medical.net

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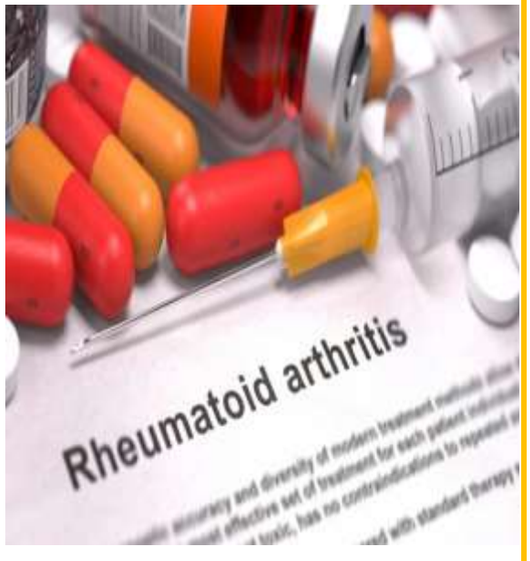
TECHNOLOGY/NDDS

2. New assay to measure underlying autoimmunity in rheumatoid arthritis patients



According to a recent research conducted at NYU Langone Medical Center and the University of Pittsburgh, the current therapies for rheumatoid arthritis (RA) are effective in reliving inflammation that lead to joint erosion, but the immunologic defect that triggers inflammation may cause relapse. According to the study results published in *Arthritis & Rheumatology* journal, the focus of clinical trials for new RA drugs should be shifted from relieving inflammation to eliminating the antibodies producing B cells.

Sensitive assays have been developed to detect a range of different autoantibodies present in the disease. Researchers have stimulated memory B cells by developing cell culture system, and used the assays to detect the antibodies produced by these B cells. When tested on patients with RA and healthy controls, high levels of anti-citrullinated protein antibodies (APCA) secreting 'memory B cells' were found among RA patients.

Looking at a subgroup of RA patients, those who were in remission from methotrexate or a TNF inhibitor treatment, it was confirmed that the APCA levels were directly proportional to the recirculating memory B cells in the blood stream. This meant that the treatments do not produce any effect on the underlying autoimmunity of the disease.

Source: news-medical.net

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TECHNOLOGY/NDDS

3. New vaccine created for breast cancer

Victoria University of Wellington's Ferrier Research Institute and the Breast Cancer Foundation New Zealand (BCFNZ) have partnered to develop a new vaccine for breast cancer.

The synthetic cancer vaccine technology is developed by the Ferrier Research Institute that can activate tumour-specific T-cells, which produces a targeted immune response. The vaccine has caused rejection of cancer in some of the animal models.

With the help of this research, the cancer vaccine has been developed, and has showed good results when used in some situations.

The Ferrier Research Institute has developed these successful drug trials in collaboration with the Albert Einstein College of Medicine in New York.

The BCFNZ will grant $500,000 to the Ferrier Institute for conducting this research under their five-year research partnership.

Source: pharmaceutical-technology.com

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