Lambda Research Newsletter

October 2019

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Research Accelerated

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GLOBAL NEWS

1. Advanced technologies to upsurge the growth of mRCC market: 2019-2024

Approximately 20-30% of patients with stage I-III localized tumors relapse after nephrectomy and progresses to stage IV metastatic renal cell carcinoma RCC (mRCC), according to the 2019 National Comprehensive Cancer Network (NCCN) Kidney Cancer guidelines. These patients will require systemic drug therapy. This unmet need has been identified by the pharmaceutical companies, which are now focusing on the development of combination treatments for heavily pre-treated and refractory RCC patients, as per the data presented at the European Society for Medical Oncology (ESMO 2019) Congress, Barcelona (29 September to 1 October).

Major players in the RCC landscape such as Bristol-Myers Squibb (BMS), Merck, Novartis and Pfizer are focusing on developing first-line combination treatments such as:

- Opdivo (nivolumab)
- Yervoy (ipilimumab)
- Keytruda (pembrolizumab)
- Avelumab with Inlyta

Several pharmaceutical companies have presented the data of their products for the treatment of RCC.

- Mavorixafor (X4P-001) + Inlyta (axitinib)
    - Overall response rate (ORR) of 18% and an increased median progression-free survival (mPFS) of 7.4 months
- Phase 2 ENTRATA study: telaglenastat + afinitor doubled PFS from 1.9 months to 3.8 months, and showed a 36% reduction in disease progression or death.

Source: realviewpoint.com

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GLOBAL NEWS

2. New scoring system to assess the risk of genetic seizure disorder

Cleveland Clinic

A new risk scoring system for epileptic or seizure disorders of genetic origin has been developed by the Cleveland Clinic-led initiative.

Some common forms of epilepsy has a large number of genes weakly implicated. Researchers used these genes to create a polygenic risk score (PRS). The score distinguishes between epileptic and healthy people, and also between epileptics with generalized and focal epilepsy victims. The findings of their research are published in the journal *Brain*.

Several previous genetic screening genome-wide association studies (GWAS) have been carried out to identify the genes that help predict the individual's risk of epilepsy. In this study, the researchers combined all common gene variants (numbering thousands) identified from multiple large populations studied using GWAS.

Using PRS from a European-ancestry genome-wide association study in generalized (GE) and focal epilepsy, researchers reported that patients with generalized epilepsy of European-ancestry had significantly higher GE-PRS as compared to patients with focal epilepsy.

The researchers concluded that common polygenic variant burden for epilepsy can be measured and is differently distributed among patients with epilepsy (i.e. generalized and focal). Estimation of PRS for epilepsies can provide physicians with an individual's overall genetic risk for epilepsy that could aid in early diagnosis and targeted treatment in the future.

Source: news-medical.net

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GLOBAL NEWS

3. 'EyeArt' automated AI screening system for detection of diabetic Retinopathy

EyeArt

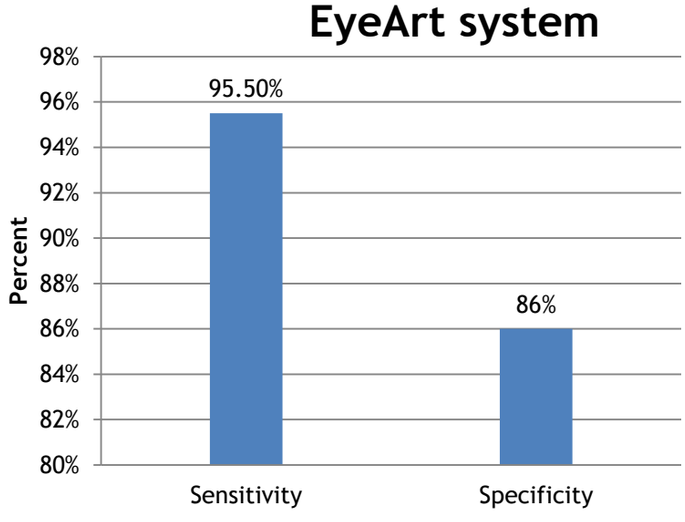
Diabetic retinopathy can develop over time in people with diabetes, especially when they have poor control over their blood sugar levels. An automated artificial intelligence (AI) screening system 'EyeArt' accurately detects diabetic retinopathy with approximately 95% sensitivity.

This system facilitates real-time screening for primary care practices and diabetes centers as it can provide a reading in 60 seconds without the inputs of an expert ophthalmologist. The research was presented at the 123rd Annual Meeting of the American Academy of Ophthalmology.

EyeArt was used to screen 893 patients with diabetes at 15 different medical locations. Results were then reviewed for clinical accuracy by certified graders.

Using only undilated images (patients' pupils were not dilated), the EyeArt system's sensitivity was 95.5%, and specificity was 86%.

Source: news-medical.net



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GLOBAL NEWS

4. Major growth expected in ophthalmic drugs market by 2025

A recent report by the MarketWatch has provided the insights on the current scenario and growth prospects of global ophthalmic drugs market for the period 2019 – 2025. The report was prepared based on the different types of products, technologies, industry verticals, applications, end-users in addition to the suppliers' data on revenue, cost, gross profit, business overview, distribution channel, and interview data.

Ophthalmic drugs are extensively used to treat glaucoma, cataract, diabetic retinopathy, and other ophthalmic disorders. Introduction of novel ocular drug delivery approaches in the market has driven the manufacturers to develop innovative therapeutic approaches for the treatment of ophthalmic disorders.

The other key factors that boost the ophthalmic drug market size include high prevalence of glaucoma worldwide and rise in transition towards development of combination therapies for the treatment of glaucoma.

The report has also disclosed the list of prominent players in this field: Santen Pharmaceutical, Valeant Pharmaceuticals, Shire, Novartis, Genentech, Allergan, Sun Pharmaceutical Industries, Actavis Generics, Regeneron Pharmaceuticals, Pfizer, Johnson and Johnson & Bausch and Lomb.

Source: marketwatch.com

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PHARMA INDIA

1. AstraZeneca to launch once-daily anti-diabetes drug in India

The Drug Controller General of India (DCGI) has approved the import and market permission in India for AstraZeneca's QTERN (fixed dose combination of Dapagliflozin 10mg + Saxagliptin 5mg). This permission paves way for the launch of QTERN in India.

QTERN is a combination anti-hyperglycemic agents with complementary mechanisms of action in a once-daily tablet.

It is comprised of sodium-glucose cotransporter 2 (SGLT2) inhibitor- dapagliflozin and a dipeptidyl peptidase-4 (DPP-4) inhibitor saxagliptin and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Source: health.economictimes.indiatimes.com

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PHARMA INDIA

2. WHO India country cooperation strategy 2019-2023

The Union Health Ministry has launched the 'The WHO India Country Cooperation Strategy 2019–2023: A Time of Transition'.

This program will provide a strategic roadmap for the World Health Organization (WHO) to collaborate with the Government of India in efforts to achieve its health sector goals that includes improving the health of its population and bringing in transformative changes in the healthcare sector.

The four areas identified for strategic cooperation of WHO with the country encompass:

1. to accelerate progress on UHC
2. to promote health and wellness by addressing determinants of health
3. to protect the population better against health emergencies
4. to enhance India's global leadership in health.

The implementation of this CCS will build on the remarkable successes in public health that India has demonstrated to the world. It's a great opportunity to showcase India as a model to the world in initiatives such as digital health, access to quality medicines and medical products, comprehensive hepatitis control programme and Ayushman Bharat.

Source: pharmabiz.com

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PHARMA INDIA

3. New STEMI registry in North India

The North Indian (NORIN) ST-Segment Elevation Myocardial Infarction (STEMI) Registry, introduced in January 2019, will provide preliminary data collected according to a new study published in *Clinical Cardiology*. The NORIN STEMI registry aims to provide important insights regarding contemporary risk factors profiles, practice patterns, and prognosis in patients with STEMI in an underserved population in North India.

Researchers will follow approximately 3,500 patients admitted for STEMI treatment to two government-funded medical centers in New Delhi, India; 558 patients have been registered till date.

Researchers have also found the average age of STEMI patients in this study is nearly ten years younger than the average age of patients in Europe and the U.S. Throughout the course of the study, researchers will follow-up with patients several times within one year of their initial treatment for STEMI.

Source: news-medical.net

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PHARMA INDIA

4. CDSCO to notify list of OTC drugs to prevent misuse of medicines

The Central Drugs Standard Control Organisation (CDSCO) will soon notify a list of over-the-counter (OTC) drugs and will provide specific provisions for their regulation in the country in order to promote self-care without compromising patient safety.

The definition for OTC drug must be laid down in the Drugs and Cosmetics (D&C) Rules, 1945 as per the recent drug consultative committee (DCC) recommendations.

The DCC recommendation comes in the wake of a subcommittee of experts' proposal for adequate labeling in the drug packaging. This will allow the consumers to "self-diagnose," "self-elect," "self-administer" and know when to stop using OTC drugs.

No standard definition exists for OTC drugs in our country. The subcommittee has suggested that a formulation should have been sold for ≥4 years for it to be considered as an OTC medicine. The experts have suggested two separate categories:

- OTC1 - for those sold at retail outlets
- OTC2 - for those sold at pharmacies.

The experts have also proposed "labelling requirements", which include a logo specifying whether a medicine is an OTC drug or an "OTC drug to be specified".

Source: pharmabiz.com

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REGULATORY ROUND-UP

1. CDRH releases 2020 draft and final guidance list

FDA's Center for Devices and Radiological Health (CDRH) on Friday released its FY 2020 draft and final guidance list, which features a few repeats from last year and new drafts regarding device servicing and remanufacturing, unique device identification and patient-reported outcome measures used in device submissions, among others. As in years past, CDRH divides the list between "A-list" draft and final guidances, which are a priority, and a smaller "B-list" of draft and final guidances, which CDRH says it will publish as resources permit.

In addition to the aforementioned A-list draft guidances, CDRH also plans to publish one on labeling for breast implants, one on implementing its new Safety and Performance Based Pathway, and two revised draft guidances on post-market surveillance and post-approval studies.

There are also repeats from last year's draft guidances A-list, such as one on the "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," and one on "Computer Software Assurance for Manufacturing, Operations, and Quality System Software."

Source: raps.org

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REGULATORY ROUND-UP

2. New pharmaceutical quality assessment system

The US Food and Drug Administration (FDA) is developing a new, more standardized system, 'Knowledge-aided Assessment & Structured Application (KASA)' in order to improve and modernize the quality assessment of drug applications. An article on the same authored by officials from FDA's Center for Drug Evaluation and Research has been featured in the latest issue of the *International Journal of Pharmaceutics*.

KASA is a new system to capture and manage information in a structured format about the inherent risk and control approaches for product design, manufacturing and facilities. KASA will help in addressing challenges related to FDA's quality assessments.

In this system, a failure mode effects and criticality analysis (FMECA) approach is employed on the information entered in the system. An objective and quantitative assessment of the information is done and the risks associated with the failure modes of drug product design and manufacturing are ranked accordingly.

Although KASA is being primarily developed as an assessment tool, "it is capable of alleviating problems" associated with the submission of drug applications via the electronic common technical document (eCTD) format, according to the FDA officials.

Source: raps.org

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REGULATORY ROUND-UP

3. Classifying software under MDR, IVDR: new guidance from MDCG

The European Commission's Medical Device Coordination Group (MDCG) has released a guidance document to help medical software manufacturers to understand the criteria for qualification of software under the new EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

For instance, medical device software (MDSW) may be independent and able to receive measurements.

An example of software that can use transrectal ultrasound findings, age and in vitro diagnostic instruments to calculate a patient's risk of developing prostate cancer is given in the guidance document. This software can

- operate, modify the state of, or control the device
  - either through an interface (e.g., software, hardware) or via the operator of this device
- or supply output related to the (hardware) functioning of that device

A decision tree is also provided in the 28-page guidance document that features five steps for the qualification of MDSW.

Source: raps.org

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REGULATORY ROUND-UP

4. FDA plots path to regulate N-of-one trials

In an editorial published in the *New England Journal of Medicine*, the US Food and Drug Administration (FDA) officials have explained how new technologies can "permit the delineation of pathways for truly individualized drug development". The FDA is monitoring the recent phenomenon where doctors are creating a tailored treatment for individual patients with a rare genetic mutation that could prove fatal.

The FDA is planning to publish draft guidance on individualized therapies regulation soon but there are several challenges in creating the guidance, which could be:

- What type of evidence is needed before exposing a human to a new drug?
- Even in rapidly progressing, fatal illnesses, precipitating severe complications or death is not acceptable, so what is the minimum assurance of safety that is needed?
- How persuasive should the mechanistic or functional data be?
- How should the dose and regimen be selected? How much characterization of the product should be undertaken?
- How should the urgency of the patient's situation or the number of people who could ultimately be treated affect the decision-making process?

The agency also needs to address potential n-of-1 failures.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Novo Nordisk and Bluebird Bio collaborate to develop genetic disease drugs

Novo Nordisk has collaborated with US-based gene therapies firm Bluebird Bio for a three-year research alliance. They will develop *in vivo* genome editing products for the treatment of genetic diseases. The companies will work together towards a gene therapy candidate to treat hemophilia A, which is expected to mitigate the need for factor replacement therapy. The project will initially focus on the correction of FVIII-clotting factor deficiency.

Bluebird has made tremendous progress on enabling an *in vivo* gene editing platform based on their megaTAL technology, including important advances in high-quality mRNA production and purification.

Novo Nordisk received US FDA approval for its drug Esperoct to treat hemophilia A in adults and children in February, 2019.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Akcea's ANTPTL3-targetting drug: Pfizer licenses for $250m

Pfizer and Ionis subsidiary Akcea have entered into a global exclusive licensing agreement for antisense therapy AKCEA-ANGPTL3-LRx. Pfizer will upfront pay $250m to Akcea and Ionis according to the terms of the agreement.

AKCEA-ANGPTL3-LRx controls the production of angiopoietin-like-3 (ANGPTL3) protein in the liver, which is known to regulate triglycerides, cholesterol, glucose and energy metabolism. These are being developed for cardiovascular and metabolic diseases.

The AKCEA-ANGPTL3-LRx drug is currently being evaluated in a Phase II clinical study for hypertriglyceridemia, type 2 diabetes and non-alcoholic fatty liver disease.

AKCEA® THERAPEUTICS

After the current agreement, Pfizer is now responsible for the further development of AKCEA-ANGPTL3-LRx in this trial and future studies, as well as regulatory activities and all the related costs.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. GSK and Lyell collaborate to develop cell therapies for cancer

GlaxoSmithKline (GSK) has entered into a 5-year partnership with US-based biotechnology firm Lyell Immunopharma. This collaboration will focus on developing technologies to boost cancer cell therapies.

Under this partnership, the cell and gene therapy programmes of GSK will be combined with Lyell's technologies in order to maximize the activity and specificity of these therapies for the treatment of solid tumors.

Patients with solid tumors are in need of equally effective treatments and GSK is observing significant scientific innovation in cell and gene therapies, transforming the treatment of blood-borne cancers.

Lyell is working to create approaches for the preparation of patient cells into therapies and the modification of cell functionality to retain activity in the tumor microenvironment.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. AI drug development: Novartis partners with Microsoft

Novartis has partnered with Microsoft to leverage the latter's artificial intelligence (AI) technology for the discovery, development and commercialization of medicines.

Novartis has established an AI innovation lab, where the datasets of the company will be combined with Microsoft's AI solutions. This will generate AI models and applications that may help researchers in drug development. The companies will work together at:

a) Novartis Campus in Switzerland
b) Novartis Global Service Center in Dublin, Ireland
c) Microsoft Research Lab in the UK.

Personalized therapies for macular degeneration, cell and gene therapies and drug design will be initially studied by the companies. For this partnership, the overall investment will involve project funding, subject-matter experts, technology and tools.

Source: pharmaceutical-technology.com

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DRUGS: APPROVALS AND LAUNCHES

1. FDA breakthrough therapy designation to niraparib

Niraparib has received the Breakthrough Therapy Designation to for the treatment of patients with BRCA1/2 gene-mutated metastatic castration-resistant prostate cancer (mCRPC) from the US Food and Drug Administration (FDA).

The FDA's decision was based on the results from a Phase II multicenter, open-label clinical trial evaluating the efficacy and safety of niraparib conducted by Janssen research and development.

Niraparib is indicated for the treatment of patients who have previously received taxane chemotherapy and androgen receptor (AR)-targeted therapy.

A Phase III trial evaluating niraparib in combination with abiraterone acetate and prednisone is currently ongoing. Niraparib is an orally-administered poly ADP-ribose polymerase (PARP) inhibitor, which may be useful for patients with mCRPC with mutations in DNA-repair genes.

Source: europeanpharmaceuticalreview.com

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DRUGS: APPROVALS AND LAUNCHES

2. US FDA approves Trikafta for cystic fibrosis

The US Food and Drug Administration (FDA) has approved Vertex Pharmaceutical's three-drug combination Trikafta (elexacaftor, ivacaftor and tezacaftor) for the treatment of cystic fibrosis (CF) in patients aged ≥12 years with ≥1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

The US FDA has approved the drug based on the positive findings from a 24-week and a four-week Phase III studies in patients (n=403) having one F508del mutation and one F/MF, as well as 107 patients with two F508del mutations (F/F), respectively.

According to company sources, the triple combination drug can be prescribed to around 6,000 patients with one F508del mutation and one minimal function mutation (F / MF). In addition to that, ~12,000 patients who have one or two F508del mutations are also eligible.

"The incredible speed of this approval underscores our shared sense of urgency with the FDA and the CF community for bringing this medicine to eligible people with CF, particularly those without a medicine targeting the underlying cause of their disease," said Reshma Kewalramani, chief medical officer and Global Medicines Development and Medical Affairs executive vice-president at Vertex Pharmaceuticals.

Source: medgazette24.com

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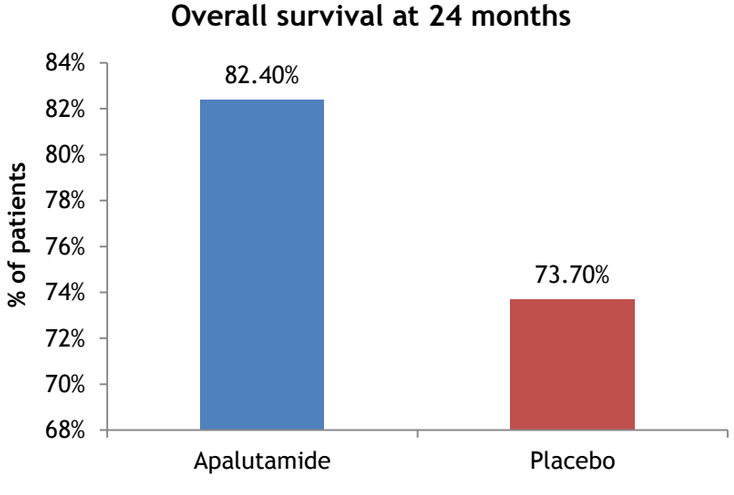
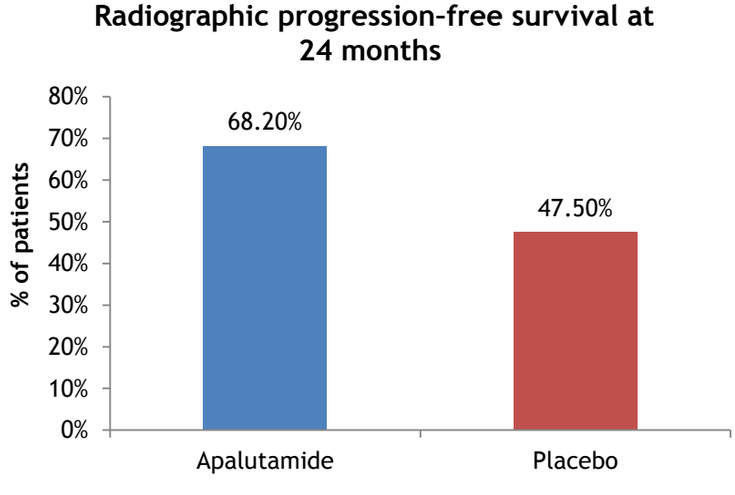
DRUGS: APPROVALS AND LAUNCHES

3. Apalutamide receives FDA approval for mCSPC

The US Food and Drug Administration (FDA) has expanded the approval of apalutamide for the treatment of men with metastatic castration-sensitive prostate cancer (mCSPC). Apalutamide (Erleada, developed by Janssen Research and Development) — an oral androgen receptor inhibitor —had already been approved for the treatment of non-metastatic castration-resistant prostate cancer.

The new indication was approved based on results of the randomized Phase III TITAN study, which included 1,052 patients with mCSPC who were randomized to androgen deprivation therapy plus either apalutamide 240 mg daily (n = 524) or placebo (n = 527). The study showed the addition of apalutamide to ADT significantly extended OS (HR = 0.67; 95% CI, 0.51-0.89) and radiographic PFS (HR = 0.48; 95% CI, 0.39-0.6).





Source: healio.com

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DRUGS: APPROVALS AND LAUNCHES

4. FDA approves new HIV-prevention drug

The US Food and Drug Administration (FDA) has approved Gilead Science's Descovy to prevent HIV infection in men and transgender women. Descovy is part of an HIV-prevention strategy called pre-exposure prophylaxis (PrEP), whereby patients at very high risk for HIV infection take medication to reduce the likelihood of infection. Descovy is only the second PrEP drug that has been approved by FDA, after Gilead's Truvada.

For the latest approval, Gilead tested Descovy in a multinational randomized double blind trial of HIV-negative patients. The trial included 5,313 men and 74 transgender women who have sex with men. The trial did not include cisgender women.

FDA approved Descovy as PrEP treatment for adults and adolescents who weigh at least 35kg, "excluding those who have receptive vaginal sex." FDA in a release explained, "Descovy is not indicated in individuals at risk of HIV-1 infection from receptive vaginal sex because the effectiveness in this population has not been evaluated."

Source: advisory.com

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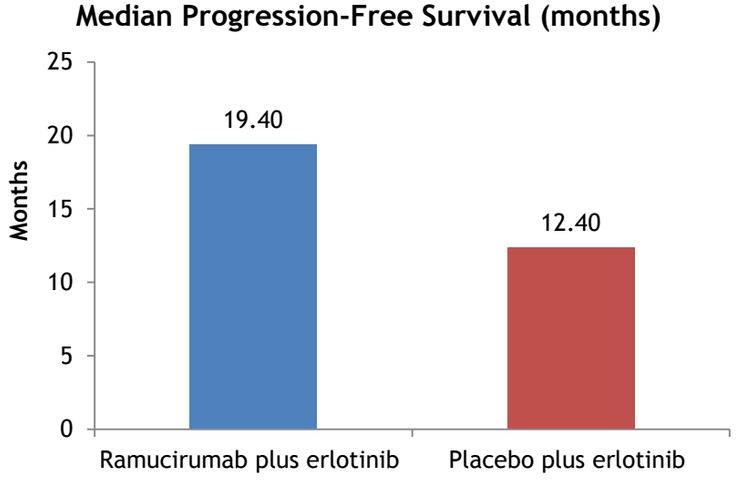
DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Ramucirumab Phase 3 data in first-line EGFR-Mutated NSCLC

Eli Lilly's Cyramza (ramucirumab) and erlotinib combination significantly improved progression-free survival (PFS) in first-line epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) patients. This data from a Phase III study is recently published in *The Lancet Oncology*.

Tyrosine kinase inhibitors (TKIs), including erlotinib, are the current standard of care for EGFR-mutated NSCLC, but many patients require multiple lines of treatment.



The RELAY trial evaluated ramucirumab in combination with erlotinib compared with placebo in combination with erlotinib as a first-line therapy in previously untreated patients (n=449) with metastatic EGFR-mutated NSCLC.

Ramucirumab plus erlotinib demonstrated a statistically significant and clinically meaningful improvement in median PFS compared with placebo plus erlotinib (19.4 months vs. 12.4 months [HR 0.59; 95% CI, 0.46-0.79; P=<0.0001]).

Source: pharmacytimes.com

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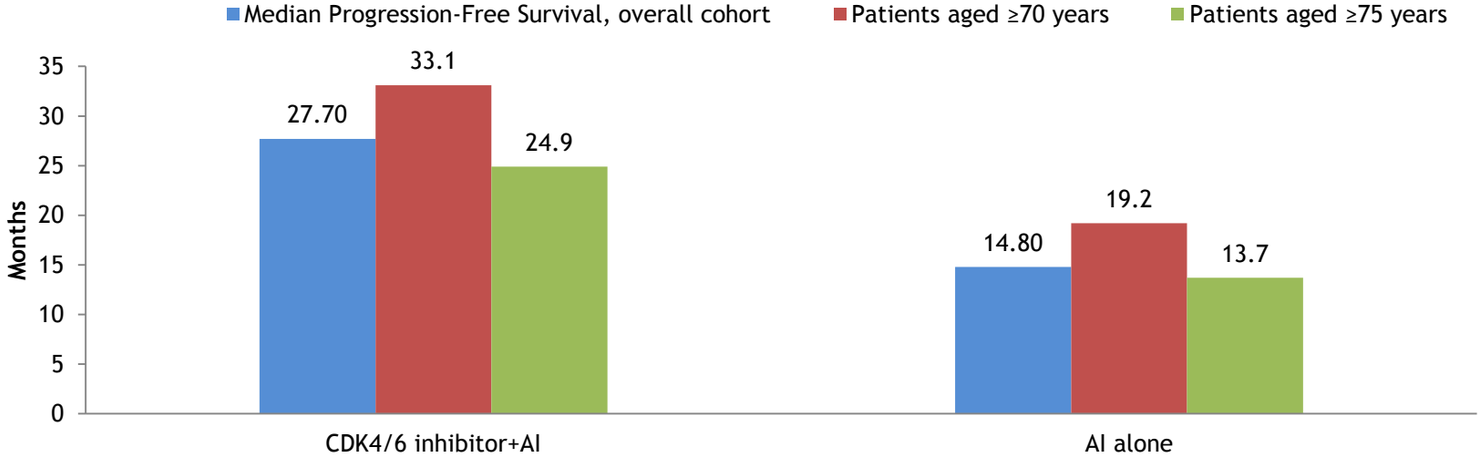
DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. CDK4/6 inhibitor + aromatase inhibitor: effective in breast cancer

A pooled analysis of data from 3 randomized clinical trials [PALOMA-2 (ClinicalTrials.gov identifier; NCT01740427; letrozole with or without palbociclib), MONALEESA- 2 (ClinicalTrials.gov identifier: NCT01958021; letrozole with or without ribociclib), or MONARCH-3 (ClinicalTrials.gov identifier: NCT02246621; anastrozole or letrozole with or without abemaciclib)] that evaluated the efficacy and safety of a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor in combination with an aromatase inhibitor (AI) as first-line treatment for women with hormone receptor-positive, HER2-negative metastatic breast cancer showed similar benefits in older and younger postmenopausal women from this treatment. However, older women experienced more toxicity.

The findings were published in the *Journal of Clinical Oncology* that included 1105 patients enrolled in the aforementioned studies. Within this group of patients, 456 (25%) and 198 (10.8%) were at least 70 or 75 years of age, respectively.



Source: cancertherapyadvisor.com

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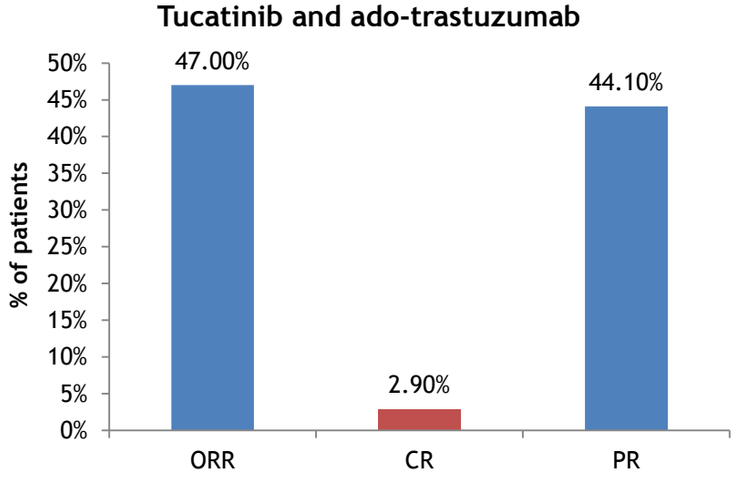
DRUGS: DEVELOPMENT & CLINICAL TRIALS

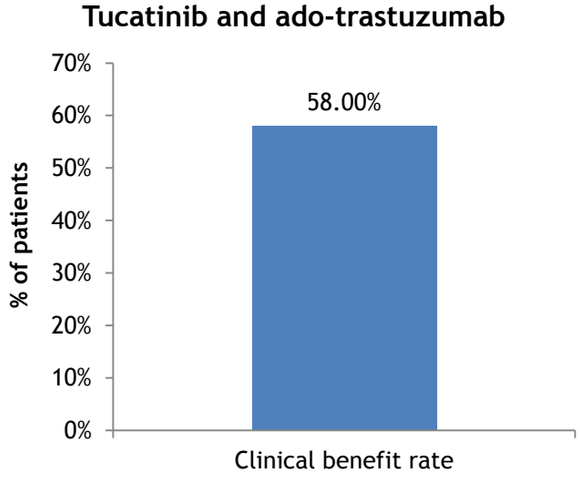
3. Tucatinib and T-DM1 in HER2+ breast cancer

HER2CLIMB

A randomized, double-blind Phase III trial, HER2CLIMB-02, investigated the combination of tucatinib and ado-trastuzumab emtansine (T-DM1, Kadcyla) in patients with locally advanced or metastatic HER2-positive breast cancer.

In this study, patients had a median age of 51 (range, 44-63) and most had an ECOG performance status of 1.





Source: targetedonc.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Oncorus to advance oncolytic virus therapies

Oncorus, a US based oncolytic virus (OV) company, has raised $79.5m (£65.56m) in advancing a portfolio of locally and systemically administered (IV) OV therapies based on its oncolytic Herpes Simplex Virus (oHSV) and Synthetic Virus Platforms.

The oncolytic virus space continues to gain momentum, as signaled by continued investment from both financial and strategic parties. Oncorus is poised to become a leader in this emerging modality.

Oncorus intends to use the proceeds from the Series B funding round to advance ONCR-177, its lead candidate into clinical development in early 2020, which has been developed on the oHSV platform. ONCR-177, which is intended to be intratumorally administered, is an oncolytic virus clinical candidate that is being developed for the treatment of various solid tumors. ONCR-177 facilitates the development of oncolytic viruses with high payload capacity for potent activation of various arms of the immune system.

Source: globalpharmaupdate.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Patent infringement lawsuit for generic oxymetazoline cream

Aclaris Therapeutics, Inc. has filed a patent infringement lawsuit against Taro Pharmaceuticals, Inc. ("Taro") in the United States District Court for the District of Delaware. The lawsuit is related to Taro's Abbreviated New Drug Application (ANDA) filed with the U.S. Food and Drug Administration (FDA) for marketing of a generic version of RHOFADE® (oxymetazoline hydrochloride) cream, 1%.

Aclaris Therapeutics, Inc. (Nasdaq: ACRS) is a physician-led biopharmaceutical company, which is focused on immuno-inflammatory diseases.

The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations 'Orange Book' for RHOFADE.

Source: nasdaq.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Patent for 'Cyclobenzaprine' as a treatment for PTSD

The European Patent Office's (EPO) Opposition Division has upheld Tonix Pharmaceuticals' European Patent 2501234B1 with claims covering compositions containing the active ingredient in TNX-102 SL, cyclobenzaprine.

The drug is intended for use in treating the development, initiation, consolidation, and perpetuation of posttraumatic stress disorder (PTSD) symptoms following a traumatic event.

The EPO had originally granted this patent in September 2017 and an opposition was filed against the patent in June 2018.

The U.S. counterpart to the European patent is U.S. Patent No. 9,918,948, the validity of which is not being challenged. Tonix owns additional patents covering TNX-102 SL and its use to treat PTSD in the U.S., Europe, and other countries. Together, these patents protect the use of TNX-102 SL in Europe and elsewhere.

Source: streetinsider.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Acorda's appeal in MS drug patent fight rejected by US supreme court

The U.S. Supreme Court has declined to hear Acorda Therapeutics Inc's appeal related to the generic versions of its multiple sclerosis treatment Ampyra. The lower court has ruled in favor of generic version and that caused a decrease in the drug's sales.

The Supreme Court justices refused to review a September 2018 decision by the U.S. Court of Appeals for the Federal Circuit to cancel Acorda's patents covering Ampyra.

Ampyra is the first approved drug to improve walking in people with multiple sclerosis.

Source: reuters.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. BioLife solutions wins three new patents

BioLife Solutions, a leading developer and supplier of best-in-class bio production tools for cell and gene therapies, has won three new patents for inventions related to cryopreservation, thawing and cold chain transport technologies.

The new patents awarded to BioLife include:

1. European Patent: Apparatuses and Compositions for Cryopreservation of Cellular Monolayers.
    a. claims related to facilitating bulk freezing of adherent cells in multi-well plates for use in high-throughput drug screening processes.
2. United States Patent: core technologies used in the ThawSTAR® automated thawing products.
3. United States Patent: Insulated Storage and Transport System
    a. core technologies used in the evo® cloud-connected precision thermal shipping containers.

Source: biospectrumindia.com

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TECHNOLOGY /NDDS

1. Microfluidic device for rapid lyme disease diagnosis

Diagnosing and treating disease early is important in achieving good patient outcomes. The current diagnostic tests for Lyme disease require both an ELISA and a western blot, which comes with several challenges including that they are cumbersome, take more time to perform, and require trained laboratory specialists; but the accuracy in identifying Lyme disease at an early stage is quite poor.

Researchers at Columbia University have developed a microfluidic device that can diagnose Lyme disease in as little as 15 minutes. The device is particularly accurate in identifying antibody biomarkers that are present during the early stage Lyme disease. This gives a hope that it could be useful in detecting cases of early infection in a doctor's office, leading to timely treatment.

The new assay method detects three biomarkers of Lyme disease in patient samples. It has demonstrated a greater sensitivity than traditional Lyme detection assays. Furthermore, it has shown better efficacy in detecting early stage Lyme disease and it has the potential to detect antibodies in the blood in the first few weeks after someone contracts Lyme disease.

Source: medgadget.com

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TECHNOLOGY /NDDS

2. Medtronic's tiny new InterStim micro neurostimulator

Medtronic has filed for the US Food and Drug Administration (FDA) approval for its InterStim Micro neurostimulator and the accompanying InterStim SureScan MRI leads.

This is a rechargeable device that can deliver sacral neuromodulation therapy to treat conditions such as overactive bladder, fecal incontinence, unobstructed urinary retention, and urinary urge incontinence.

Sacral stimulation involves modulating signals passed between the brain, bowel, and bladder, improving performance of the underlying muscles. The new implant is 80% smaller, recharge-free and is more comfortable to wear. Also, it should function for 15 years without needing replacement surgery.

Source: medgadget.com

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TECHNOLOGY /NDDS

3. Low power MRI helps image lungs, brings costs down

The new days clinical magnetic resonance imaging (MRIs) have a pretty powerful magnetic field strengths of 1.5 or 3.0 Tesla in general. But these devices are very expensive owing to their strength. While such strengths have been standard for a long time, the internal hardware and software beyond the magnets have been improving steadily.

The researchers at the National Institutes of Health in collaboration with a team at Siemens are evaluating a modern low strength operated MRI. In order to make them affordable, it is advisable to build weaker MRIs. The researchers used a Siemens MAGNETOM Aera, normally a 1.5T scanner, which was toned down to .55T and compared the difference in the scanner's output with 1.5T scanner in healthy volunteers and patients with lung diseases.

The new low strength MRI scanner could detect lung cysts and the surrounding anatomy in those with lymphangioleiomyomatosis. Interestingly, inhaled oxygen worked more effectively, as an easy to use contrast agent, than with more powerful MRIs. The researcher concluded that low power MRI may be an excellent imaging modality for lung conditions.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. New drug capsule for oral delivery of insulin, protein-based drugs

Researchers at MIT and Novo Nordisk have collaborated to create a swallowable pill that can carry and deliver insulin into the body. The pill form is the most common amongst the route of drug administration, but some need to be injected to avoid gastrointestinal tract metabolism. Insulin is by far the most injected medication in the world.

The new insulin pill is developed by the researchers through polymer coating which allows it to pass safely through the stomach and reach the small intestine, where the pill disintegrates at the surrounding pH of about 6.

Three appendages pop out that have microneedles on their surface, which allows the appendages to stick to the interior wall of the small intestine, and the microneedles serve as a route for the drug to reach the tissue. To aid in safety and to make sure that the device doesn't block the narrow lumen of the small intestine, the appendages break apart soon after delivery.

Researchers have tested the device on pigs and found that insulin can be delivered in useful quantities and it is quickly absorbed into the body soon after administration.

Source: medgadget.com

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