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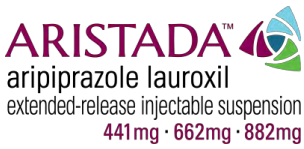
PHARMA HIGHLIGHTS

FDA Approves New Injectable Drug to Treat Schizophrenia

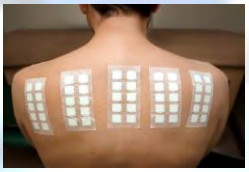
The U.S. Food and Drug Administration approved Aristada (aripiprazole lauroxil) extended release injection manufactured by Alkermes, Inc. of Waltham, Massachusetts to treat adults with schizophrenia on October 5, 2015. Aristada is administered by a health care professional every four to six weeks using an injection in the arm or buttocks. Schizophrenia is a chronic, severe brain disabling disorder affecting about one percent of Americans. Typically, symptoms are first seen in adults younger than 30 years of age and include hearing voices, believing that other people are reading their minds or controlling their thoughts and being suspicious or withdrawn. The efficacy of Aristada was demonstrated in part by a 12-week clinical trial in 622 participants. In participants with acute schizophrenia who had been stabilized with oral aripiprazole, Aristada was found to maintain the treatment effect compared to a placebo. Aristada and other atypical antipsychotic drugs used to treat schizophrenia have boxed health-care professionals about an increased risk of death associated with the off-label use of these drugs to treat behavioral problems in older people with dementia-related psychosis. No drug in this class is approved to treat patients with dementia-related psychosis. Aristada must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. The most common side effect reported by participants receiving Aristada in clinical trials was feeling the urge to move constantly, a phenomenon known as akathisia. **-Fabiha Tasnim**



http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465801.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Patch Testing Guidelines for Allergic Contact Dermatitis

Allergic contact dermatitis, a cutaneous inflammatory process, is responsible for considerable morbidity and is a common cause of occupation-related skin disease. Patch testing is used to diagnose the problem and identify responsible agents. Experts convened by the European Society of Contact Dermatitis developed guidelines regarding the use of this important diagnostic tool. Patch testing is indicated when contact allergy is a consideration. It may also be useful in:



1) Resistant cases of atopic, stasis or seborrheic dermatitis with a possible superimposed contact allergy,
2) Inflammatory disorders of mucous membranes,
3) When reactions to implants are suspected and
4) Some cases of erythema multiforme, lichen planus, psoriasis, and granulomatous reactions.

When interpretation might be difficult (e.g., in patients taking immunosuppressive medications, when the dermatitis involves skin sites chosen for patch test application or when patch test sites have recently been exposed to topical steroids or ultraviolet radiation), postponing patch testing might be prudent. Oral antihistamine use and topical steroids at sites other than the patch test sites are not a contraindication. In patients with immunosuppressive diseases or in whom withdrawal of immunosuppressive medications is impossible, patch testing can be performed, although test sensitivity may be reduced. Patch testing is generally very safe but adverse effects include irritant reactions, sensitization to chemicals, pigmentary changes, flare of dermatitis in other body areas and persistent reactions. Scarring and necrosis are extremely unlikely but have been described. **–Tanisha Momtaz**

http://www.jwatch.org/na38996/2015/09/22/patch-testing-guidelines-allergic-contact-dermatitis?query=topic_allergy&jwd=000020044402&jspc=

Best Practices for Standard Operating Procedures

One of the first things FDA investigators will look at during an inspection is how well written is the standard operating procedures. A well-written SOP helps to demonstrate the compliance and say to inspectors: "We know what we are doing — and why." But what exactly does an SOP need to contain to be "adequate?" What information, if any, should be omitted? How does one write them so that employees can easily understand and follow them and when do they need to be changed? A new management report from FDA news will teach one the practical techniques one needs for crafting well-written, fast-read, flexible and compliant SOPs that will meet FDA requirements as well as today's globalized expectations. This report will provide best practices for SOP development including the characteristics of a good SOP, regulatory requirements for SOPs from the FDA and EMA, lessons from FDA warning letters, the business costs of poor SOPs, what a process map is and how to create one, advanced SOP strategies, including how to save time and reduce overhead in SOP development, frequent mistakes in SOPs, maintenance and control SOPs etc. The report also includes checklists and templates for writing SOPs as well as examples of good SOPS. **-Noshin Mubtasim**

http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=2323357997&message_id=11257413&user_id=FDANEWS&group_id=1373975&jobid=30341493

Ultrasound shows promising effect in treatment of Alzheimer's disease

Over the years many research brought about drugs for treatment of the most common dementia, Alzheimer's disease but they all gradually proved to be either ineffective or had prominent side-effects. University of Queensland in Australia tried to bring about a new dimension to the treatment of Alzheimer's disease by carrying out a research on mice using a non-invasive method and it brought about great success in mice. The non-invasive method involved use of high energy sound waves known as focused therapeutic ultrasound. It has been determined that accumulation of beta-amyloid clumps is one of the reasons for development of Alzheimer's disease as these clumps or plaques form a sticky mass that end up between neurons and hamper transmission of signals through neurons. The research showed that when genetically engineered mice with beta-amyloid plaques are exposed to super fast ultrasound, the

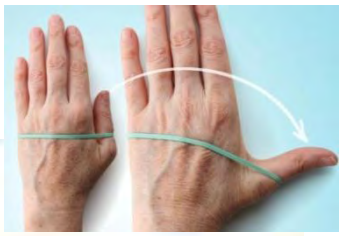
beam of sound waves open up blood brain barrier and cause stimulation of microglial cells of the brain. Thus the microglial cells become activated and as per their function of removing waste clear up the beta-amyloid plaques resulting in relief from the worst symptom of Alzheimer's disease. This was successful in 75% of the mice and also showed to enhance memory of the mice through three memory tasks. However, this is a very initial level of research that inferred such new finding in only mice which may not have same response in human so further studies must be carried out before drawing any final conclusion of this research on treatment of this complex disease. **–Nausheen Sayeara**

http://www.nhs.uk/news/2015/03march/pages/ultrasound-breakthrough-in-treating-alzheimers-in-mice.aspx

Exercise Program for Hand Osteoarthritis

The women having hand OA (Osteoarthritis) were very successful to minimize the joint pain, achieved a better function and also got a greater grip strength after a 3-months of exercise involvement.

Osteoarthritis is degenerative joint disease or "wear and tear" arthritis. Osteoarthritis (OA) is the most common chronic condition of the joints. It occurs when the cartilage or cushion between joints breaks down leading to pain, stiffness and swelling. There are many treatments or medicines for the patients who have hand osteoarthritis like acetaminophen, NSAID (nonsteroidal anti-inflammatory drug), topical therapies, local injections, splints, and surgery. Hand-exercise therapy is also recommended but few data support its use. The study was conducted over 80 women (average age, 61) having hand OA which was diagnosed according to American College of Rheumatology criteria. After that at least three hand OA–related activity limitations were randomized to a home-based hand-exercise program or an information-only control group. An instruction was given to the exercise group to perform the hand exercise program three times weekly and the program would continue with 10 repetitions of each exercise during the first 2 weeks, 12 repetitions during the next 2 weeks, and 15 repetitions during the rest of the exercise period. The average change in activity performance was finally found based on the 10-point Patient-Specific Functional Scale after 3 months. The change was 1.8 points in the exercise group and 0.2 points in the control group which is very noteworthy. Some important differences for joint pain, grip strength and hand fatigue were also noted in favor of the exercise group. Even if those exercises gradually incremented hand pain the effects lessened with time. **-Sohanur Rahman**



http://www.jwatch.org/na38839/2015/09/17/exercise-program-hand-osteoarthritis?query=topic_ard&jwd=000020044402&jspc=

Cancer Treatment with Diabetes-Land of Many Opportunities

Chronic myelogenous leukemia, one of the most dangerous and life-threatening disease associated with a high mortality rate is mainly caused by chromosomal translocation results in the creation of fused gene producing as oncoprotein, BCR-ABL contributes to the abnormal increase of White Blood Cells. In the world of clinical improvement, drugs like imatinib (Gleevec) and other tyrosine kinase inhibitor targeting the particular oncoprotein has shown some real promise with less cures due to the presence of dormant (nonreplicating) cancer stem cell which can be activated further in the future to cause etiological sign of CML in the future. Activation of Peroxisome proliferator-activated receptor gamma (PPARγ) leads to a molecular pathway activates majority of cancer stem cell, thus making the patients more vulnerable to treatment which is suggested by the reports of a French Team. The same team added that usage of PPARγ -activating drug pioglitazone, a drug approved for diabetes, responded to imatinib to those patient not achieving complete molecular response previously (involving eradication of BCR-ABL Transcripts). The report has shown that the complete molecular response lasted as long as 4.7 years. Non-randomized phase II trail (ACTIM; still in progress) in the studies by the same author has reported preliminary results of 57% of the patients achieving complete molecular response so far. This concept would help in the effective treatment of cancer by targeting the oncoprotein completely due to the complete response of the cancer which will help in the cure of cancer patients in the near future.

-Samin Huq

http://www.jwatch.org/na39317/2015/10/15/could-diabetes-drug-cure cml?query=etoc_jwgenmed&jwd=000020044402&jspc=

Drugs Approved by FDA on September 2015

Name of Drug	Pharmaceutical uses
Insulin Degludec	For glycemic control in adults with mellitus
Tipiracil Hydrochloride and Trifluridine	For the treatment of metastatic colorectal cancer
Rolapitant	For the prevention of delayed nausea and vomiting associated with chemotherapy
Uridine Triacetate	For the treatment of hereditary oroticaciduria
Cariprazine	For the treatment of schizophrenia and bipolar disorder

http://www.fda.gov **-Raihanatul Anwar**

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