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# PHARMA HIGHLIGHTS

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## Erelzi, a New Biosimilar, Receives FDA Approval for Multiple Inflammatory Diseases


Erelzi (etanercept-szzs), a biosimilar drug manufactured by Sandoz Inc, New Jersey has been given approval for multiple inflammatory diseases by the U.S. Food and Drug Administration. The drug is a biosimilar to Enbrel (etanercept), manufactured by Amgen Inc, California. Enbrel was approved by FDA back in 1998. It treats several inflammatory diseases by inhibiting TNFα, a key regulator of inflammation. The newly approved Erelzi is also intended for the treatment of moderate to severe rheumatoid arthritis (either as a standalone treatment or in combination with methotrexate), active psoriatic arthritis, active ankylosing spondylitis, chronic moderate to severe plaque psoriasis in adults as well as moderate to severe polyarticular juvenile idiopathic arthritis in patients aged two and above. The approval of Erelzi is based upon evidence-based review involving structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data and other clinical safety and effectiveness data. According to Janet Woodcock MD, director of the FDA's Center for Drug Evaluation and Research, targeting key inflammatory pathways represents an excellent strategy for the treatment of rheumatic and autoimmune diseases. However, the FDA warns that Erelzi has potential side effects like infections, neurologic events, congestive heart failures, and hematologic events. Erelzi is not intended for use in patients with sepsis. A Boxed Warning on Erelzi alerts patients about enhanced risk of serious infections including tuberculosis, invasive fungal infections (such as histoplasmosis) which could result hospitalization or even death. **- Dr. Zulfiquer Hossain**

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm51863

## Omega 3: Role in Eradication of Heart Attack

Cardiovascular diseases, being one of the leading causes of deaths accounts for 801,000 deaths in the United States alone and scientist and research investigators have been striving for generation in the development of list of ways for the minimization of fatalities from heart complications. Studies containing analysis of over 45000 patients in 16 countries conducted through a partnership between the School of Medicine, Standford University and Friedman School of Nutrition Science, Tufts University finding consistent results across multiple factors such as age, sex, race, diabetes, aspirin or cholesterol-lowering medication depicts the clear connection between Omega-3 fatty acids and their protective effects over the heart. Liana C. Del Gobbo, PhD, leader of the study group claimed their study providing the most comprehensive picture till date on the influence of Omega-3 fatty acid on heart disease. The study also found that compilation of results obtained on the use of major sources of Omega-3 fatty acid could mitigate 10% of risk of fatal heart attacks. Furthermore, another 25 percent of risk of fatal heart diseases can be averted on the high level of Omega-3 obtained from the study results employing a comparative analysis of Omega-3 fatty acid level in blood and tissues. In addition to that, the same studies also bolstered the facts that there is no involvement of Omega-3 fatty acid on the risks of nonfatal heart attacks. **- Samin Huq**

http://www.labroots.com/trending/cardiology/3541/omega-3-fatty-acids-fix-broken-heart

## Amjevita, a Biosimilar to Humira, Wins FDA Approval


Amgen's Amjevita (adalimumab-atto) is the first adalimumab (Humira) biosimilar approved by the U.S. Food and Drug Administration (FDA) on September 23, 2016. It is used for the treatment of seven inflammatory diseases, including rheumatoid arthritis, Crohn's disease, and plaque psoriasis. Amjevita is an anti-TNF-α monoclonal antibody that has the same amino acid sequence as adalimumab. Amjevita is not approved as an interchangeable product, indicating that the pharmacist needs direction from the prescribing doctor to substitute Amjevita for Humira. The most serious known side effects with Amjevita are infections and malignancies. Common side effects include increased risk of infections and injection site reactions. Amjevita will be commercially available in a prefilled syringe or autoinjector. A biosimilar is a biological product that is approved based on an evidence that shows it is highly similar to an already-approved biological product and has no clinically meaningful differences in terms of safety, purity and potency (i.e., safety and effectiveness) from the reference product. In addition to meeting other criteria specified by law. According to Janet Woodcock, M.D., Director of the FDA's Center for Drug Evaluation and Research "This is the fourth FDA-approved biosimilar. The biosimilar pathway is still a new frontier and one that we expect will enhance access to treatment for patients with serious medical conditions". Amjevita is manufactured by Amgen, Inc., of Thousand Oaks, California. Humira was approved in December 2002 and is manufactured by AbbVie Inc. of North Chicago, Illinois. **Source: FDA**

## Fighting Allergy Season with Medications

An allergy is a heightened immune system reaction to a substance that your body has identified as an invader. Allergic rhinitis affects more than 30 million children and adults in the United States and more than 500 million people worldwide. It may be seasonal or year-round. Seasonal allergies aren't just a nuisance, they are real diseases that can interfere with work, school or recreation, and can range from mild to severe. If allergy is suspected, "The first step is to get appropriate testing to determine what you're actually reacting to. Tests include a skin prick test, which involves placing the allergen extract on the skin and pricking so it goes under the skin's surface then wait 15 minutes to obseve any swelling. An injection of a small amount of an allergen, or a blood test, which can detect and measure antibodies to certain allergens can also be done. Once allergy testing is done medication can be indicated to relive symptoms and to desensitize. Symptoms of allergy can be reated by using 1st generation antihistamines such as, diphenhydramine. Newer second generation antihistamines such as fexofenadine and loratadine may also be used. In addition, nasal sprays and eye drops can help improve some allergic symptoms. If you don't respond to medications to relieve symptoms, allergy shots to decrease sensitivity to inhaled allergens can be given weekly.

**Source: FDA**

## FDA Accepts KEYTRUDA® for First-Line Treatment of Patients with Advanced Non-Small Cell Lung Cancer

The U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) for KEYTRUDA® (pembrolizumab) for Priority Review. KEYTRUDA® is Merck's anti-PD-1 therapy that is used as the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC). The FDA also granted Breakthrough Therapy Designation for this indication. Merck has also submitted a Marketing Authorization Application to the European Medicines Agency for KEYTRUDA®. Phase 3 study showed that KEYTRUDA monotherapy resulted in superior progression-free survival (PFS) as well as overall survival (OS) compared with standard chemotherapy in patients with advanced NSCLC whose tumors expressed high levels of PD-L1 (tumor proportion score of 50 percent or more). Based on the results, the trial was stopped early to give patients still on chemotherapy the opportunity to receive KEYTRUDA.

According to Dr. Roger M. Perlmutter, president, Merck Research Laboratories, "Chemotherapy has been the foundation of first-line treatment for non-small cell lung cancer for decades, so the significant improvement in survival in patients with high PD-L1 expression seen with KEYTRUDA compared to chemotherapy is welcome news. We appreciate the opportunity to work with regulatory authorities to make KEYTRUDA a first-line treatment option in non-small cell lung cancer." **Source: FDA**


## Bristol-Myers Squibb's ORENCIA® (abatacept) is Approved by European Commission for the Treatment of Adult Patients with Rheumatoid Arthritis

Bristol-Myers Squibb Company has announced that the European Commission has approved ORENCIA ® (abatacept) intravenous (IV) infusion and subcutaneous (SC) injection, combined with methotrexate (MTX), for treating highly active and progressive disease in adult patients with rheumatoid arthritis (RA) not previously treated with MTX. Through this approval, ORENCIA has turned out as the first biologic therapy with an indication in the European Union (EU) specifically applicable to the treatment of MTX-naive RA patients with highly active and progressive disease. This approval permits the expanded marketing of ORENCIA in all 28 Member States of the EU. According to Brian J. Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb, "Across the globe we remain committed to advancing care for those living with RA. The European Commission's approval of ORENCIA in the EU for MTX-naive RA patients who have highly active and progressive disease is a testament to Bristol-Myers Squibb's commitment to advancing the science of earlier identification of patients with progressive RA prior to their suffering debilitating joint damage."


**Source:** https://igeahub.com/2016/10/28/top-pharma-news-september-and-october-2016/