FDA approves first interchangeable biosimilar for inflammatory diseases

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(HealthDay)—The first interchangeable biosimilar product to Humira

(adalimumab) was approved by the U.S. Food and Drug Administration on Oct. 15, the agency announced Monday.

Cyltezo (adalimumab-adbm), originally approved in 2017 for treatment of multiple chronic inflammatory diseases, is the first monoclonal antibody to be granted "interchangeable" status across various indications in adults: moderately to severely active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, moderately to severely active Crohn disease, moderately to severely active ulcerative colitis, and moderate-to-severe chronic plaque psoriasis. It is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis in children ages 2 years and older and children 6 years or older with Crohn disease.

The approval was based on data from the phase III randomized VOLTAIRE-X clinical trial investigating the effects of multiple switches between Humira and Cyltezo. Data showed no meaningful clinical differences in pharmacokinetics, efficacy, immunogenicity, or safety between patients switching and those receiving continuous treatment.

Cyltezo is offered in a single-dose, prefilled glass syringe, either 40 mg/0.8 mL or 20 mg/0.4 mL, and is administered subcutaneously under physician guidance. The FDA notes the most serious side effects of Cyltezo are infections and malignancies, and the most common adverse reactions include upper respiratory and sinus infections, injection site reactions, headache, and rash.

Similar to Humira, Cyltezo labeling includes a boxed warning about an increased risk for serious infection that could lead to hospitalization or death, as well as a warning about the potential for lymphoma and other malignancies that have been reported in children and adolescents treated with tumor necrosis factor blockers, including adalimumab.

Approval was granted to Boehringer Ingelheim. Cyltezo will not be commercially available in the United States until July 1, 2023.

More information: More Information