Generic Name:
Adalimumab-afzb
Trade Name:
Abrilada
Company:
Pfizer
Notes:

On November 18, 2019, Pfizer announced FDA approval of adalimumab-afzb, a tumor necrosis factor (TNF) blocker and biosimilar to adalimumab (Humira), to treat certain patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis.

FDA approval was based on the review of a comprehensive data package, which demonstrated biosimilarity of adalimumab-afzb to the reference product. This includes results from the REFLECTIONS B538-02 clinical comparative study, which evaluated the efficacy, safety, and immunogenicity of adalimumab-afzb and found no clinically meaningful differences compared to the reference product, each taken in combination with methotrexate, in patients with moderate to severe rheumatoid arthritis.3

The labeling carries a boxed warning that patients treated with adalimumab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. The drug should be discontinued if a patient develops a serious infection or sepsis.

The most common adverse reactions in clinical trials were infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Medication Monitor Categories:
Supplemental Approvals