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FDA approves Pfizer’s biosimilar for multiple inflammatory conditions

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Pfizer Inc. has announced the United States (U.S.) Food and Drug Administration (FDA) has approved ABRILADA™ (adalimumab-afzb), as a biosimilar to Humira® (adalimumab), for the treatment of certain patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis. For full details of indications please see the approved label.

“Biosimilars like ABRILADA represent an opportunity to help improve access to important treatment options for patients living with chronic, and often debilitating, inflammatory conditions,” said Richard Blackburn, Global President, Pfizer Inflammation and Immunology. “Our current portfolio of approved biosimilar products is one of the broadest in the industry and we are proud to offer additional treatment options for patients.”

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

Biosimilars have been a significant catalyst for change for the healthcare industry over the last decade, with the potential to drive cost savings for healthcare systems. With more than 10 years of global in-market experience and eight approved biosimilar products in the U.S., Pfizer is proud to be a leader and at the forefront of this vital healthcare segment.

Pfizer is working to make ABRILADA available to U.S. patients as soon as feasible based on the terms of our agreement with AbbVie. Our current plans are to launch in 2023. We will provide further updates as the date approaches.