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FDA approves Pfizer’s biosimilar RUXIENCE

24 July 2019 | News

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Pfizer has announced that USFDA has approved RUXIENCE™ (rituximab-pvvr), a biosimilar to Rituxan® (rituximab) for the treatment of adult patients with non-Hodgkin’s lymphoma (NHL), chronic lymphocytic leukemia (CLL), and granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).

Andy Schmeltz, Global President, Pfizer Oncology said, “Biosimilars like RUXIENCE have the potential to deliver real value in healthcare, improving access to and affordability of an important cancer treatment which could help more patients receive optimal care. The FDA approval marks our third oncology biosimilar to be approved in the U.S. this year, reinforcing our commitment to bring these important medicines to patients living with cancer.”

The FDA approval was based on the review of a comprehensive data package, which demonstrated biosimilarity of RUXIENCE to the reference product. This includes results from the REFLECTIONS B3281006 clinical comparative study, which evaluated the efficacy, safety and immunogenicity, pharmacokinetics and pharmacodynamics of RUXIENCE and found no clinically meaningful differences in safety or efficacy compared to the reference product in patients with CD20-positive, low tumor burden follicular lymphoma.

Dr. Jeff Sharman, medical director, US Oncology Hematology Research said, “Rituximab became one of the first monoclonal antibody (mAb) cancer treatments when it was initially approved by the FDA, representing a significant treatment advance and the only option available to oncologists and their patients for a period of time. With this FDA approval, clinicians have an additional treatment option that will help improve access to care for patients in need of anti-CD20 mAb therapy.”

Biosimilars have been a significant catalyst for change for the healthcare industry over the last decade, with the potential to create a more sustainable healthcare system. With more than 10 years of global in-market experience and seven approved biosimilar products in the U.S., Pfizer is proud to be a leader and at the forefront of this vital healthcare segment. RUXIENCE is Pfizer's third oncology mAb biosimilar to be approved by the FDA this year.

RUXIENCE has also been filed for regulatory approval with the European Medicines Agency (EMA) and is under review.

RUXIENCE is a mAb biosimilar to Rituxan which works by targeting a protein called CD20, which is present on the surface of B cells. When it attaches to CD20, rituximab helps destroy the B cells.