# FDA Approves First Biosimilar for Non-Hodgkin's Lymphoma

Review of evidence indicates Truxima works similarly to Rituxan.

November 28, 2018 By Food and Drug Administration (FDA)

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FDA approves first biosimilar for treatment of adult patients with non-Hodgkin's lymphoma

The U.S. Food and Drug Administration today approved Truxima (rituximab-abbs) as the first biosimilar to Rituxan (rituximab) for the treatment of adult patients with CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) to be used as a single agent or in combination with chemotherapy. Truxima is the first biosimiliar to be approved in the U.S. for the treatment of non-Hodgkin's lymphoma.

"As part of the FDA's Biosimilars Action Plan we're advancing new policies to make the development of biosimilars more efficient and to enable more opportunities for biosimilar manufacturers to make these products commercially successful and competitive. Our goal is to promote competition that can expand patient access to important medicines," said FDA Commissioner Scott Gottlieb, MD "The Truxima approval is our third biosimiliar approval in the past month. The growing pipeline of biosimilars is encouraging. We're seeing more biosimilar drugs gain market share as this industry matures. We'll continue to make sure biosimilar medications are evaluated efficiently through a process that makes certain that these new medicines meet the FDA's rigorous standards for approval."

Truxima is indicated for the treatment of adult patients with:

- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent;

- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; and

- Non-progressing (including stable disease), low-grade, CD20 positive, B-cell NHL as a single

agent after first-line cyclophosphamide, vincristine and prednisone (CVP) chemotherapy.

Biological products are generally large, complex molecules and may be produced through biotechnology in a living system, such as a microorganism, plant cell or animal cell. A biosimilar is a biological product that is approved based on data showing that it is highly similar to a biological product already approved by the FDA (reference 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.

The FDA's approval of Truxima is based on a review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic data, clinical immunogenicity data, and other clinical data that demonstrates Truxima is biosimilar to Rituxan. Truxima has been approved as a biosimilar, not as an interchangeable product.

The most common side effects of Truxima are infusion reactions, fever, abnormally low level of lymphocytes in the blood (lymphopenia), chills, infection and weakness (asthenia). Health care providers are advised to monitor patients for tumor lysis syndrome (a complication of treatment where tumor cells are killed off at the same time and released into the bloodstream), cardiac adverse reactions, damage to kidneys (renal toxicity), and bowel obstruction and perforation. Patients should not receive vaccinations while in treatment. Women who are pregnant or breastfeeding should not take Truxima because it may cause harm to a developing fetus or newborn baby.

Like Rituxan, the labeling for Truxima contains a Boxed Warning to alert health care professionals and patients about increased risks of the following: fatal infusion reactions, severe skin and mouth reactions, some with fatal outcomes; Hepatitis B virus reactivation, that may cause serious liver problems including liver failure and death; and Progressive Multifocal Leukoencephalopathy, a rare, serious brain infection that can result in severe disability or death. This product must be dispensed with a patient Medication Guide that provides important information about the drug's uses and risks.

The FDA granted approval of Truxima to Celltrion. Rituxan was approved in November 1997 and is manufactured by Genentech.

With the Truxima approval, the FDA has approved 15 biosimiliars. On Oct. 30, 2018, the FDA approved Hyrimoz (adalimumab-adaz), from Sandoz, as a biosimilar to Humira (adalimumab) and on Nov. 2, 2018, the FDA approved Udenyca (pegfilgrastim-cbqv) from Coherus, as a biosimilar to Neulasta (pegfilgrastim).

This announcement was originally published on the Food and Drug Administration website on November 28, 2018.

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