Medical Xpress

Truxima approved as first biosimilar to non-Hodgkin's lymphoma drug

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(HealthDay)—Truxima (rituximab-abbs) has been approved by the U.S. Food and Drug Administration as the first biosimilar to the non-Hodgkin's lymphoma drug Rituxan, the agency said Wednesday.

A biosimilar is a biological product that is approved based on data showing it is "highly similar" to a drug already approved by the FDA, with no "clinically meaningful differences in terms of safety, purity and potency," the agency said in a news release.

Truxima, as with Rituxan, is approved to treat adults with CD20-positive, B-cell non-Hodgkin's lymphoma. The most common side effects of Truxima are infusion reactions, fever, low blood lymphocytes, chills, infection and weakness.

The drug's label includes a boxed warning that users also may be at increased risk of fatal infusion reactions, severe skin and mouth reactions, reactivation of hepatitis B, and a rare deadly brain infection known as PML.

Users should not receive vaccinations while in treatment with Truxima, the agency warned, adding that women who are pregnant or breastfeeding shouldn't take the drug.

Truxima is produced by the South Korean drugmaker Celltrion. Rituxan, produced by the San Francisco firm Genentech, was approved in 1997.

More information: Visit the FDA to learn more.