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# FDA grants Roche’s Polivy accelerated approval to treat lymphoma

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**New targeted medicine shown to improve clinical outcomes in people with relapsed or refractory diffuse large B-cell lymphoma compared to a commonly used regimen**


Roche recently announced that the US Food and Drug Administration (FDA) has granted accelerated approval to Polivy™ (polatuzumab vedotin-piiq) in combination with bendamustine plus Rituxan® (rituximab) (BR) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), who have received at least two prior therapies.

Accelerated approval was granted for this indication based on complete response rates observed in a randomised, controlled clinical trial. The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

“Despite meaningful progress in the treatment of diffuse large B-cell lymphoma, treatment options are very limited when the disease is refractory to or recurrent after multiple regimens,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Today’s approval of this Polivy combination will provide a novel treatment that is both immediately available and very much needed for people with this aggressive disease.”

The accelerated approval of Polivy was based on the results from the phase Ib/II GO29365 study. This is the first and only randomised pivotal clinical trial to show higher response rates over BR, a commonly used regimen, in people with R/R DLBCL who are ineligible for a haematopoietic stem cell transplant.

The US FDA granted Priority Review for the company’s Biologics License Application for Polivy in February 2019. Priority Review designation is granted to medicines that the FDA considers to have the potential to provide significant improvements in the safety and effectiveness of the treatment, prevention or diagnosis of a serious disease.

In addition, Polivy was granted Breakthrough Therapy Designation by the FDA and PRIME (PRIority MEdicines) designation by the European Medicines Agency for the treatment of people with R/R DLBCL in 2017. Breakthrough Therapy Designation

is designed to expedite the development and review of medicines intended to treat a serious condition with preliminary evidence that indicates they may demonstrate substantial improvement over existing therapies.