



CLL/SLL

FDA grants Breakthrough Therapy Designation to venetoclax and obinutuzumab for adult patients with previously untreated CLL



Philippa Redondo | Mar 08, 2019

On 7 March 2019, the chemotherapy-free combination of venetoclax (Venclexta[®]) and obinutuzumab (Gazyva[®]), was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) following submission of a supplemental New Drug Application (sNDA) for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) and co-existing medical conditions.¹

The Breakthrough Therapy Designation granted by the FDA was based on the results of the open-label, multicenter, randomized phase III CLL14 trial ([NCT02242942](https://clinicaltrials.gov/ct2/show/study/NCT02242942)) which assessed the venetoclax and obinutuzumab combination, compared to standard-of-care obinutuzumab and chlorambucil.² The trial met its primary endpoint, demonstrating the combination of venetoclax and obinutuzumab significantly reduced the risk of disease progression or death. In addition to this, the treatment combination demonstrated no new safety concerns regarding the individual toxicities.

This is the fifth Breakthrough Therapy Designation for venetoclax across a number of disease areas. According to the drug manufacturers, many patients with untreated CLL “are ineligible for intensive chemotherapy-based options.”

References

1. PharmacyTimes. FDA grants Breakthrough Designation to chemotherapy-free combo therapy for CLL. <https://www.pharmacytimes.com/news/fda-grants-breakthrough-designation-to-chemotherapy-free-combo-therapy-for-ctl> [Accessed 2019 Mar 08]
2. [Fischer K. et al.](#) Safety and efficacy of venetoclax and obinutuzumab in patients with previously untreated chronic lymphocytic leukemia (CLL) and coexisting medical conditions: final results of the run-in phase of the randomized CLL14 trial (B025323). [Blood](#). 2016 Dec 1; 128(22): 2054.

© 2019 Scientific Education Support Ltd. This PDF is provided for personal use only. For wider or commercial use, please seek permission from secretariat@scientificeducationsupport.com and attribute the source as: <<https://lymphomahub.com/medical-information/fda-grants-breakthrough-therapy-designation-to-venetoclax-and-obinutuzumab-for-adult-patients-with-previously-untreated-ctl>>