



CLL/SLL

## FDA grants approval to ibrutinib (Imbruvica®) in combination with obinutuzumab (Gazyva®) for patients with previously untreated CLL/SLL



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On 28 January 2019, ibrutinib (Imbruvica®), a Bruton's tyrosine kinase (BTK) inhibitor, in combination with obinutuzumab (Gazyva®) was granted approval by the U.S. Food and Drug Administration (FDA) for the treatment of adults with previously untreated chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL). This approval comes after the combination of ibrutinib and obinutuzumab was granted Priority Review status by the FDA on 17 October 2018.

The approval granted by the FDA was based on the positive results obtained from the international, multicenter, randomized phase III iLLUMINATE trial ([NCT02264574](https://clinicaltrials.gov/ct2/show/study/NCT02264574)) assessing ibrutinib in combination with obinutuzumab, in patients with previously untreated CLL/SLL. This study is one of the first to compare an anti-CD20, chemotherapy-free combination regimen to a chemo-immunotherapy for patients with CLL/SLL.

The phase III iLLUMINATE study demonstrated a statistically significant improvement in progression-free survival of ibrutinib in combination with obinutuzumab *versus* chlorambucil plus obinutuzumab as assessed by an Independent Review Committee (IRC), corresponding to a 77% reduction in the risk of progression or death in the ibrutinib arm (HR = 0.23; 95% CI, 0.15–0.37;  $P < 0.0001$ ). The results of the phase III iLLUMINATE study was recently presented at the American Society of Hematology (ASH) 2018 Annual Meeting and Exposition, and published in *The Lancet Oncology*.

According to the drug manufacturers, the FDA approval of ibrutinib in combination with obinutuzumab provides “physicians and patients a new option to treat CLL and SLL without the need for chemotherapy”.

### References

1. PR Newswire. AbbVie announces U.S. FDA approval of IMBRUVICA® (ibrutinib) plus obinutuzumab (GAZYVA®) – first chemotherapy-free, anti-CD20 combination regimen approved for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) in previously untreated patients. <https://www.prnewswire.com/news-releases/abbvie-announces-us-fda-approval-of-imbruvica-ibrutinib-plus-obinutuzumab-gazyva-first-chemotherapy-free-anti-cd20-combination-regimen-approved-for-chronic-lymphocytic-leukemiasmall-lymphocytic-lymphoma-cll-sll-in-pr-300784838.html> [Accessed 2019 Jan 29]

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