LymphomaHub

CLL/SLL

Venetoclax (Venclyxto®) plus rituximab granted approval by the European Commission for the treatment of CLL patients

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On 1 November 2018, the European Commission (EC) granted approval to venetoclax (Venclyxto®) in combination with rituximab for the treatment of patients with relapsed/refractory chronic lymphocytic leukemia (R/R CLL) who have received at least one prior therapy. This comes after the regimen of venetoclax in combination with rituximab for the treatment of people with previously treated CLL or small lymphocytic lymphoma (SLL), with or without 17p deletion was granted approval by the US Food and Drug Administration (FDA) in June 2018.[1]

The EC approval was based on results from the multicenter, open-label, randomized phase III MURANO trial (NCT02005471), which evaluated the efficacy and safety of venetoclax in combination with rituximab (n = 194) compared with bendamustine in combination with rituximab (n = 195) in 389 patients (median age = 65 years; range, 22–85) with R/R CLL who had received at least one prior therapy.[2]

The phase III MURANO study met its primary endpoint, investigator (INV)-assessed progression-free survival (PFS), in which patients who were treated with venetoclax plus rituximab had a significant reduction in the risk of disease progression or death by 83% (HR = 0.17, $P < 0.0001$) compared to patients treated with bendamustine in combination with rituximab. In addition, patients in the venetoclax plus rituximab arm had a better overall survival (OS) compared to bendamustine in combination with rituximab, a standard of care chemoimmunotherapy regimen (2-year OS, 91.9% *vs* 86.6% respectively, HR = 0.48) .[1,2]

Undetectable minimal residual disease (MRD) was the secondary endpoint of the phase III MURANO study. Professor Peter Hillmen, St James's University Hospital, Leeds, UK, discussed the results from the MRD kinetics of the MURANO study in an interview with Lymphoma Hub. He noted that "a key secondary endpoint was MRD eradication from peripheral blood." He said that after 9 months of therapy, "there was a much higher rate of MRD reduction with venetoclax plus rituximab, 62%, compared with bendamustine plus rituximab, 13%." He concluded that "MRD is an important endpoint in CLL as it shows that venetoclax plus rituximab is a more effective therapy."

According to the drug manufacturers, the approval by the EC makes venetoclax plus rituximab the “first chemotherapy-free combination with a 24-month fixed duration for the treatment of patients with CLL who have received at least one prior therapy.”[1]

References

1. PR Newswire: AbbVie Receives European Commission Approval of VENCLYXTO® (venetoclax) Plus Rituximab for the Treatment of Patients with Chronic Lymphocytic Leukemia Who Have Received at Least One Prior Therapy. 2018 Nov 01.https://www.prnewswire.com/news-releases/abbvie-receives-european-commission-approval-of-venclyxto-venetoclax-plus-rituximab-for-the-treatment-of-patients-with-chronic-lymphocytic-leukemia-who-have-received-at-least-one-prior-therapy-300741883.html [Accessed 2018 Nov 01].

2. Seymour J. F. *et al.* Venetoclax–rituximab in relapsed or refractory chronic lymphocytic leukemia. N Engl J Med. 2018 Mar 22; 378: 1107–1120. DOI: 10.1056/NEJMoa1713976.