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AbbVie recieves EC approval of VENCLYXTO in combination with Rituximab

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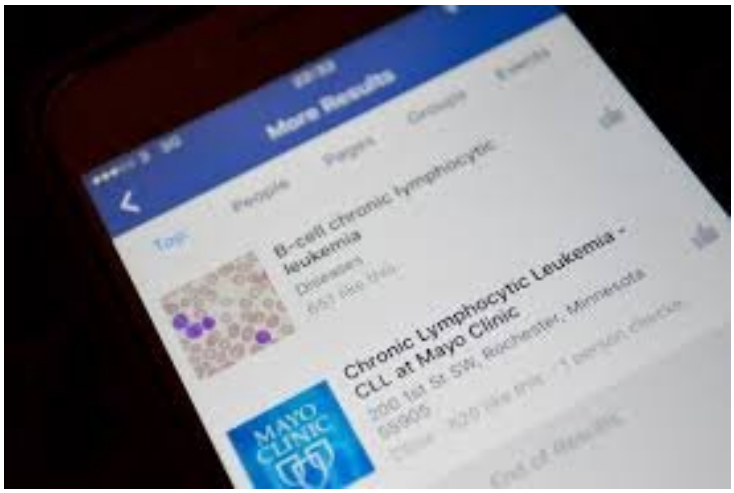
The EC approval is based on results from the MURANO Phase 3 randomized clinical trial, which evaluated the efficacy and safety of VENCLYXTO in combination with rituximab compared to bendamustine in combination with rituximab, an established standard of care chemoimmunotherapy regimen for patients with R/R CLL.



AbbVie, a research-based global biopharmaceutical company has announced that the European Commission (EC) has approved the type-II variation application for VENCLYXTO (venetoclax) 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 approval allows more patients to receive VENCLYXTO in the second-line setting and gives healthcare providers the ability to prescribe this medicine to a broader population of patients with R/R CLL than the previously approved indication for VENCLYXTO as monotherapy in the European Union (EU). The approval is valid in all 28 member states of the EU, as well as Iceland, Liechtenstein and Norway.

The EC approval is based on results from the MURANO Phase 3 randomized clinical trial, which evaluated the efficacy and safety of VENCLYXTO in combination with rituximab compared to bendamustine in combination with rituximab, an established standard of care chemoimmunotherapy regimen for patients with R/R CLL. At the time of the primary analysis, the trial demonstrated a statistically significant improvement in investigator-assessed progression-free survival (PFS; the time on treatment without disease progression or death2) in patients who received VENCLYXTO plus rituximab, resulting in an 83 percent reduction in the risk of disease progression or death (hazard ratio [HR]:0.17; 95% confidence interval [CI]: 0.11-0.25; P<0.0001) and prolonged overall survival (OS) compared to the standard of care chemoimmunotherapy (HR: 0.48; 95% CI: 0.25-0.90; overall survival data are not yet mature).

In the MURANO Phase 3 clinical trial, undetectable minimal residual disease (uMRD) was a secondary endpoint assessed at the end of combination therapy (nine-month assessment1,3). The majority of patients in the trial who received VENCLYXTO plus rituximab achieved uMRD in the peripheral blood, with 62.4 percent of patients achieving uMRD versus 13.3 percent with bendamustine in combination with rituximab.1 uMRD is an objective measure defined as the presence of less than one CLL cell in 10,000 white blood cells remaining in the blood or bone marrow following treatment. Earlier prospective clinical trials have provided evidence that achieving uMRD in CLL patients is associated with improved clinical outcomes.

"Chronic lymphocytic leukemia can relapse and become refractory to first-line treatment, and there is a need for better therapies to treat these patients who otherwise have limited options," said Prof. John Seymour, MBBS, Ph.D., lead investigator of the MURANO trial and Director of Cancer Medicine at the Peter MacCallum Cancer Centre & Royal Melbourne Hospital in Australia. "The venetoclax plus rituximab combination provides these patients with an alternative treatment option that is superior to a type of chemoimmunotherapy and can achieve deep responses, as shown by MRD negativity rates in the peripheral blood and bone marrow, allowing for a fixed duration of treatment without the need for chemoimmunotherapy."

CLL is a slow-growing form of leukemia, or blood cancer, in which too many immature lymphocytes (a type of white blood cell) are found predominantly in the blood and bone marrow.4 CLL accounts for approximately one third of new leukemia diagnoses.

In September 2018, AbbVie announced the European Committee for Medicinal Products for Human Use (CHMP) granted a positive opinion for the Marketing Authorization Application for VENCLYXTO plus rituximab for the treatment of patients with R/R CLL.

"The approval of VENCLYXTO in combination with rituximab is an important step forward in providing patients with relapsed/refractory chronic lymphocytic leukemia a strong chance to live longer without their disease progressing," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "We look forward to bringing VENCLYXTO to more patients with chronic lymphocytic leukemia, while continuing to further the research and development of therapies with the potential to transform the standards of care in blood cancers."

VENCLYXTO is being developed by AbbVie and Roche. It is jointly commercialized by AbbVie and Genentech, a member of the Roche Group, in the U.S. and by AbbVie outside of the U.S.