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AbbVie has announced that its investigational medicine Venetoclax, an inhibitor of the B-cell lymphoma-2 (BCL-2) protein that is being developed in partnership with Genentech and Roche, has been granted Breakthrough Therapy Designation by the FDA for the treatment of chronic lymphocytic leukemia (CLL) in previously treated (relapsed/refractory) patients with the 17p deletion genetic mutation.

CLL accounts for approximately one quarter of the new cases of leukemia diagnosed in the United States. Approximately 3-10 percent of CLL patients have 17p deletion at diagnosis, and it occurs in 30-50 percent of patients with relapsed/refractory CLL. The 17p deletion mutation is a genomic alteration in which a part of chromosome 17 is absent. The median life expectancy for CLL patients with 17p deletion is less than 2-3 years.

"The breakthrough therapy designation of venetoclax supports the continued development of this investigational medicine in CLL patients with 17p deletion. The continuing advancement of the venetoclax development program is one example of AbbVie's focus on delivering innovative medicines that address unmet clinical needs," said Dr Michael Severino, executive vice-president of research and development and chief scientific officer, AbbVie.

According to the FDA, breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation includes preliminary clinical evidence demonstrating a drug may have substantial improvement on at least one clinically significant endpoint compared to available therapy. A breakthrough therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program.