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EMA grants Orphan Drug Designation to venetoclax for treatment of acute myeloid leukemia

Published on February 26, 2016 at 8:15 AM

AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced the European Medicines Agency (EMA) has granted Orphan Drug Designation to venetoclax, an investigational, oral B-cell lymphoma-2 (BCL-2) inhibitor, for the treatment of acute myeloid leukemia (AML). AML can be a rapidly progressing cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. Venetoclax is being developed by AbbVie in partnership with Genentech and Roche.

AML is generally a disease of older people and is uncommon before the age of 45, with the average age being 67 years of age. In AML, the body produces too many of a specific type of white blood cell (myeloblast), which can crowd out healthy blood cells. In Europe, the annual incidence rate of AML is estimated to be 1/33,000-1/25,000.

The EMA previously granted Orphan Drug Designation to venetoclax for the treatment of chronic lymphocytic leukemia (CLL). Orphan Designation is granted to therapies aimed at the treatment, prevention or diagnosis of life-threatening diseases that affect no more than five in 10,000 persons in the European Union (EU) and for which no satisfactory therapy is available. The medicine must also provide significant benefit to those affected by the condition.

"There have been very few treatment advances for patients with AML who are older than 60, the patient population that is most often affected by this aggressive and life-threatening cancer," said Michael Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie. "These designations for venetoclax not only underscore the unmet need for patients with AML, but also reinforce our ongoing commitment to battling cancer and researching scientific advances in oncology."

The U.S. Food and Drug Administration recently granted venetoclax both Breakthrough Therapy Designation (BTD) and Orphan Drug Designation (ODD) for the treatment of patients with AML. The FDA has also granted venetoclax Breakthrough Therapy Designation for the treatment of CLL in previously treated (relapsed/refractory) patients with the 17p deletion genetic mutation and in combination with rituximab for the treatment of patients with relapsed/refractory chronic lymphocytic leukemia (R/R CLL). Additionally, venetoclax recently received validation from the EMA for its Marketing Authorization Application (MAA) for the treatment of CLL patients with 17p deletion or *TP53* mutation, as well as acceptance by Health Canada for the New Drug Submission (NDS) for the treatment of patients with CLL who have received at least one prior therapy, including patients with 17p deletion.

Source:
AbbVie