AbbVie submits supplemental NDA to FDA for venetoclax to treat acute myeloid leukemia

July 20, 2018

AbbVie, a research-based global biopharmaceutical company, today announced it submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for venetoclax in combination with a hypomethylating agent (HMA) or in combination with low-dose cytarabine (LDAC) for the treatment of newly diagnosed patients with acute myeloid leukemia (AML) who are ineligible for intensive chemotherapy.

The sNDA submission is based on investigational data from two studies: M14-358, a Phase 1b trial evaluating venetoclax in combination with an HMA (azacitidine or decitabine), and M14-387, a Phase 1/2 trial of venetoclax in combination with LDAC.

“AML is an especially lethal and aggressive form of blood cancer with limited advances in care in three decades and few treatment options for patients ineligible for intensive chemotherapy,” said Michael Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie. “The data submitted to the FDA may potentially reshape how AML is treated. We look forward to working with the FDA and other health authorities during the review of these data.”

AML, primarily a disease of older patients, is the most common form of acute leukemia in adults, in which the bone marrow makes abnormal, immature types of white blood cells, red blood cells or platelets. AML is an aggressive blood cancer that, if left untreated, can progress quickly. In the U.S., it is

estimated there will be 19,520 new cases and 10,670 deaths due to AML in 2018.

Approximately 27 percent of patients diagnosed with AML will survive five years or more. Disease recurrence occurs in most patients with AML within three years of diagnosis. Although few treatments are available, AML patients who are ineligible for intensive remission induction therapy may be treated with LDAC or HMAs. Only about one-third of AML patients older than age 60 are able to tolerate the intensive chemotherapy required to achieve optimal results. Median survival is five to 10 months in older AML patients who are ineligible for intensive chemotherapy.

The challenges of treating AML, including in older adults, is an ongoing topic of discussion among the medical community. Daniel Pollyea, M.D., director of Leukemia Services at University of Colorado Hospital, recently reflected on his experience treating patients with AML. “We have an incredible opportunity to develop better treatment options for people with AML. Still, right now every aspect of this disease represents an unmet need,” he said. For more on Dr. Pollyea’s perspective, please read “A Physicians View: Facing the Challenges of Treating AML in Older Adults.”

Venetoclax, an oral B-cell lymphoma-2 (BCL-2) inhibitor, has been granted four Breakthrough Therapy Designations (BTDs) from the FDA including for the combination of venetoclax with an HMA (azacitidine or decitabine) for treatment-naïve patients with AML who are ineligible to receive standard induction therapy (high-dose chemotherapy) and for the combination of venetoclax with LDAC for treatment-naïve patients with AML who are ineligible for intensive chemotherapy. According to the FDA, BTD is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant

endpoint(s).

If approved in AML, venetoclax would be available for use in two blood cancers, chronic lymphocytic leukemia (CLL) and AML. Venetoclax recently received expanded approval in the U.S. for use alone or in combination with rituximab for the treatment of relapsed/refractory (R/R) CLL or small lymphocytic lymphoma (SLL) patients, with or without 17p deletion, who have received at least one prior therapy.

In addition to CLL and AML, venetoclax is being studied in a range of hematologic malignancies including multiple myeloma (MM), non-Hodgkin lymphoma (NHL) and myelodysplastic syndrome (MDS). Venetoclax is being developed by AbbVie and Roche and 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. Together, the companies are committed to BCL-2 research with venetoclax, which is currently being evaluated in clinical trials in several hematologic cancers.

Source:

https://news.abbvie.com/news/abbvie-announces-submission-supplemental-new-drug-application-to-us-fda-for-venetoclax-in-newly-diagnosed-acute-myeloid-leukemia-patients-ineligible-for-intensive-chemotherapy.htm