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Pfizer bags USFDA approval for Besponsa

21 August 2017 | News

The regulatory agency approved the Besponsa, drug fro the treatment of leukemia, under Priority Review and Breakthrough Therapy status

The US FDA recently announced the approval of Pfizer's Besponsa (inotuzumab ozogamicin) for the treatment of adults with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (ALL). The regulatory agency approved the product under Priority Review and Breakthrough Therapy status. The drug had won a priority review in February.

B-cell precursor ALL is a rapidly progressing cancer in which the bone marrow makes too many B-cell lymphocytes, an immature type of white blood cell.

The approval was based on results from the Phase 3 INO-VATE ALL trial, a randomized, open-label, international, multicenter study evaluating the safety and efficacy of BESPONSA compared with Investigator's choice of chemotherapy in 326 adult patients with relapsed or refractory B-cell ALL.

Mr Hagop M. Kantarjian, M. D., INO-VATE ALL lead study investigator and professor, The University of Texas MD Anderson Cancer Center, said, "Based on the results seen in the INO-VATE ALL trial, BESPONSA improved multiple efficacy measures, including rates of hematologic remission, MRD-negativity and stem cell transplantation. I look forward to seeing the impact this important new therapy may have on my patients."

The U.S. labeling for BESPONSA includes a boxed warning, the agency's severest form of warning reserved to caution against the most serious side effects, for hepatotoxicity, including hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), and increased risk of post-HSCT non-relapse mortality.

"The approval of BESPONSA is an important step forward for adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia, a rare disease that can be fatal within a matter of months if left untreated," said Liz Barrett, global president, Pfizer Oncology.

"BESPONSA will help address a significant need for new treatment options in B-cell acute lymphoblastic leukemia, and may help more patients reach stem cell transplant, which provides the best chance for long term remission. We're proud to build

on our continued commitment to patients with hematologic malignancies, and will continue our work to find new treatments in acute lymphoblastic leukemia and other blood cancers.”