For Immediate Release: February 17, 2014

FDA Grants Accelerated Approval for Ibrutinib for CLL

The US Food and Drug Administration (FDA) on Wednesday granted accelerated approval for the expanded use of ibrutinib, marketed as Imbruvica, for chronic lymphocytic leukemia (CLL) patients who have previously received at least one therapy. The drug is notable for its relative lack of toxic effects.

“Their approval provides an important new treatment option for CLL patients whose cancer has progressed despite having undergone previous therapy. The FDA completed its review of Imbruvica’s new indication under the agency’s accelerated approval process, which played a vital role in rapidly making this new therapy available to those who need it most.”

Richard Pazdur, MD
FDA Office of Hematology and Oncology Products, CDER

The US Food and Drug Administration (FDA) on Wednesday granted accelerated approval for the expanded use of ibrutinib, marketed as Imbruvica, for chronic lymphocytic leukemia (CLL) patients who have previously received at least one therapy. This approval was based on a phase 1b-2 open-label, multicenter study that was designed to determine the safety, efficacy, pharmacokinetics, and pharmacodynamics of Imbruvica in patients with relapsed or refractory CLL or small lymphocytic lymphoma.

FDA’s approval comes after reviewing a study of 48 patients who had been diagnosed with CLL an average of 6.7 years prior to the study. They received orally administered 420 mg ibrutinib until they experienced unacceptable toxicity or their disease progressed. Significantly, overall response rate (cancer shrinkage) was observed in 58 percent of participants over a duration of 5.6 to 24.2 months. It’s still early, however, to establish impact on survival or disease-related symptoms.

“Their approval provides an important new treatment option for CLL patients whose cancer has progressed despite having undergone previous therapy,” said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “The FDA completed its review of Imbruvica’s new indication under the agency’s accelerated approval process, which played a vital role in rapidly making this new therapy available to those who need it most.”

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According to the National Cancer Institute, CLL is the most common leukemia in adults; it affected 15,580 adults in 2013 and was responsible for 4,580 deaths. The B-cell receptor signaling pathway, specifically the downstream protein Bruton’s tyrosine kinase (BTK), has been shown to drive the disease. BTK in turn promotes cell survival by activating Akt, ERK, and the NK-kB signaling pathways along with the activation of cytokine-driven homing and adhesion of B-cells. This makes BTK an attractive target for inhibition in CLL therapy.

Ibrutinib is an orally bioavailable BTK inhibitor that demonstrated immense potential in several preclinical studies. The absence of toxic effects on normal T-cells distinguishes the drug from most other CLL regimens.

The most common side-effects observed in the trial included thrombocytopenia, diarrhea, bruising, neutropenia, anemia, upper respiratory tract infection, fatigue, musculoskeletal pain, pyrexia, rash, constipation, stomatitis, peripheral edema, nausea, sinusitis, and dizziness.

Ongoing trials for Imbruvica include randomized trials to compare the drug’s safety profile with current CLL therapies, which include two phase III studies (RESONATE; ClinicalTrials.gov number NCT01578707 and RESONATE-2, NCT01722487).

The drug is being developed jointly by Pharmacyclics and Janssen Biotech, Inc.

For more information on this press release visit: http://www.abnewswire.com/pressreleases/fda-grants-accelerated-approval-for-ibrutinib-for-cll_8608.html

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