FDA Grants Accelerated Approval to Scemblix for Newly Diagnosed Chronic Myeloid Leukemia

By Clinical Oncology News Staff

The FDA granted accelerated approval to asciminib (Scemblix, Novartis AG) for adult patients with newly diagnosed Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).

The efficacy of asciminib for newly diagnosed Ph+ CML in CP was evaluated in ASC4FIRST (ClinicalTrials.gov. Identifier: NCT04971226), a multicenter, randomized, active-controlled, open-label trial. A total of 405 patients were randomized (1:1) to receive either asciminib or investigator-selected tyrosine kinase inhibitors (IS-TKIs) (bosutinib [Bosulif, Pfizer], dasatinib, imatinib or nilotinib [Tasigna, Novartis]). The main efficacy outcome measure was the major molecular response (MMR) rate at 48 weeks. The MMR rate at 48 weeks was 68% (95% CI, 61%-74%) in the asciminib arm and 49% (95% CI, 42%-56%) in the IS-TKI arm (difference, 19%; 95% CI, 10%-28%; $P<0.001$). Within the imatinib stratum, the MMR rate was 69% (95% CI, 59%-78%) in the asciminib arm and 40% (95% CI, 31%-50%) in the IS-TKI arm (difference, 30%; 95% CI, 17%-42%; $P<0.001$).

In the pooled safety population in patients with newly diagnosed and previously treated Ph+ CML in CP, the most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain and diarrhea. The most common laboratory abnormalities (≥40%) in patients with newly diagnosed Ph+ CML in CP were decreased lymphocyte count, leukocyte count, platelet count, neutrophil count and calcium corrected.

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