Scemblix® (asciminib) – New indication

- On October 29, 2024, Novartis announced the FDA approval of Scemblix (asciminib), for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
    - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).
- Scemblix is also approved for the treatment of adult patients with:
    - Previously treated Ph+ CML in CP
    - Ph+ CML in CP with the T315I mutation.
- The approval of Scemblix for the new indication was based on ASC4FIRST, a randomized, active-controlled, and open-label study in 405 patients with newly diagnosed Ph+ CML in CP. Patients were randomized to Scemblix or investigator selected tyrosine kinase inhibitors (IS-TKIs). Patients were stratified based on re-randomization selection of TKI (imatinib or other TKIs stratum composed of nilotinib, dasatinib, and bosutinib). The main efficacy outcome was major molecular response rate (MMR) at 48 weeks.
    - In all patients, the MMR rate was 68% with Scemblix vs. 49% with IS-TKIs (difference 19, 95% CI: 10, 28; $p < 0.001$).
    - The MMR rate was 69% with Scemblix vs. 40% in the imatinib stratum (difference 30, 95% CI: 17, 42; $p < 0.001$.
- The recommended dose of Scemblix in newly diagnosed Ph+ CML in CP patients is 80 mg taken orally once daily at approximately the same time each day or 40 mg orally twice daily at approximately 12-hour intervals.
    - Treatment with Scemblix should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs.
    - Refer to the Scemblix drug label for dosing for its other indications.

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