FDA Approves Imbruvica Plus Rituxan for Chronic Lymphocytic Leukemia

Imbruvica plus Rituxan delayed disease progression when compared with a triple chemotherapy regimen.

April 22, 2020 By Food and Drug Administration (FDA)

On April 21, 2020, the Food and Drug Administration expanded the indication of ibrutinib (IMBRUVICA, Pharmacyclics LLC) to include its combination with rituximab for the initial treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this application, a modified Project Orbis was undertaken because of the timing of submission to other regulatory agencies. Nevertheless, the FDA is collaborating with the Australian Therapeutic Goods Administration, Health Canada, and Swissmedic as they review the application.

Approval was based on the E1912 trial (NCT02048813), a 2:1 randomized, multicenter, open-label, actively controlled trial of ibrutinib with rituximab compared to fludarabine, cyclophosphamide, and rituximab (FCR) in 529 adult patients 70 years or younger with previously untreated CLL or SLL requiring systemic therapy. Patients with 17p deletion were excluded. Ibrutinib was administered at 420 mg daily until disease progression or unacceptable toxicity.

The main efficacy outcome measure was progression-free survival (PFS). The trial demonstrated a statistically significant improvement in PFS for patients receiving ibrutinib plus rituximab compared with those receiving FCR (HR 0.34; 95% CI: 0.22, 0.52; $p<0.0001$). Median PFS was not reached in either arm after a median follow-up duration of 37 months.

The most common adverse reactions (≥30%) in patients with CLL/SLL receiving ibrutinib are thrombocytopenia, diarrhea, fatigue, musculoskeletal pain, neutropenia, rash, anemia, bruising, and nausea.

The recommended ibrutinib dose is 420 mg taken orally once daily with a glass of water. Rituximab was initiated in Cycle 2 and administered at 50 mg/m2 on Day 1, 325 mg/m2 on Day 2, and 500 mg/m2 on Day 1 of 5 subsequent cycles, for a total of 6 cycles.

View full prescribing information for IMBRUVICA.

FDA used the Real-Time Oncology Review and Assessment Aid Pilot Programs for this application and the application was granted priority review. The Assessment Aid is being used to facilitate discussions among the regulatory agencies participating in Project Orbis. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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