FDA Approves Copiktra for Adults With Certain Types of Leukemia or Lymphoma

Duvelisib granted regular approval for chronic lymphocytic leukemia and accelerated approval for follicular lymphoma.

September 24, 2018 By Food and Drug Administration (FDA)

On Sept. 24, 2018, the Food and Drug Administration granted regular approval to duvelisib (COPIKTRA, Verastem, Inc.) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.

In addition, duvelisib received accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.

The CLL and SLL indication is based on a randomized, multicenter, open-label trial (NCT02004522) comparing duvelisib to ofatumumab in patients with relapsed or refractory CLL or SLL. The trial randomized patients (1:1) to either duvelisib 25 mg orally twice daily or ofatumumab. Ofatumumab was administered intravenously at an initial dose of 300 mg, followed one week later by 2000 mg once weekly for 7 doses, and then 2000 mg once every 4 weeks for 4 additional doses.

Among 196 patients receiving at least 2 prior therapies (95 randomized to duvelisib, 101 to ofatumumab), the estimated median progression-free survival, as assessed by an independent review committee (IRC), was 16.4 months in the duvelisib arm and 9.1 months in the ofatumumab arm (hazard ratio of 0.40; standard error 0.2). The overall response rate (ORR) per IRC was 78% and 39% for the duvelisib and ofatumumab arms, respectively (39% difference, standard error 6.5%).

The FL indication is based on a single-arm multicenter trial of duvelisib (NCT02204982) enrolling 83 patients with FL who were refractory to rituximab and to either chemotherapy or radioimmunotherapy. The ORR, determined by an IRC, was 42% (95% CI: 31, 54), with 41% of patients experiencing partial responses and one patient having a complete response. Of the 35 responding patients,15 (43%) maintained responses for at least 6 months and 6 (17%) maintained responses for at least 12 months. Continued approval for the FL indication may be contingent upon verification of clinical benefit demonstrated in a planned randomized trial.

The prescribing information contains boxed warnings for fatal and/or serious infections, diarrhea or colitis, cutaneous reactions, and pneumonitis and warnings for neutropenia and hepatotoxicity. Of 442 patients with hematologic malignancies treated with duvelisib at the approved dose, 65% had serious adverse reactions, with the most frequent being infection, diarrhea or colitis, and pneumonia. The most common adverse reactions (incidence ≥ 20%) were diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia. Adverse reactions resulted in permanent discontinuation of duvelisib in 35% of patients., Dose reduction occurred in 24%.

The recommended duvelisib dose is 25 mg orally twice daily, taken continuously in 28-day treatment cycles.

View full prescribing information for COPIKTRA.

FDA granted this application priority review. FDA expedited programs are described 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.

This announcement was originally published on the Food and Drug Administration website on September 24, 2018.

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