FDA Approves Rylaze for Leukemia and Lymphoma

New recombinant drug may be an option for patients with hypersensitivity to standard asparaginase chemotherapy.

July 2, 2021 By Food and Drug Administration (FDA)

On June 30, 2021, the Food and Drug Administration approved asparaginase erwinia chrysanthemi (recombinant)-rywn) (Rylaze, Jazz Pharmaceuticals, Inc.) as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.

Efficacy was evaluated in Study JZP458-201 (NCT04145531), an open-label, multi-cohort, multicenter trial in 102 patients with ALL or LBL with hypersensitivity to E. coli-derived asparaginase as a component of a multi-agent chemotherapeutic regimen. The median age was 10 years with a range of 1 to 24 years. Patients received Rylaze intramuscularly at various dosages.

The main efficacy outcome measure was demonstration of the achievement and maintenance of nadir serum asparaginase activity (NSAA) above the level of 0.1 U/mL. The results of modeling and simulations showed that for a dosage of 25 mg/m^2 administered intramuscularly every 48 hours, the proportion of patients maintaining NSAA ≥ 0.1 U/mL at 48 hours after a dose of Rylaze was 93.6% (95% CI: 92.6%, 94.6%).

The most common adverse reactions (incidence > 20%) were abnormal liver test, nausea, musculoskeletal pain, fatigue, infection, headache, pyrexia, drug hypersensitivity, febrile neutropenia, decreased appetite, stomatitis, bleeding, and hyperglycemia.

When replacing a long-acting asparaginase product, the recommended dosage of Rylaze is 25 mg/m2 administered intramuscularly every 48 hours for the required duration of asparaginase activity.

View full prescribing information for Rylaze.

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 review, FDA collaborated with Health Canada.

This review used the Real-Time Oncology Review (RTOR) pilot program, which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. The FDA approved this application 10 months ahead of the FDA goal date.

This application was granted fast track and orphan drug designation. 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.

This announcement was originally published on the Food and Drug Administration website on June 30, 2021.
