Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]rywn) – New orphan drug approval

- On June 30, 2021, the FDA announced the approval of Jazz Pharmaceuticals' Rylaze (asparaginase erwinia chrysanthemi [recombinant]rywn), 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.

- ALL occurs in approximately 5,700 patients annually, about half of whom are children. It is the most common type of childhood cancer. One component of the chemotherapy regimen is an enzyme called asparaginase that kills cancer cells by depriving them of substances needed to survive.

    — An estimated 20% of patients are allergic to the standard *E. coli*-derived asparaginase and need an alternative their bodies can tolerate.

- Rylaze is an enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. The pharmacological effect of Rylaze is based on the killing of leukemic cells due to depletion of plasma asparagine.

- The efficacy of Rylaze was established in an open-label, multi-cohort study in 102 patients with ALL or LBL who have developed hypersensitivity to *E. coli*-derived asparaginase. The determination of efficacy was based on a demonstration of the achievement and maintenance of nadir serum asparaginase activity (NSAA) above the level of 0.1 U/mL.

    — 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%).

- Rylaze is contraindicated in patients with a history of:

    — Serious hypersensitivity reactions to *Erwinia asparaginase*, including anaphylaxis
    — Serious pancreatitis during previous asparaginase therapy
    — Serious thrombosis during previous asparaginase therapy
    — Serious hemorrhagic events during previous asparaginase therapy

- Warnings and precautions for Rylaze include hypersensitivity reactions, pancreatitis, thrombosis, hemorrhage, and hepatotoxicity.

- The most common adverse reactions (> 20%) with Rylaze use 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/m^2 administered intramuscularly every 48 hours.

    — See the full prescribing information for the long-acting asparaginase product to determine the duration of administration of Rylaze as replacement therapy.

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- Jazz Pharmaceuticals plans to launch Rylaze in mid-July 2021. Rylaze will be available as a 10 mg/0.5 mL solution in a single-dose vial.

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