



Jazz Pharmaceuticals Receives CHMP Positive Opinion for JZP458 (a recombinant *Erwinia* asparaginase or crisantaspase) for the Treatment of Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma

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DUBLIN, July 21, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the marketing authorization of JZP458 (a recombinant *Erwinia* asparaginase or crisantaspase) for use 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 and older) who developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase.

"Today's positive CHMP opinion is welcome news for those in the ALL and LBL community who are unable to be treated with *E. coli*-derived asparaginase due to hypersensitivity reactions," says Robert Iannone, MD., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "We look forward to receiving the final decision that will help bring us one step closer to delivering a reliable supply of recombinant *Erwinia* asparaginase to patients in the European Union."

The CHMP's recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines in all European Union Member States, Iceland, Norway, and Liechtenstein, and is expected to make a final decision soon.

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is a cancer of the blood and bone marrow that can progress quickly if not treated.^{1,2} ALL is the most common childhood malignancy, accounting for 80% of leukemia diagnoses in children, compared to 20% of adults.³ Long-term survival rates for pediatric patients have improved significantly over the last few decades.⁴ The estimated overall incidence of ALL and lymphoblastic lymphoma (LBL) in Europe is 1.28 per 100,000.⁵

Asparaginase is a core component of multi-agent chemotherapeutic regimens in ALL,⁶ however, up to 30% of patients develop hypersensitivity to *E. coli*-derived asparaginase,⁷ necessitating treatment discontinuation or a switch to a non-*E. coli*-derived asparaginase preparation.⁸ Patients not receiving asparaginase due to hypersensitivities and those not receiving all prescribed doses have been shown to have poor outcomes.^{9,10}

About Lymphoblastic Lymphoma (LBL)

Lymphoblastic Lymphoma (LBL) is a rare, fast-growing, aggressive subtype of non-Hodgkin's lymphoma (NHL), which is very rare in adults and is most often seen in teenagers and young adults under the age of 35.^{11,12} LBL is a type of high-grade lymphoma – which means the lymphoma grows quickly with early spread to different parts of the body.¹² LBL is the second most common type of NHL in childhood and adolescence, accounting for 25-35% of cases.¹³

About JZP458

JZP458 is a recombinant *Erwinia* asparaginase or crisantaspase that uses a *Pseudomonas fluorescens* expression platform.⁹ It is being developed for use as a component of a multi-agent chemotherapeutic regimen in the treatment of pediatric and adult patients with acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) who developed hypersensitivity to *E. coli*-derived asparaginase products. JZP458 was approved by the U.S. Food and Drug Administration (FDA) in June 2021 for the treatment of this patient population and became commercially available in July of the same year in the U.S.¹⁴

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. We are a leader in sleep disorders and epilepsy; further developing in movement disorders and PTSD; and focused on hematologic malignancies and solid tumors. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland, and has employees around the globe, serving patients in nearly 75 countries. Please visit www.jazzpharmaceuticals.com for more information.

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