

Bionical Emas launches Expanded Access Program for JZP458 - a recombinant *Erwinia Asparaginase*

May 10th, 2021

Bionical Emas, a global specialist Clinical Research Organization (CRO), has today announced the launch of a U.S. Expanded Access Program for Jazz Pharmaceuticals' investigational therapy JZP458 (asparaginase *Erwinia chrysanthemi* (recombinant)) for the treatment of adult and pediatric patients with Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL) following hypersensitivity or silent inactivation to *E. coli*-derived asparaginases. JZP458 is currently under FDA review for marketing authorization in the United States. The Expanded Access Program (EAP) provides a mechanism to fulfill unsolicited physician requests in the U.S. and support the special need of a patient.

"This EAP for JZP458 provides a potential therapy option for pediatric and adult patients with ALL or LBL who have not tolerated certain asparaginase treatments and currently have limited treatment options, and we're pleased that this program is now open to eligible patients across the US," said **John Efthimiou**, Chief Medical Officer, Bionical Emas.

Legal Warning

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

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. They are dedicated to developing life-changing medicines for people with serious diseases – often with limited or no therapeutic options. They have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. They actively explore new options for patients including novel compounds, small molecules and biologics, and through cannabinoid science and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries.

For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

Bionical Emas

Bionical Emas is a specialist CRO combining Clinical Development, Early Access Programs and Clinical Trial Supply.



Its Early Access Programs provide companies a route to allow access to pre-approved medicines to help patients with unmet medical needs.

Access is provided in response to physician requests, where the physician determines JZP458 is the most appropriate treatment option for their patient and the patient is not eligible for clinical trials for the condition.

<https://bionicalemas.com/>

About JZP458

JZP458 is a recombinant *Erwinia* asparaginase that uses a novel *Pseudomonas fluorescens* expression platform and is supplied as a sterile, stable liquid formulation. 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) or lymphoblastic lymphoma (LBL) who have developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase products. JZP458 received Fast Track designation from the FDA in October 2019. The JZP458 Biologics License Application (BLA) is being reviewed by FDA under the Real-Time Oncology Review (RTOR) pilot program, an initiative of the FDA's Oncology Center of Excellence designed for the efficient delivery of safe, effective cancer treatments to patients.

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Program enquiries: Healthcare professionals wishing to request access to JZP458 under the Expanded Access Program or who would like to find out more should do so by emailing: Patient.Access@Bionical-Emas.com.

Patients, and families/carers of those, with an ALL or LBL diagnosis wanting to know more about JZP458 should contact their treating physician to discuss the Expanded Access Program.