

Bionical Emas launches Managed Access Program for JZP 458 - a recombinant Crisantaspase produced in *Pseudomonas fluorescens*

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Bionical Emas, a global specialist Clinical Research Organization (CRO) has today announced the launch of a Managed Access Program for Jazz Pharmaceuticals' medicinal product JZP-458 for the treatment of patients with Acute Lymphoblastic Leukaemia (ALL) and Lymphoblastic Lymphoma (LBL) following hypersensitivity to E. Coli-derived asparaginases. The Managed Access Program provides a mechanism through which unsolicited physician requests, to fulfil the special need of a patient can be supported.

"JZP-458 provides a further therapy option for paediatric and adult patients with ALL or LBL who have not tolerated certain asparaginase treatments and currently have limited treatment options, and we're pleased to support this program," said **John Efthimiou**, Chief Medical Officer, Bionical Emas.

Initially, the Managed Access Program is being launched in select countries within Europe. Bionical Emas plans to expand the program to include more countries in Europe and internationally over time.

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 dedicated to developing and commercializing life-changing medicines that transform the lives of patients with serious diseases - often with limited or no options. They have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Their focus is in neuroscience, including sleep and movement disorders, and in oncology, including hematologic malignancies and solid tumours. They actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 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 JZP-458 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 JZP-458

JZP-458 is a recombinant *Erwinia* asparaginase that uses a novel *Pseudomonas fluorescens* expression platform. It is being developed for use as a component of a multi-agent chemotherapeutic regimen in the treatment of paediatric and adult patients with acute lymphoblastic leukaemia (ALL) or lymphoblastic lymphoma (LBL) who are hypersensitive to *E. coli*-derived asparaginase products. JZP-458 was granted Fast Track designation by the FDA in October 2019 for the treatment of this patient population.

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Program enquiries: Healthcare professionals wishing to request access to JZP-458 under the Managed 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 JZP-458 should contact their treating physician to discuss the Managed Access Program.