



## REVISED ORDERING PROCESS

February 19, 2018

**Subject: ERWINAZE® (asparaginase Erwinia chrysanthemi)  
Notice of \*Revised\* Ordering Process through 3<sup>rd</sup> party HUB: Limited to  
Immediate Patient Need**

**Dear Health Care Provider:**

The purpose of this letter is to alert you that Jazz Pharmaceuticals is making additional changes to the ordering process for ERWINAZE® (asparaginase Erwinia chrysanthemi) in order to limit available supply to patients with an immediate treatment need.

Jazz Pharmaceuticals anticipates being able to fill orders through its wholesaler, McKesson Plasma and Biologics during the week of March 4th, at the earliest. We will be implementing this new ordering process when we have Erwinaze back in stock. We appreciate your understanding and cooperation as we implement new steps intended to provide available supply to patients for whom there is an immediate treatment need.

### **Background**

Jazz licenses ERWINAZE from Porton Biopharma Limited (“PBL”), a company that is wholly owned by the UK Department of Health and Social Care. PBL is the sole manufacturer of ERWINAZE. While Jazz has been working with PBL to improve reliability of supply and we anticipate resuming ERWINAZE shipments in the US the week of March 4th, Jazz unfortunately expects further supply outages to continue. We are disappointed that the ongoing manufacturing issues continue to negatively impact the ability to provide patients with this treatment. Jazz remains committed to taking all actions within our control to maximize availability of ERWINAZE for patients.

As part of that commitment to patients, Jazz is changing the ordering process required to facilitate the ordering of vials for immediate patient use, and to minimize any surplus inventory being held by institutions. The new ordering process is consistent with recommendations from multidisciplinary expert opinion guidelines that may be implemented during times of oncology drug shortages<sup>1,2</sup>. This revised process allows a 3<sup>rd</sup> party HIPAA covered entity to monitor and evaluate new orders in an effort to provide ERWINAZE for patients with an

immediate dosing need and mitigate surplus inventory held by institutions not for immediate use. We thank you in advance for your cooperation as we implement this process.

### **Revised Order Process**

Upon product availability, McKesson Plasma and Biologics will accept limited orders for patients from institutions via telephone only at 1-877-625-2566.

- ❖ ***Importantly, institutions will also need to complete an Erwinaze Order Request Form and fax the order form to 1-866-850-7793 to verify the number of packs requested.***

The form is attached to this letter and is also available for download at [erwinazesupply.com](http://erwinazesupply.com). A hard copy of the form is also enclosed with the mailed version of this letter.

### **Important Information about the new process:**

- An Erwinaze Order Request form MUST be submitted for each Erwinaze Order via fax to 1-866-850-7793
- Orders are accepted only when product is in stock. There will be no vials 'set aside' for future patient need.
- Orders will be approved for patients for whom treatment is scheduled to begin within 14 days of the order placement date

The order form will require the following information for each patient ***and must be signed by an authorized Health Care Provider (i.e MD, NP, PA, PharmD)***:

- Patient First and Last Name
- Patient Date Of Birth
- Patient BSA (m<sup>2</sup>)
- Planned start date of current Erwinaze course
- Number of ERWINAZE vials required for treatment scheduled to begin within 2 weeks of order date
- Date of when 1st course of Erwinaze administered (leave blank if it is 1st course of treatment)
- Anticipated date of next treatment course
- Anticipated number of future courses

Jazz has recently contracted with ConnectiveRx, a 3<sup>rd</sup> party HUB vendor, which is a HIPAA covered entity and is authorized to receive Patient Identifiable Information (PII). The completed Erwinaze Order Request Form will be received at this vendor who will verify the completeness of the information and approve the order. If the information is incomplete, the ConnectiveRx agent will contact the customer for information. In order to avoid delays in processing the

order, we encourage you to provide complete and accurate information. If you have any questions regarding how to submit the Erwinaze order form you can reach ConnectiveRx at 1-866-850-7792. ConnectiveRx agent will be responsible to communicate to you if there is a variance between quantities ordered versus quantity approved. Please note that by faxing the Order Request form does not guarantee that Erwinaze will be available for current or future cycles.

**Ordering Instructions:**

**Step 1:** Call McKesson Plasma Biologics (MPB) at 1-877-625-2566 to place an order

**Step 2:** Fax the completed and signed Erwinaze Order Request form to 1-866-850-7793

**Step 3:** Call Erwinaze special handling instructions at 1-855-510-2284

**Upon order approval, MPB will contact you with confirmation of shipment.**

Institutions may order the appropriate amount of ERWINAZE to provide the patient their next 6 doses (to replace 1 dose of pegaspargase) in their treatment regimen, according to the recommended ERWINAZE schedule:

	<b>Substitute for pegaspargase</b>
<b>Recommended dose</b>	25,000 IU/m <sup>2</sup>
<b>Administration</b>	Intramuscular/Intravenous
<b>Dosing schedule</b>	6 doses of ERWINAZE for each planned dose of pegaspargase, 3 times a week (Mon/Wed/Fri)

For example, if a patient has a BSA of 0.8 m<sup>2</sup>, each dose of ERWINAZE would be 20,000 IU (or 2 vials). A total of 12 vials would be needed for to complete this patient's 6 doses. An order would be placed and filled for 3 packs (15 vials), leaving 3 vials for future use.

Please note the Special Handling Instructions that have accompanied packs of ERWINAZE will continue to be required until further notification. This includes required use of a 5-micron filter needle for reconstitution and use of a 0.2-micron, low protein binding, in-line filter for IV administration.

**REFERENCES**

1. Decamp M, Joffe S, Fernandez CV, Faden RR, Unguru Y; Working Group on Chemotherapy Drug Shortages in Pediatric Oncology. Chemotherapy drug shortages in pediatric oncology: a consensus statement. *Pediatrics*. 2014 Mar;133(3):e716-724.
2. Unguru Y, Fernandez CV, Bernhardt B, Berg S, Pyke-Grimm K, Woodman C, Joffe S. An Ethical Framework for Allocating Scarce Life-saving Chemotherapy and Supportive Care Drugs for Childhood Cancer. *JNCI*. 2016;108(6):1-7.

### ***Further Information***

Please see accompanying Full Prescribing Information for ERWINAZE. For more information, visit [www.erwinaze.com](http://www.erwinaze.com) or call 1-800-520-5568.

### ***Call for reporting***

Healthcare providers should report product quality problems and all suspected adverse events associated with the use of ERWINAZE to Jazz Pharmaceuticals, Inc. at 1-800-520-5568.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Sincerely,



Noam Frey, MD MBA

Vice President, Medical Affairs

Jazz Pharmaceuticals, Inc.