From: Paglia Robert S.PHARMUS
To: AGO - High Cost Prescription Drugs
Cc: Bolton Michael S.PHARMUS; Carmela Crimeni
Subject: Servier Pharmaceuticals-New drug reporting
Date: Friday, December 20, 2019 2:41:12 PM

December 20, 2019

Via E-Mail: AGO.highcostprescriptiondrugs@vermont.gov

Re: New Drug Introduction Report Pursuant to 18 V.S.A. §4637(c)

To the Office of Attorney General:

On November 13, 2019, Servier Pharmaceuticals LLC ("Servier") completed its first commercial sale of the drug listed below:

NDC Number	Drug Product Description
72694-515-01	Asparlas (calaspargase pegol-mknl) 750 U/mL 5 mL vial

Pursuant to 18 V.S.A. §4637(c), Servier provides the following additional product information listed below.

1. US and international marketing and pricing plans used at launch
    a. Because this information is not in the public domain or publicly available and is confidential, Servier declines to provide this information in accordance with 18 V.S.A. §4637(d).

2. Estimated volume of patients
    a. The estimated number of patients who may be prescribed Asparlas is not in the public domain, not publicly available, and is confidential. While the estimated volume of patients who may be prescribed Asparlas is not known to Servier, Asparlas is approved specifically for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years. In the U.S., the National Cancer Institute estimates that approximately 5,930 people (of all ages) will be diagnosed with acute lymphoblastic leukemia in 2019. Regarding the estimated number of patients in the US that may be prescribed Asparlas for acute lymphoblastic leukemia, Servier is limiting its response to that which is publicly available. Please see full prescribing information attached to this email.

3. Whether the FDA granted breakthrough therapy designation or priority review
    a. Neither breakthrough therapy designation nor priority review was granted by the FDA.

4. Date and price of acquisition
    a. This is inapplicable – Servier did not acquire the product from another manufacturer.

Please feel free to contact me if you have any questions and/or require any additional information.

Regards,
Robert Paglia

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