Confidential and Proprietary Information – Not Subject to Disclosure under 1 V.S.A. §315, *et seq.* or Otherwise

January 4, 2019

AGO.highcostprescriptiondrugs@vermont.gov

Report Concerning a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Astellas Pharma US, Inc. ("Astellas") is issuing this notice pursuant to 18 V.S.A. § 4637(c), which requires prescription drug manufacturers to report certain information to the Office of the Attorney General (the "Office") within thirty calendar days of providing initial notice to the Office that the manufacturer has released a drug in the commercial market whose wholesale acquisition cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On December 5, 2018, Astellas sent the Office an initial notice that it introduced XOSPATA® (gilteritinib) into the commercial market at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

Below is the information related to XOSPATA® which Astellas is required to report under 18 V.S.A. § 4637(c). As Astellas is not obligated to track, confirm, refute, or otherwise report publicly available information not specifically released by Astellas, the below information is limited to what Astellas has specifically released into the public domain.

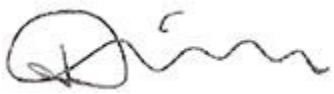
18 V.S.A. § 4637(c) Reporting Requirement	**Response for XOSPATA® (gilteritinib)**
Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	In the United States, the WAC for XOSPATA® is $22,500 for a 30-day course of treatment. The only other country in which XOSPATA® is approved is Japan. The Japanese government has set the price of XOSPATA® at 19,409.10 yen per pill. Astellas has not released any of the remaining requested information in the public domain. Further, Astellas does not believe this information is in the public domain or publicly available. As a result, Astellas is limiting its response to this reporting requirement pursuant to 18 V.S.A. § 4637(d).
Estimated volume of patients who may be prescribed the drug	Astellas has not released this information in the public domain. Further, Astellas does not believe this information is in the public domain or publicly available. As a result, Astellas is limiting its

	response to this reporting requirement pursuant to 18 V.S.A. § 4637(d).
Whether the drug was granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval	N/A
Whether the drug was granted priority review by the federal Food and Drug Administration prior to final approval	The Food and Drug Administration granted priority review of gilteritinib on May 29, 2018, which was prior to final approval.
The date and price of acquisition if the drug was not developed by Astellas	N/A

Lastly, we understand that, pursuant to 18 V.S.A. § 4637(e), the Office will publish information reported pursuant to 18 V.S.A. § 4637(c) on its website. Accordingly, we have attached a single-page version of this notice the Office can publish on its website while preserving the signatory's right to privacy, consistent with 1 V.S.A. § 317(c)(10). We ask that the Office only publish the single-page version of this notice on its website, pursuant to 18 V.S.A. § 4637(e).

In the event 18 V.S.A. § 4637 is found invalid, Astellas reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Astellas does not waive any legal claims or legal rights related to potential constitutional defects with 18 V.S.A. § 4637.

Sincerely,



Lei Ding, Vice President, Payer Strategy, Contracts and Pricing
Astellas Pharma US, Inc.

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