December 5, 2018

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(b)

Dear Office of the Vermont Attorney General,

Astellas Pharma US, Inc. ("Astellas") is issuing this notice pursuant to 18 V.S.A. § 4637(b), which requires prescription drug manufacturers to provide the Office of the Attorney General (the "Office") written notice within three calendar days of releasing 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.

Astellas released XOSPATA® (gilteritinib) into the commercial market on December 3, 2018. Astellas anticipates XOSPATA® (gilteritinib)'s WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Astellas is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

Accordingly, for the purpose of 18 V.S.A. § 4637, Astellas considers a drug to be "release[d] . . . in the commercial market" when it moves to the "available" stage with our Third Party Logistics Provider.

Please note that the WAC-related information provided in this notice may be subject to change.

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, Exec Dir Contracts and Pricing
Astellas Pharma US, Inc.

Astellas Pharma US, Inc.
1 Astellas Way, Northbrook, IL 60062
Tel: 224-205-8800 Fax: 224-205-5436