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April 30, 2019

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

Dear Office of the Vermont Attorney General,

Par Pharmaceutical, Inc. (“Par”) is issuing this notice pursuant to 18 V.S.A. § 4637(b), which asks 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.

On April 29, 2019, Par informed potential customers the following drug products are available for order:

NDC #	Product Description
49884-0353-62	Ambrisentan Tablets 5mg 10s
49884-0353-11	Ambrisentan Tablets 5mg 30s
49884-0354-62	Ambrisentan Tablets 10mg 10s
49884-0354-11	Ambrisentan Tablets 10mg 30s

The WAC for the drug product identified above exceeds the threshold set for a specialty drug under the Medicare Part D Program. Please note that the WAC-related information provided in this notice may be subject to change.

18 V.S.A. § 4637 does not currently define “release of the drug in the commercial market.” Further, Par 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.

As of the date of this letter, Par has not yet received a customer order for Ambrisentan Tablets. Additionally, Par has not yet shipped or fulfilled any orders for Ambrisentan Tablets.

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Par reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Par does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,

Michael Altamuro, SVP, Commercial Operations & Marketing