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October 29, 2019

**NOTIFICATION PURSUANT TO
18 V.S.A. § 4637(b)**

Subject: New prescription drug report

To: The Office of the Attorney General of Vermont

Celltrion USA, Inc. hereby notifies the Attorney General of Vermont of the following new prescription drug report pursuant to 18 V.S.A. § 4637(b).

Name of New Prescription Drug	NDC Number	Date of Commercial Availability	Wholesale Acquisition Cost as of the date of Commercial Availability
TEMIXYS™ (lamivudine and tenofovir disoproxil fumarate)	72606-0002-01	09/30/2019	\$850

Breakthrough Therapy/Priority Review/ Acquisition Date:

Temixys™ was developed by Celltrion and was not acquired, and was not granted breakthrough therapy designation or priority review by the FDA prior to final approval.

Marketing Plan Description:

Celltrion USA Inc. is a new pharmaceutical company and has not yet begun direct-to-consumer marketing activities. We will be working towards increasing awareness of the availability of a new branded generic product to healthcare providers (HCPs) through speaker engagements and seminars, and provide FDA approved medication information through print material, mobile application, and website. A copay card will be offered to eligible commercially-insured patients.

Estimated Number of Patients:

According to the Centers for Disease Control and Prevention (CDC), the prevalence for HIV is 1.1 million patients. As Temixys™ is indicated for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg, in combination with other antiretroviral agents. In 2017, 38,739 people received an HIV diagnosis, and the annual number of new HIV diagnoses in the U.S. have remained stable from 2012 to 2016. This data suggests that there is an estimate of 3,228 patients per month. Depending on the patient's medical history, blood test results, allergies, and known resistance to lamivudine, a patient may or may not be prescribed Temixys™. Celltrion estimates 3,000 as the average number of patients who will be prescribed the new prescription drug.

Please let us know if any additional information is required.

Sincerely,


Bondoong Kim
CEO