Date: December 23, 2021

To: Office of the Attorney General of Vermont

Re: Vermont New Drug Report

Via Email: AGO.highcostprescriptiondrugs@vermont.gov

Pursuant to 18 V.S.A. § 4637(c) Takeda Pharmaceuticals America is providing the following new drug report to the Office of the Attorney General of Vermont:

Description of New Drug	NDC Number	Date of Commercial Availability	Wholesale Acquisition Cost (WAC) as of Date of Commercial Availability
LIVTENCITY™(maribavir) tablets	64764-0800-28	11/23/2021	$6,224.96
LIVTENCITY™(maribavir) tablets	64764-0800-56	11/23/2021	$12,449.92

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally
Takeda's marketing and pricing plans are confidential and proprietary, and not available in the public domain. However, marketing to support product launch will include print and digital media materials, including a product website for healthcare professionals, attendance at industry congresses, and educational materials for sales representatives to share with appropriate healthcare professionals. Takeda's approach to pricing medicines in the U.S. reflects our strong commitment to bringing the right treatment options to patients who may benefit from them. In pricing our products, Takeda considers and believes in: (i) the value medicine brings to patients and society; (ii) access to medicines; and (iii) providing a thoughtful approach that allows us to continue to deliver innovative medicines. For more information, please see Takeda's US Pricing Philosophy at: https://www.takeda.com/en-us/corporate-responsibility/takeda-pricing-philosophy/.

The estimated volume of patients who may be prescribed the drug
Due to the nature of the disease for which LIVTENCITY™ (maribavir) is indicated, Takeda has not determined a specific volume of patients for whom LIVTENCITY may be prescribed, and therefore an estimated volume of patients in the US for whom LIVTENCITY may be prescribed is not available in the public domain. FDA has designated LIVTENCITY as an orphan drug. LIVTENCITY is approved for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet, a rare condition. In the U.S. data show that in 2019 there were nearly 40,000 solid organ transplants (SOT) and more than 20,000 hematopoietic cell transplants (HSCT) performed. A subset of these patients may develop CMV infection, a common post-transplant viral infection. Based on an observational, systematic literature study by Takeda from 2020, the prevalence of CMV in the US ranges between 15.5% to 81.8%, depending on the transplant type, the level of patient's immunosuppression, and other factors such as donor-recipient serostatus. A subset of those CMV patients may develop refractory/resistant CMV infection and be candidates for LIVTENCITY. The estimated range of refractory CMV infection based on the same Takeda literature study is 19.9-47.4% in HSCT and 19.9-20.6% in SOT. The estimated range of resistant CMV infection is 1.8-19.0% in HSCT and 0.6-13.8% in SOT.

Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval
Yes, Livtencity was granted breakthrough therapy designation and priority review by the FDA prior to final approval.

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Date and price of acquisition if the drug was not developed by the manufacturer
Not applicable.

For any questions concerning this notification please contact me at jessica.blain@takeda.com

Sincerely,

Jessica Blain

Associate Director, Contracts and Pricing Compliance

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