Date: October 20, 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
EXKIVITY™(mobocertinib) capsules	63020-0040-12	09/20/2021	$25,000.00

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally
While specific marketing and pricing plans are not available in the public domain, generally we do plan to market Exkivity in the US through print and digital media materials created to be used by sales representatives to share information on Exkivity with prescribers and through the use of print and digital materials made available to educate patients about Exkivity. We will also promote Exkivity to appropriate healthcare professionals, who treat individuals diagnosed with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 20 insertion, a rare condition, through engagement at scientific meetings and conferences. Takeda considers a number of factors when deciding the price at which to set its prescription drugs, including, but not limited to: (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. Patients with epidermal growth factor receptor (EGFR) Exon20 insertion+ non-small cell lung cancer (NSCLC) make up approximately 1-2% of patients with NSCLC. This disease carries a worse prognosis than other EGFR mutations and has been historically underserved. Exkivity is a first-in-class, oral tyrosine kinase inhibitor (TKI) specifically designed to selectively target epidermal growth factor receptor (EGFR) Exon20 insertion mutations. In establishing WAC, Takeda also evaluated the access landscape for EGFR Exon20 insertion+ NSCLC patients, including the current treatment landscape and associated costs, likelihood of payor coverage, and options for patients without coverage. In addition, Takeda considered its ability to continue to fund the discovery of future oncology innovations and the resources needed to bring new therapies to market.

The estimated volume of patients who may be prescribed the drug
The estimated number of patients in any given state in the United States (U.S.) with a condition for which EXKIVITY may be prescribed each month is not known but EGFR exon 20 disease makes up 1% to 2% of all NSCLC cases, or about 2,000 to 4,000 patients per year in the U.S.

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

Date and price of acquisition if the drug was not developed by the manufacturer
Not applicable. Takeda Pharmaceuticals America, Inc. did not purchase the rights to Exkivity.

For any questions concerning this notification please contact me at michelle.lucas@takeda.com.

Sincerely,

Michelle Lucas

Government Pricing and Reporting Lead

Takeda Pharmaceuticals America, Inc.