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OR VERMONT PUBLIC RECORDS LAW**

VIA E-MAIL

February 9, 2023

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Office of the Vermont Attorney General
Attention: Attorney General, Susanne R. Young
109 State Street
Montpelier, VT 05609
AGO.highcostprescriptiondrugs@vermont.gov

Dear Attorney General Donovan:

This letter provides information, as required by Section 4637(b) of Vermont Act 193, as codified at 18 VT. Stat. Ann. § 4637 (“Act 193”). This report is in addition to the notice that Gilead Sciences, Inc. (“Gilead”) provided to the Office of the Attorney General (the “Office”) on February 9, 2023 regarding the market entry of the following new prescription drugs:

- SUNLENCA[®] (lenacapvir) sterile solution for injection, 309 mg/mL, 1.5 mL/vial, 2 vial kit (NDC 61958-3002-01);
- SUNLENCA[®] (lenacapvir) tablet, 300 mg, 4 count, blister pack (NDC 61958-3001-01); and
- SUNLENCA[®] (lenacapvir) tablet, 300 mg, 5 count, blister pack (NDC 61958-3001-02).

This letter provides the information required by Section 4637(c) of Act 193 for SUNLENCA sterile solution for injection and tablets, in the chart below:

| <u>Section 4637(c) Reporting Requirements</u> | <u>Response for SUNLENCA</u> |
|---|--|
| A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally. | Consistent with Section 4637(d) of Act 193, Gilead is limiting its response to that which is otherwise in the public domain or publicly available. This information is not in the public domain or publicly available. |
| The estimated volume of patients that may be prescribed the drug. | Approximately 5000 patients. Consistent with Section 4637(d) of Act 193, Gilead is providing the best publicly available estimated number of patients in the |

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| | United States with a condition for which SUNLENCA may be prescribed. |
| Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval? | Yes, the drug was granted breakthrough therapy designation by the FDA. |
| Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval? | Yes, the drug product received a priority review by the FDA. |
| The date and price of acquisition if the drug was not developed by the manufacturer. | This information is not applicable. |

We understand that, pursuant to Section 4637(e) of Act 193, the Office will publish information reported pursuant to Section 4637 on its website. Accordingly, we have attached a single-page version of this report the Office can publish on its website while preserving the signatory’s right to privacy, consistent with Section 317(c)(10) of Title 1 of the Vermont Statutes Annotated. We ask that the Office only publish the single-page version of this notice on its website, pursuant to Section 4637(e) of Act 193.

Sincerely,

DocuSigned by:

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William J. Hillmer
Senior Director, Trade Strategy and Operations
Gilead Sciences, Inc.

Notice of New Drug Pursuant to Section 4637 of Vermont Act 193

This letter provides notice, as required by Section 4637(b) of Vermont Act 193, as codified at 18 VT. Stat. Ann. § 4637, that Gilead Sciences, Inc. released the following new prescription drugs to market on January 11, 2023 at a wholesale acquisition cost above that of a specialty drug under the Medicare Part D program:

- SUNLENCA[®] (lenacapvir) sterile solution for injection, 309 mg/mL, 1.5 mL/vial, 2 vial kit (NDC 61958-3002-01);
- SUNLENCA[®] (lenacapvir) tablet, 300 mg, 4 count, blister pack (NDC 61958-3001-01);
and
- SUNLENCA[®] (lenacapvir) tablet, 300 mg, 5 count, blister pack (NDC 61958-3001-02).

The WAC exceeding the Medicare Part D program price reflects SUNLENCA's clinical efficacy, safety profile, as well as access and market conditions.