sanofi

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24 April 2023

RE: Notification of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

To: The Office of the Vermont Attorney General

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

Pursuant to 18 V.S.A. § 4637(b), Bioverativ Therapeutics, Inc., a Sanofi company, (referred to herein as "Sanofi"), provided notice on March 30, 2023 of the commercial launch of ALTUVIIIO™ (efanesoctocog alfa) for the treatment of hemophilia A, a rare and life-threatening bleeding disorder. This letter provides the additional information that 18 V.S.A. § 4637(c) requires manufacturers to report within 30 days of the initial notice. Sanofi has limited the information reported to that which is otherwise in the public domain or publicly available, as authorized by 18 V.S.A. § 4637(d).

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally:

In the US, marketing initiatives are expected to include print and digital media, engagement at scientific meetings attended by HCPs most likely to manage patients with hemophilia A patients, materials to be used by sales representatives to educate about hemophilia A and to share information on ALTUVIIIO™ as a treatment for hemophilia A patients with HCPs, and materials to educate patients about hemophilia A and ALTUVIIIO™. Direct to Consumer (DTC) outreach for ALTUVIIIO™ will include printed materials, search, website, email, and online ad placements. DTC initiatives are not expected to include any TV, radio or national magazine advertising.

Ex-US, marketing initiatives are expected to include print and digital media, engagement at scientific meetings attended by HCPs most likely to manage patients with hemophilia A, materials to be used by sales representatives to share information on ALTUVIIIO™ with HCPs and materials to educate patients about hemophilia A and ALTUVIIIO™.

At Sanofi, we work passionately to prevent, treat, and cure illness and disease, understand and solve health care needs of people across the world, and transform the practice of medicine. Sanofi has a longstanding commitment to promote health care systems that make our treatments accessible and affordable to patients in need.

Sanofi understands and shares concerns about the affordability of medicines for patients while also recognizing that we are only one of many stakeholders in the health care system. In order to maintain an environment that will continue to bring new health care solutions to patients, we must encourage a transition to a value-driven health care system that provides incentives for the highest-quality care. This evolution will enable both affordable access to treatment and continued

investment in medical innovation. Sanofi is committed to helping address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are controlled by other stakeholders in the health care system, we believe we have a responsibility to be a leader in solving issues of patient access and system viability. For our part, we price our medicines according to their value, while contributing to broader solutions that improve patient outcomes and support affordability within the U.S. health care system.

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers a holistic assessment of value through clinical, economic and societal lens; similar treatment options, affordability and unique factors specific to the medicine at time of launch (i.e., longer-term outcome studies, sophisticated patient support tools, etc.).

(2) The estimated volume of patients who may be prescribed the drug:

Hemophilia A, also called factor VIII (8) deficiency or classic hemophilia, is a genetic disorder caused by missing or defective factor VIII (FVIII), a clotting protein. Although it is passed down from parents to children, about 1/3 of cases found have no previous family history. Hemophilia is an inherited bleeding disorder primarily affecting males—but females can also have hemophilia. Patients are classified as mild, moderate, or severe hemophilia. More than half of people diagnosed with hemophilia A have the severe form. Hemophilia A is four times as common as hemophilia B. Hemophilia affects all races and ethnic groups.

ALTUVIIIO is approved for the treatment of Hemophilia A patients regardless of gender, age, or disease severity, and it is indicated for use for prophylaxis, on-demand, and perioperative use. Currently, there are an estimated 25,000 patients in the US with hemophilia A across all severity levels, including men and women with the rare blood disorder. Approximately 13,000 are treated and have the potential to be prescribed ALTUVIIIO.

(3) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval:

Yes, ALTUVIIIO™ was granted both breakthrough therapy designation and priority review by the FDA.

(4) The date and price of acquisition if the drug was not developed by the manufacturer:

Not applicable.

In providing this notice, Sanofi expressly reserves any and all rights or claims it may have with respect to 18 V.S.A. § 4637, the company's interpretation thereof, or the statute's application to Bioverativ Therapeutics, Inc., Sanofi, or any other entity affiliated with or otherwise under the control of Sanofi.

Sincerely,

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