Via E-Mail
April 8, 2020

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), sanofi-aventis U.S. LLC (referred to herein as "Sanofi"), provided notice on March 11, 2020 of the commercial launch of SARCLISA (isatuximab-irfc) with the NDC code(s) 0024-0656-01 for 500mg/ 25 mL single dose vial, for the treatment of certain previously-treated patients with Relapsed/Refractory Multiple Myeloma (RRMM). 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:

Marketing initiatives are expected to include print and digital media, engagement at scientific meetings attended by HCPs most likely to manage patients with relapsed refractory multiple myeloma, materials to be used by sales representatives to share information on SARCLISA with prescribers, and materials to educate patients about relapsed refractory multiple myeloma and SARCLISA. Direct to Consumer (DTC) outreach for SARCLISA will include search, website, and online ad placements. DTC initiatives are not expected to include any TV, radio or national magazine advertising.

Sanofi's commitment to pricing rests on three principles: a holistic assessment of value when setting launch prices, year-over-year price increases that are limited to National Health Expenditure projections, and disclosure of our aggregate gross and net prices changes to provide greater transparency about the pricing of our medicines.

These comprehensive principles were drafted to address questions around the price of medicines in the United States. Our goal is to make our medicines accessible and affordable to all patients.
We share concerns about the affordability of medicines, and we believe deeply in the important role we play in providing treatments for serious illnesses. We are determined to do our part in pricing our medicines with greater transparency and according to their value, while continuing to advance scientific knowledge and bringing life-saving treatments to patients worldwide.

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

In the United States, it is estimated that there are 131,392 people living with multiple myeloma (MM). In 2019, according to the American Cancer Society, MM was the third most common hematologic malignancy with 32,110 new cases. The national Surveillance Epidemiology and End Results (SEER), reported an annual age-standardized rate of 6.9 per 100,000 persons for MM. MM remains an incurable disease with

many patients relapsing multiple times throughout the course of the disease. It is estimated that 48%-66% of all treated patients are relapsed refractory multiple myeloma patients. Patients with relapsed refractory multiple myeloma may or may not be prescribed SARCLISA. Thus, Sanofi is unable to provide an estimate of the volume of patients that will be prescribed this product.

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

No breakthrough designation nor priority review granted

(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 sanofi-aventis U.S. LLC.

Sincerely,

Phillip Ridolfi
Head of Business Operations and Support, Sales Support