Report Submitted 4/26/2024 to the Vermont Office of the Attorney General for Introduction of a New Prescription Drug to Market
Actelion Pharmaceuticals US, Inc.
Information required pursuant to 18 VSA § 4637(c),(d)
OPSYNVI

Requirement	OPSYNVI Response
18 VSA § 4637(c)(1) A 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 plan to market in the US and promote to appropriate healthcare professionals who treat adult patients with PAH and WHO FC II or III. The pricing plan has WAC set for the 10/20mg 30-ct bottle and 10/40mg 30-ct bottle each at $12,635.31. The pricing plan has WAC set for the 10/20mg 7-ct blister pack at $2,948.24, and a WAC set for the 10/40mg 10-ct blister pack at $4,211.77. The list price of OPSYNVI will also be discounted as required under the 340 B program, Federal Supply Schedule, and other government programs. The Janssen Pharmaceutical Companies of Johnson & Johnson has submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of a single tablet combination therapy of macitentan 10 mg and tadalafil 40 mg (M/T STCT) for the long-term treatment of pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) in adult patients of WHO functional class (FC) II-III. International pricing plans are based on ensuring compliance with local laws and processes. Member states pricing and reimbursement negotiations are ongoing and are based upon local funding choices.
18 VSA § 4637(c)(2) The estimated volume of patients who may be prescribed the drug	The estimated number of patients in the United States with a condition for which OPSYNVI may be prescribed is not in the public domain or publicly available.
18 VSA § 4637(c)(3) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	The drug was not granted breakthrough therapy designation and priority review.
18 VSA § 4637(c)(4) The date and price of acquisition if the drug was not developed by the manufacturer.	Not an acquisition
Note: as provided in 18 VSA § 4637(d), we are limiting the information reported to that which is in the public domain or publicly available	