Avadel CNS Pharmaceuticals, LLC

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To: The Office of the Attorney General

Subject: Notice to Vermont for introduction of LUMRYZ – Full Report

In compliance with 18 V.S.A. § 4637, on May 2, 2023 Avadel CNS Pharmaceuticals ("Avadel") provided written notice to the Office of the Attorney General that it introduced 8 NDCs related to LUMRYZ, a new prescription drug ("the Products"), to the commercial market on May 1, 2023 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

Table 1: 3-day written notice of 8 NDCs for LUMRYZ

NDC	Description	WAC
13551-001-07	LUMRYZ 4.5 g (sodium oxybate) for extended-release oral suspension, #7 Each Powder in Packet	$2,037.00
13551-001-30	LUMRYZ 4.5 g (sodium oxybate) for extended-release oral suspension, #30 Each Powder in Packet	$8,730.02
13551-002-07	LUMRYZ 6.0 g (sodium oxybate) for extended-release oral suspension, #7 Each Powder in Packet	$2,716.00
13551-002-30	LUMRYZ 6.0 g (sodium oxybate) for extended-release oral suspension, #30 Each Powder in Packet	$11,640.02
13551-003-07	LUMRYZ 7.5 g (sodium oxybate) for extended-release oral suspension, #7 Each Powder in Packet	$3,395.01
13551-003-30	LUMRYZ 7.5 g (sodium oxybate) for extended-release oral suspension, #30 Each Powder in Packet	$14,550.03
13551-004-07	LUMRYZ 9.0 g (sodium oxybate) for extended-release oral suspension, #7 Each Powder in Packet	$4,074.01
13551-004-30	LUMRYZ 9.0 g (sodium oxybate) for extended-release oral suspension, #30 Each Powder in Packet	$17,460.03

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Products. Avadel notes that the Office of the Attorney General has requested a PDF format for submissions under this section but has not restricted the contents to a particular template format. Further, as authorized by 18 V.S.A. § 4637(d), Avadel has limited the information reported to that which is in the public domain or publicly available.

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

LUMRYZ will be marketed to Healthcare Professionals, Patients, Payers, and other appropriate audiences. Avadel engaged extensively with health economists, public health experts, and payers about LUMRYZ. We have established a price for LUMRYZ that reflects the overall value this treatment brings to patients, caregivers, and society, and one that will enable continuous innovation and is in line with other products within the therapeutic class. Avadel has determined the launch price of LUMRYZ based on our belief in the impact of treatment as well as the size of the appropriate patient population based on the entry criteria of our clinical trials.

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

There are approximately 140,000 patients in the United States with conditions treated by this therapeutic class of drugs. However, it is unknown at this time what percentage of them might be prescribed LUMRYZ.

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

The Products were not granted a priority review nor were they given a breakthrough therapy designation.

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

The Products were not the result of a product acquisition.