Avadel Pharmaceuticals

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Dear Community Members,

We are reaching out in response to the questions we have received regarding the commercial status of LUMRYZ™ (sodium oxybate) extended-release oral suspension for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy.

As you may have seen, the Food and Drug Administration (FDA) granted tentative approval to LUMRYZ (pronounced "LOOM rize"). We realize that "tentative approval" may be an unfamiliar term.

Tentative approval means that LUMRYZ has met all requirements for the efficacy, safety and quality standards necessary for FDA approval. LUMRYZ will have a REMS (Risk Evaluation and Mitigation Strategy), as required by the FDA, to assure safe distribution and use.

A tentative approval means a medication can't be finally approved by FDA until a patent or other exclusivity expires. In the case of LUMRYZ, final approval may not occur until a REMS patent, listed in FDA's database for another oxybate product, expires on June 17, 2023.

A drug that receives tentative approval is not an FDA-approved drug until it receives final approval.

Until LUMRYZ receives FDA final approval, LUMRYZ can't be made commercially available for patients.

We want to assure you that Avadel remains fully committed to the patient community and its supporters. We are pursuing all options to secure final approval from FDA for LUMRYZ earlier than June 2023, as we believe people living with narcolepsy deserve more options.

We understand you may have more questions. More detailed information about the tentative approval is available on avadel.com.

Best regards,

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