IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	REDACTED PUBLIC VERSION FILED AUGUST 12, 2025 C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DECLARATION OF JENNIFER GUDEMAN

I, Jennifer Gudeman, declare:

1. I submit this Declaration in support of Avadel's Opposition to Jazz's Renewed Motion for a Permanent Injunction. I have personal knowledge of the facts stated herein. If called as a witness in this matter, I could and would competently testify to each of the facts set forth below.

2. I am the Senior Vice President, Medical and Clinical Affairs at Avadel Pharmaceuticals. I joined Avadel in December 2020.

3. I have over twenty years of experience in the pharmaceutical industry. I am a pharmacist by training and received a bachelor's degree in pharmacy and a doctorate in pharmacy from St. Louis College of Pharmacy in 1999 and 2000, respectively.

4. In my role at Avadel, I am responsible for collecting the scientific body of evidence about LUMRYZ's use as a therapeutic, including through clinical trials. I also oversee those portions of regulatory submissions that relate to the scientific evidence concerning LUMRYZ.

5. I understand that the Court is familiar with the FDA's determination that for patients with narcolepsy, the benefits of LUMRYZ make a major contribution to patient care, such that LUMRYZ was awarded Orphan Drug **Exclusivity** ("ODE") by FDA. FDA awarded that ODE to LUMRYZ when it was approved for use in narcolepsy. The award of ODE is the final step in that review. Earlier in the process, FDA makes a determination about awarding Orphan Drug **Designation** ("ODD"), which is an important milestone in the process of a drug receiving ODE.

6. LUMRYZ was recently awarded orphan drug designation ("ODD") for idiopathic hypersomnia ("IH"). FDA awarded ODD on the basis that LUMRYZ may provide a major contribution to patient care due to [its] once nightly dosing for patients with IH, which is the same basis on which it previously awarded LUMRYZ ODE for narcolepsy. The FDA is aware that Xywav is used once-nightly in a subset of IH patients, and FDA still determined that LUMRYZ's

once-nightly dosing may provide a major contribution to patient care. If Avadel is able to apply for approval for LUMRYZ for use in treating IH, FDA will consider whether LUMRYZ should be granted not just ODD but also ODE, that is, FDA will make a final determination about whether LUMRYZ makes a major contribution to patient care for patients with IH based on the full application for approval, including based on additional scientific evidence collected on LUMRYZ's benefits. That FDA ruling would, however, only come about if FDA is able to consider an application from Avadel to get LUMRYZ approved for use in IH. FDA does not provide ODE determinations to a drug that is not being approved.

7. Avadel is currently conducting its phase 3 REVITALYZ trial of LUMRYZ for the treatment of IH. The purpose of the REVITALYZ trial is to support Avadel's eventual application for the use of LUMRYZ to treat IH. It is a double-blind, placebo-controlled, randomized withdrawal, multicenter study of the efficacy and safety of LUMRYZ in patients diagnosed with IH. Details are at https://clinicaltrials.gov/study/NCT06525077?term=NCT06525077&rank=1). Avadel cannot apply for FDA approval for the use of LUMRYZ to treat IH until the trial is completed, that is, a successful trial is a predicate for that application.

8. While Avadel is hopeful that enrollment in that trial will be completed by the end of 2025, the enrollment rate and timing of that trial are subject to factors beyond Avadel's control.

9. Once the REVITALYZ study concludes, Avadel will need to review the data to determine whether it supports applying for an IH indication for LUMRYZ. While Avadel is again optimistic about the results of that study, there are no guarantees regarding the outcome; that is why clinical studies are done.

10. After completion of enrollment, the generation, processing and reviewing the data, as well as preparing the sNDA submission is a time consuming process [redacted]

[redacted]. Even if Avadel timely completes the REVITALYZ study and based on a review of the data determines there is support to apply for an IH indication for LUMRYZ, there is no certainty as to when Avadel will submit an sNDA to the FDA requesting approval for an IH indication for LUMRYZ.

11. And even if Avadel applies for an IH indication for LUMRYZ, that application will still have to undergo review by FDA, and there is no guarantee that FDA will approve Avadel's application.

12. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July ___, 2025.

29-Jul-2025

Signed by:
Jennifer Gudeman
Signer Name: Jennifer Gudeman
Signing Reason: I approve this document
Signing Time: 29-Jul-2025 | 9:45:47 AM CDT
81CADD0FE04A4B31B520F0DC35B6527D

Jennifer Gudeman

Jennifer Gudeman