Avadel Pharmaceuticals Shares New LUMRYZ™ (sodium oxybate) For Extended-release Oral Suspension (CIII) Data at SLEEP 2024

May 22, 2024 at 8:00 AM EDT

– 11 accepted abstracts, including new data reiterating satisfaction, preference and clinical benefit of LUMRYZ –

– Presentations highlight Avadel's continued commitment to address gaps in narcolepsy care –

DUBLIN, May 22, 2024 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, announced today it will present 11 posters, and one oral presentation, supporting the use of LUMRYZ as a narcolepsy treatment option at SLEEP 2024, the 38th annual joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society on June 1-5, 2024, in Houston.

Approved by the U.S. Food and Drug Administration (FDA) in 2023, LUMRYZ is the first and only extended-release formulation of sodium oxybate and indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

"Presentations at this year's SLEEP 2024 add to our increasing collection of data on LUMRYZ as an effective and preferred narcolepsy treatment option for patients to help improve their daytime symptoms of narcolepsy without disrupting sleep for a second middle-of-the-night dose," said Jennifer Gudeman, PharmD, Senior Vice President, Medical and Clinical Affairs of Avadel. "Part of our presentations will underscore new patient preference findings from our RESTORE study, revealing that in addition to previously reported data which showed that 94% of patients who switched from a twice-nightly oxybate stated a preference for once-nightly dosing, 91% of study participants reported they were better able to sleep through the night with LUMRYZ, and 89% of participants would recommend LUMRYZ to a family or friend with narcolepsy."

LUMRYZ has a boxed warning as a central nervous system depressant, and for its potential for abuse and misuse. LUMRYZ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy called the LUMRYZ REMS. Most common adverse reactions (incidence >5% and greater than placebo) reported for all doses of LUMRYZ combined were nausea, dizziness, enuresis, headache, and vomiting.

Highlights from the presentations of new data presented at the meeting include:

- End-of-study survey data from the RESTORE open-label/switch study demonstrating that patients experienced a high level of satisfaction with once-at-bedtime LUMRYZ, including improved symptom control, an improvement in dosing adherence and a preference for LUMRYZ over twice-nightly oxybate treatment options.
- Findings from a human factor study revealing that individuals with narcolepsy, regardless of their prior experience with oxybate treatment, can successfully follow the label instructions for safe use of LUMRYZ.
- Data showing consistent and acceptable dissolution of LUMRYZ at prescribed doses in various flavored liquids, which may be preferred by some patients as alternatives to water.
- Post hoc analysis from Avadel's completed pivotal REST-ON clinical trial that showed treatment with LUMRYZ improved symptoms of EDS and cataplexy in people with narcolepsy regardless of gender.
- A poster comparing baseline narcolepsy characteristics among three age groups (youngest: 16–25 years of age; middle: 26–34 years of age; oldest: 35–72 years of age) of participants from the REST-ON clinical trial which indicated that baseline measures of EDS were similar among age groups. Additionally, objective data from polysomnography showed worse disrupted nighttime sleep (DNS) in older participants, indicating DNS may worsen with age.
- Findings from a social listening analysis of content posted on MyNarcolepsyTeam, a social network for people with narcolepsy, which concluded that gaining a better understanding of patient experiences and self-management strategies enables sleep specialists to more effectively identify challenges and needs of patients, leading to quicker diagnoses and tailored treatments.

All abstracts have been published in an online supplement in the journal *Sleep*. Presentation details are as follows:

Title	Presenter	Presentation Details
Monday, June 3		
Composite Response With Once-Nightly Sodium Oxybate: Symptom Improvement in Participants With Narcolepsy Type 1 in REST-ON	Luis Ortiz	Session: **P-13** Poster Number: **#251** Time: **10-10:45 a.m. CT**
Stability of Once-Nightly Sodium Oxybate in Alternative Liquid Reconstitution Vehicles	Maggie Lavender	Session: **P-13** Poster Number: **#253** Time: **10-10:45 a.m. CT**
Magnitude of Improvement in Excessive Daytime Sleepiness with the Once-at-Bedtime Oxybate for Narcolepsy	John Harsh	Session: **P-13** Poster Number: **#255** Time: **10-10:45 a.m. CT**

Comparison of Demographics and Baseline Narcolepsy Symptoms Between Participants with NT1 and NT2 from the Phase 3 REST-ON Clinical Trial	Yves Dauvilliers	Session: **P-13** Poster Number: **#261** Time: **10-10:45 a.m. CT**
Efficacy Outcomes Among Male and Female Participant Subgroups: A Post Hoc Analysis from REST-ON	Jennifer Gudeman	Session: **P-13** Poster Number: **#262** Time: **11-11:45 a.m. CT**
Assessing Usability of Once-Nightly Sodium Oxybate Extended-Release Oral Suspension for Narcolepsy	Maggie Lavender	Session: **P-13** Poster Number: **#250** Time: **11-11:45 a.m. CT**
Consistent Efficacy of Once-Nightly Sodium Oxybate Regardless of Patient Demographic and Baseline Disease Characteristics	Michael Thorpy	Session: **P-13** Poster Number: **#252** Time: **11-11:45 a.m. CT**
Patient Preferences of Sodium Oxybate Treatment for Narcolepsy: RESTORE End-of-Study Survey Data	Akinyemi Ajayi	Session: **P-13** Poster Number: **#258** Time: **11-11:45 a.m. CT**
Comparison of Baseline Narcolepsy Characteristics Among Participant Age Groups: Analysis From REST-ON Clinical Trial	Thomas Roth	Session: **P-13** Poster Number: **#260** Time: **11-11:45 a.m. CT**
Tuesday, June 4		
Consistent Efficacy of Once-Nightly Sodium Oxybate Regardless of Patient Demographic and Baseline Disease Characteristics	Michael Thorpy	Session: **O-18** *(also presented as poster #252)* Time: **3:30-3:45 p.m. CT**
Wednesday, June 5		
Caregiver Preferences for Narcolepsy Treatment: A Discrete Choice Experiment	Luis Ortiz	Session: **P-42** Poster Number: **#279** Time: **10-10:45 a.m. CT**
Understanding the Debilitating Nature of Narcolepsy in Patients' Own Words: A Social Listening Analysis	Anne Marie Morse	Session: **P-42** Poster Number: **#286** Time: **11-11:45 a.m. CT**

Additionally, Avadel will host a product theater for U.S. healthcare professionals titled, "Evolving Narcolepsy Care: Expert Perspectives on LUMRYZ, the First and Only Once-At-Bedtime Sodium Oxybate," on Tuesday, June 4 at 11:45 a.m. CT at the George R. Brown Convention Center. The symposium will feature Maggie Lavender, MSN, APRN, FNP-C of Comprehensive Sleep Medicine Associates, Michael J. Thorpy, M.D., Director of the Sleep-Wake Disorders Center at Montefiore and Professor of Neurology at Albert Einstein College of Medicine, and a person with narcolepsy. Interested attendees can register at www.AvadelProductTheater.com.

About LUMRYZ™ (sodium oxybate) for extended-release oral suspension

LUMRYZ, is an extended-release sodium oxybate medication approved by the FDA on May 1, 2023, as the first and only once-at-bedtime treatment for cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

The FDA approval of LUMRYZ was supported by results from REST-ON, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial in adults with narcolepsy. LUMRYZ demonstrated statistically significant and clinically meaningful improvements in the three co-primary endpoints: EDS, clinicians' overall assessment of patients' functioning (CGI-I) and cataplexy attacks, for all three evaluated doses when compared to placebo.

With its approval, the FDA also granted seven years of Orphan Drug Exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently available oxybate treatments. In particular, the FDA found that LUMRYZ makes a major contribution to patient care over currently available, twice-nightly oxybate products by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose.

IMPORTANT SAFETY INFORMATION

WARNING: Taking LUMRYZ™ (sodium oxybate) with other central nervous system (CNS) depressants, such as medicines used to make you fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope) and death.

The active ingredient of LUMRYZ (sodium oxybate) is a form of gamma hydroxybutyrate (GHB), a controlled substance. Abuse or misuse of illegal GHB alone or with other CNS depressants (drugs that cause changes in alertness or consciousness) have caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma and death. Call your doctor right away if you have any of these serious side effects.

Because of these risks, LUMRYZ is available only by prescription and filled through certified pharmacies in the LUMRYZ REMS. You must be enrolled in the LUMRYZ REMS to receive LUMRYZ. Further information is available at www.LUMRYZREMS.com or by calling 1-877-453-1029.

INDICATIONS

LUMRYZ (sodium oxybate) for extended-release oral suspension is a prescription medicine used to treat the following symptoms in adults with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy)

- excessive daytime sleepiness (EDS)

It is not known if LUMRYZ is safe and effective in people less than 18 years of age.

Do not take LUMRYZ if you take other sleep medicines or sedatives (medicines that cause sleepiness), drink alcohol or have a rare problem called succinic semialdehyde dehydrogenase deficiency.

Keep LUMRYZ in a safe place to prevent abuse and misuse. Selling or giving away LUMRYZ may harm others and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Anyone who takes LUMRYZ should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery or flying an airplane, for at least six (6) hours after taking LUMRYZ. Those activities should not be done until you know how LUMRYZ affects you.

Falling asleep quickly, including while standing or while getting up from the bed, has led to falls with injuries that have required some people to be hospitalized.

LUMRYZ can cause serious side effects, including the following:

- **Breathing problems,** including slower breathing, trouble breathing and/or short periods of not breathing while sleeping (e.g., sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they take LUMRYZ.
- **Mental health problems**, including confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness and difficulty concentrating. Tell your doctor if you have or had depression or have tried to harm yourself. **Call your doctor right away if you have symptoms of mental health problems or a change in weight or appetite.**
- **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you start sleepwalking.

Tell your doctor if you are on a salt-restricted diet or if you have high blood pressure, heart failure or kidney problems. LUMRYZ contains a lot of sodium (salt) and may not be right for you.
The most common side effects of LUMRYZ in adults include nausea, dizziness, bedwetting, headache and vomiting. Your side effects may increase when you take higher doses of LUMRYZ. LUMRYZ can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of LUMRYZ.

For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

Please see full Prescribing Information, including BOXED Warning.

About Avadel Pharmaceuticals plc
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company focused on transforming medicines to transform lives. Our approach includes applying innovative solutions to the development of medications that address the challenges patients face with current treatment options. Avadel's commercial product, LUMRYZ™, was approved by the U.S. Food & Drug Administration (FDA) as the first and only once-at-bedtime oxybate for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. For more information, please visit **www.avadel.com**.

Cautionary Disclosure Regarding Forward-Looking Statements
This press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects or other events. Such forward-looking statements include, but are not limited to, expectations regarding the potential therapeutic benefit of LUMRYZ and the potential market preference for LUMRYZ; and statements regarding the results and analysis of Avadel's trials and studies including the details and content thereof. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "could," "believe," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project," "next steps" and similar expressions and the negatives thereof (if applicable).

The Company's forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, the Company's business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the company's business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in the Company's forward-looking statements include the risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission (SEC) on February 29, 2024, and subsequent SEC filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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