# Avadel Pharmaceuticals Announces Tentative Approval of LUMRYZ™ (sodium oxybate) extended-release oral suspension

July 19, 2022

- Validates the safety profile and clinical efficacy of LUMRYZ

- Pursuing strategies to accelerate final approval

DUBLIN, Ireland, July 19, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today announced that the U.S. Food and Drug Administration (FDA) has granted tentative approval to LUMRYZ, also known as FT218. Tentative approval indicates that LUMRYZ has met all required quality, safety, and efficacy standards necessary for approval in the U.S. Final approval is pending disposition of U.S. Patent No. 8,731,963 (the "REMS patent") which is listed in FDA's Orange Book. LUMRYZ is a once-at-bedtime investigational formulation of sodium oxybate for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.

"We have reached a critical milestone, as tentative approval confirms the safety profile and clinical efficacy of LUMRYZ for adults with narcolepsy," said Greg Divis, Chief Executive Officer at Avadel Pharmaceuticals. "Tentative approval is an important regulatory step forward and indicates LUMRYZ could potentially be granted final approval in 11 months or less. We believe once-at-bedtime LUMRYZ offers the opportunity to positively transform the lives of oxybate eligible patients living with narcolepsy. Our extensive market research indicates Avadel is well-positioned to capture significant share of the oxybate eligible patient population which we estimate to be in excess of 30,000 patients. We are pursuing all options to accelerate final approval on or before June 2023 and prepare for commercial launch."

With tentative approval now secured, Avadel is continuing the following actions, including those that can potentially accelerate FDA's final approval decision and shorten the timeline between approval and launch of LUMRYZ:

- Filed a motion in the U.S. District Court for the District of Delaware on June 23, 2022, to delist the REMS patent from FDA's Orange Book. A court order requiring the patent holder to delist the REMS patent from the Orange Book could provide a pathway for a final approval of LUMRYZ prior to June 2023.
- Preparing for a claim construction hearing ("Markman hearing") scheduled for August 31, 2022, that the Court previously stated is needed in order to rule on the pending patent delisting motion.
- Continuing key activities in anticipation of final approval, including planning for the final preparation of the LUMRYZ REMS program and the continued manufacturing of commercial supply.

Based on extensive patient and physician research, Avadel estimates the total patient population could be greater than 30,000, and expects LUMRYZ, if approved, to be the treatment of choice for patients suffering from narcolepsy-related EDS or cataplexy. The current twice-nightly U.S. narcolepsy oxybate market is estimated at $1.8 billion comprised of approximately 16,000 patients. In addition, Avadel estimates that in the last three years, 10,000 – 15,000 patients have discontinued their twice-nightly oxybate use, many due to complications associated with middle of the night dosing. Furthermore, based on an analysis of U.S. claims data, the Company believes that each year approximately 3,000 patients initiate oxybate treatment for the first time and expects this to grow by 25-50% over time with the introduction of LUMRYZ. Based on the estimated total patient population, the potential market opportunity could be in excess of $3.0 billion annually.

**About LUMRYZ**
LUMRYZ is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of EDS or cataplexy in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of LUMRYZ in adults with narcolepsy. Among the three co-primary endpoints, LUMRYZ demonstrated statistically significant and clinically meaningful results in EDS, the clinician's overall assessment of the patient's functioning, and reduction in cataplexy attacks for all three evaluated doses compared to placebo.

In January 2018, the FDA granted LUMRYZ Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that LUMRYZ may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for those with narcolepsy due to the consequences of middle-of-the-night dosing of the approved product.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. Final approval of LUMRYZ cannot be granted until the expiration or other disposition of U.S. Patent No. 8,731,963, which expires on June 17, 2023.

Avadel is currently evaluating the long-term safety and tolerability of LUMRYZ in the open-label RESTORE clinical study. For more information, visit: www.restore-narcolepsy-study.com.

**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. Our current lead drug candidate, LUMRYZ, is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of excessive daytime sleepiness and cataplexy 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, the timing and receipt of final approval from the FDA of the LUMRYZ NDA, the results of the Company's efforts to accelerate the FDA's final approval decision and to accelerate the timing between approval and launch, if approved. 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).

Our 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, our business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of our 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 our forward-looking statements include the risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, which we filed with the Securities and Exchange Commission on March 16, 2022, 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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