Avadel Pharmaceuticals Requests Final FDA Approval for LUMRYZ™ (sodium oxybate) extended-release oral suspension

March 2, 2023

- Submitted amendment on March 1, 2023 to the LUMRYZ NDA seeking final FDA approval

DUBLIN, Ireland, March 02, 2023 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, announced today that it has submitted an amendment to the U.S. Food and Drug Administration ("FDA") requesting final approval for LUMRYZ for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. This submission follows a unanimous 3-0 panel decision by the United States Court of Appeals for the Federal Court ("Fed Circuit") on February 24, affirming the previous ruling from the United States District Court for the District of Delaware (the "Delaware Court"), ordering Jazz Pharmaceuticals ("Jazz") to delist its U.S. Patent No. 8,731,963 ("REMS Patent") from FDA's Orange Book. Jazz submitted its request to delist the REMS Patent to FDA on February 28.

"Today is an important day as we've taken what we believe is the last step in the NDA review process with the submission of our amendment to the LUMRYZ NDA seeking final approval. We look forward to working with FDA to bring LUMRYZ to all eligible patients as soon as possible," said Greg Divis, Chief Executive Offer at Avadel Pharmaceuticals. "The value proposition of LUMRYZ, demonstrated by its important benefit to people living with narcolepsy, has been our driving motivation throughout this process, and we stand ready to bring LUMRYZ to the narcolepsy community following an approval."

Based on extensive patient and physician research, Avadel estimates the total potential patient population for once-at-bedtime LUMRYZ 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 oxybate market for narcolepsy in the U.S. 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 number to grow by 25-50% over time with the introduction of LUMRYZ. Based on the estimated total potential patient population, the market opportunity could be in excess of $3.0 billion annually.

On July 18, 2022, LUMRYZ received tentative approval from the FDA. On November 18, 2022, ruling on Avadel's previously filed motion, the Delaware Court issued its written opinion ordering Jazz to request delisting of the REMS Patent. On February 24, 2023, the Fed Circuit affirmed the Delaware Court's order. Following Jazz' request to delist the REMS Patent on February 28, 2023, Avadel filed a minor amendment with the FDA on March 1, 2023, removing its certification to the REMS Patent and requesting final approval of LUMRYZ.

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 cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON study, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of LUMRYZ in patients 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 when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (FDA) granted LUMRYZ Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that LUMRYZ may be safer than the twice-nightly formulation of sodium oxybate already approved by the FDA due to the ramifications associated with the dosing regimen of that product.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or EDS in adults with narcolepsy.

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 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 cataplexy or 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; the outcome and timing of FDA's final decision regarding approval for LUMRYZ; ongoing efforts of the Company to accelerate potential final FDA approval of LUMRYZ; the Company's efforts to make LUMRYZ commercially available (if approved);

expectations regarding the potential market opportunity and market impact of LUMRYZ (if approved); and the anticipated market acceptance of LUMRYZ (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).

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, 2021, which was filed with the Securities and Exchange Commission (SEC) 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. 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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Source: Avadel Pharmaceuticals plc