Avadel Pharmaceuticals Announces FDA Authorization to Import Tentatively-Approved LUMRYZ™ Ahead of Anticipated Final Approval Decision

March 22, 2023

Importation of LUMRYZ to the U.S. shortens the time to product availability following a final approval decision

DUBLIN, Ireland, March 22, 2023 (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 approved its Pre-Launch Activities Importation Requests (PLAIR) for LUMRYZ.

Through its PLAIR, Avadel is authorized to import unapproved drug product into the U.S. ahead of anticipated final approval of the tentatively approved LUMRYZ NDA, to prepare for market launch. By importing LUMRYZ into the U.S. before anticipated final approval, Avadel is able to further shorten the time to product availability following a final approval decision by the FDA.

"The granting of our PLAIR request by the FDA followed the submission of our amendment requesting a final approval decision for LUMRYZ. The approval to import LUMRYZ comes at an important time for Avadel as the availability of commercial supply allows us to further shorten the timeline between a potential approval and being able to provide LUMRYZ to patients," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We remain committed to working collaboratively with FDA to bring LUMRYZ to people living with narcolepsy."

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. LUMRYZ is currently under review by the FDA.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or EDS in adults with narcolepsy. Avadel submitted a minor amendment to the FDA on March 1, 2023, requesting final approval of LUMRYZ. This minor amendment submission occurred shortly after the delisting of the REMS Patent from FDA's Orange Book by Jazz Pharmaceuticals in response to the unanimous 3-0 panel decision by the United States Court of Appeals for the Federal Circuit on February 24, affirming the previous ruling from the United States District Court for the Federal District of Delaware, ordering Jazz to do so.

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 PLAIR

A PLAIR allows for applicants with a pending NDA, ANDA, or CDER-regulated BLA nearing an FDA application decision to request permission to import an unapproved finished dosage form drug product for reconditioning in the form of approval. FDA's granting of a PLAIR does not represent an implicit or explicit statement of the approvability of the NDA, ANDA, or CDER-regulated BLA. Rather, PLAIR facilitates the process for importing unapproved finished dosage form products to prepare for market launch based on anticipated approval of the pending application.

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 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 FDA's potential final approval of LUMRYZ, including the timing of thereof; the anticipated time savings between a potential approval and commercial launch of LUMRYZ attributable to the FDA's grant of the PLAIR; the Company's preparation for launch of LUMRYZ (if approved); and the 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