Avadel Pharmaceuticals Announces Publication of Data from Pivotal Phase 3 REST-ON Trial of FT218 in Adults with Narcolepsy in SLEEP

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DUBLIN, Ireland, Aug. 16, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating excessive daytime sleepiness (EDS) and cataplexy in adults with narcolepsy, announced today the publication of data from its pivotal Phase 3 REST-ON trial of FT218 in *SLEEP*, the journal of the Sleep Research Society. The paper, titled "Once-Nightly Sodium Oxybate (FT218) Demonstrated Improvement of Symptoms in a Phase 3 Randomized Clinical Trial in Patients With Narcolepsy," can be accessed at https://academic.oup.com/sleep/advance-article/doi/10.1093/sleep/zsab200/6343406?searchresult=1.

"The publication of the REST-ON trial results in the peer-reviewed journal *SLEEP* validates the potential of FT218 as a once-at-bedtime option that could, if approved, transform the treatment landscape for adults suffering from the burdensome symptoms of narcolepsy," said Jennifer Gudeman, Pharm.D., Vice President of Medical and Clinical Affairs at Avadel. "We believe FT218 has tremendous potential to provide clinically meaningful results for people with narcolepsy. As we approach our October PDUFA date, we remain confident in the potential of FT218 and are committed to making FT218 accessible to patients, if approved."

Topline data from the completed randomized, double-blind, placebo-controlled REST-ON trial were announced in April 2020. The study was designed to investigate the efficacy and safety of once-at-bedtime FT218 for the treatment of EDS and cataplexy in patients with narcolepsy. FT218 is currently under review at the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target date of October 15, 2021.

About FT218
FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's proprietary, drug delivery technology. In March of 2020, the Company completed the REST-ON study, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. In December 2020, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021. FT218 has been granted Orphan Drug Designation from the FDA for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company primarily focused on the development and FDA approval of FT218, an investigational, once-nightly, extended-release formulation of sodium oxybate designed to treat 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 the Company's 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 tolerability or therapeutic benefits of FT218, the timing of the FDA's review of the NDA for FT218, the sufficiency of data supporting the NDA for FT218, the commercial launch of FT218 (if approved), and the market acceptance of FT218 (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 risk that positive results from the REST-ON trial may not necessarily be predictive of the results of future or ongoing clinical studies; the risk that the NDA for FT218 is not approved by the FDA or such approval is delayed; the risk that FT218 (if approved) may not receive a 7-year Orphan Drug Exclusivity; the risk that commercial launch of FT218 (if approved) is delayed or never occurs; the risk that the potential market performance for FT218 (if approved) may differ materially from projections; and the risk that the impact of the current COVID-19 pandemic on the Company's financial results and results of operations could be greater than we anticipate and 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, 2020, which was filed with the Securities and Exchange Commission (SEC) on March 9, 2021 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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