Avadel Pharmaceuticals Achieves Enrollment Target in REST-ON Phase 3 Pivotal Trial of FT218 for Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy

November 25, 2019

205 patients enrolled; additional patients currently in screening will be allowed to enroll if eligible

Topline data from the REST-ON study expected in Q2 2020

DUBLIN, Ireland, Nov. 25, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, announced today that it has achieved its patient enrollment target of 205 patients in the REST-ON Phase 3 clinical trial for its once-nightly sodium oxybate, FT218. Additional patients currently in the screening process will also be allowed to enroll in the study if they meet eligibility criteria. The last patient's last visit is expected to occur by the end of the first quarter of 2020, with topline data expected in the second quarter of 2020.

"Achieving the patient enrollment target in the pivotal REST-ON study marks an important milestone in our development efforts for our lead asset, FT218. We expect to announce topline data from the study in the second quarter of 2020, as we continue to advance this program towards submission for regulatory approval," stated Dr. Jordan Dubow, Chief Medical Officer. "Being able to accelerate this achievement by up to 12 months is a testament to the hard work of the study investigators, staff, and patients, as well as the Avadel team."

Based on the Company's industry research, it believes FT218, if approved by the FDA, has the potential to take a significant share of the twice-nightly sodium oxybate market. Currently, this market is valued at an estimated annualized rate of $1.7 billion[1].

The REST-ON study is a double-blind, randomized, placebo-controlled Phase 3 trial to assess the efficacy and safety of once-nightly FT218, a formulation of sodium oxybate using Avadel's proprietary Micropump™ technology for extended-release oral suspension, in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. The REST-ON study is under a Special Protocol Assessment agreement with FDA.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The company is currently conducting the REST-ON study, a 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. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to a 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.

Footnote:
1. Annualized Xyrem revenues from Jazz Pharmaceuticals Q3 2019 earnings press release, November 5, 2019

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company's primary focus is the development and potential FDA approval of FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. 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. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project" 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 of our research, development and commercialization activities 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, 2018, which we filed with the Securities and Exchange Commission on March 15, 2019.

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 the forward-looking statements contained in this Annual Report.

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