Avadel Pharmaceuticals Announces an Oral Presentation on Investigational Once-Nightly Sodium Oxybate (FT218) at the World Sleep 2019 Congress on September 25th

September 18, 2019

DUBLIN, Ireland, Sept. 18, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced that Dr. Michael Thorpy, Director of the Sleep-Wake Disorders Center at the Montefiore Medical Center, will be providing an oral presentation highlighting the pharmacokinetic (PK) data for Avadel's FT218 from four Phase 1 studies at the World Sleep 2019 Congress, which is taking place from September 20-25, 2019 at the Vancouver Convention Centre, Vancouver, Canada. Data will be presented on the pharmacokinetic comparison of 4.5 and 6 g of once-nightly FT218 to 4.5 g and 6 g of twice-nightly sodium oxybate, the food effect of FT218, as well as dose proportionality data on FT218.

Presentation Details
Title: The Pharmacokinetics of once-nightly controlled-release sodium oxybate (FT218): Overview of results from four Phase 1 Studies
Presenter: Dr. Michael Thorpy, Director of the Sleep-Wake Disorders Center at the Montefiore Medical Center and Professor of Clinical Neurology at Albert Einstein College of Medicine
Date: Wednesday September 25th
Presentation Time: 4:30 PM Pacific Time

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 that is 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 branded specialty pharmaceutical 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 contains "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements (which may be identified by words such as "will," "look forward," "should," "planned" and "anticipate") are not statements of historical facts regarding FT218, the FDA review process relating thereto including the expected timing of that process, and the possible commercial launch of FT218. All forward-looking statements involve risks and uncertainties, including, without limitation, the risks that i) the Company may encounter challenges in the remaining development efforts for FT218, ii) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218, iii) FT218 may not have the therapeutic benefits the Company anticipates, iv) the commercial launch of FT218 could be delayed, v) FT218 may not achieve commercial acceptance, vi) other companies may develop competing products that may receive FDA approval before FT218, and vii) the other risks detailed in Avadel's filings with the SEC, including, without limitation, its Form 10-K, Forms 10-Q and other reports on Forms 8-K, all of which can be obtained on the SEC website at www.sec.gov. Avadel assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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