Avadel Pharmaceuticals Announces FDA Acceptance of New Drug Application for FT218 in Adults with Narcolepsy for the Treatment of Excessive Daytime Sleepiness and Cataplexy

March 1, 2021

FT218 assigned PDUFA target action date of October 15, 2021

DUBLIN, Ireland, March 01, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) for FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. The FDA assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021.

"The FDA's acceptance of our NDA for once-nightly FT218 and assignment of a PDUFA target action date of October 15th represents another important milestone on the path towards receiving approval. We are confident in our regulatory filing strategy and we look forward to working with the Agency in our pursuit of bringing this important treatment to patients," said Greg Divis, Chief Executive Officer of Avadel. "If approved, FT218 will be the first and only once-nightly oxybate medication, a significant advancement to the twice-nightly regimen that has been required for nearly 20 years."

"It's important to remember that FT218 was granted Orphan Drug Designation by the FDA based on the plausible hypothesis that it may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the Agency for the same indication. If the FDA approves FT218 and grants Orphan Drug Exclusivity, then we would be awarded a seven-year period of market exclusivity in the U.S.," concluded Mr. Divis.

The NDA submission is supported by positive data from the pivotal Phase 3 REST-ON study, which was completed under a Special Protocol Assessment (SPA) agreement with the FDA. The Company plans on presenting data from the study for the three primary endpoints, as well as a number of secondary endpoints and post-hoc analyses at upcoming conferences in the first half of 2021.

About FT218
FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release (CR) technology. 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. 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 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 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 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, the FDA's review of the NDA for FT218, the benefits of Orphan Drug Exclusivity for FT218, if granted by the FDA, commercial launch of FT218, if approved, and 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).

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 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 risk that the FDA does not approve the NDA for FT218 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, 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 our 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 our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 2020 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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