



Avadel Pharmaceuticals Announces Submission of New Drug Application for FT218 to the FDA

December 16, 2020

DUBLIN, Ireland, Dec. 16, 2020 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy.

"The submission of our NDA represents a significant milestone for the Company. We look forward to working with the FDA during the NDA review process in order to get once-nightly FT218 approved and commercially available to patients with narcolepsy who suffer from excessive daytime sleepiness and cataplexy," said Greg Divis, Chief Executive Officer of Avadel. "If approved, we believe once-nightly FT218 has the potential to provide a valuable treatment option for sodium oxybate eligible narcolepsy patients, including those who are not satisfied with the current twice-nightly treatment, which requires waking up in the middle of the night to take a second dose."

About FT218

FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. 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. 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 an emerging biopharmaceutical company. The Company's primary focus is 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 and commercial launch 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 accept the NDA submission for FT218, the risk that such NDA is not approved by the FDA or such approval is delayed, 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.

Contacts:

Investor Contacts

Tom McHugh

Chief Financial Officer

Phone: (636) 449-1843

Email: tmchugh@avadel.com

Tim McCarthy

LifeSci Advisors, LLC

Phone: (212) 915.2564

Email: tim@lifesciadvisors.com

Media Contact

Patrick Burse

LifeSci Communications, LLC
Phone: (646) 970-4688
Email: pbursey@lifescicomms.com



Source: Avadel Pharmaceuticals plc