Avadel Pharmaceuticals Appoints Dr. Jennifer Gudeman as Vice President of Medical and Clinical Affairs

December 7, 2020

DUBLIN, Ireland, Dec. 07, 2020 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy, today announced the appointment of Dr. Jennifer Gudeman to the newly formed role of Vice President, Medical and Clinical Affairs, effective immediately. In this role her responsibilities will include overseeing all medical and clinical affairs activities, including the company's lead program, once-nightly FT218.

"We are pleased to further strengthen our team with the appointment of Dr. Gudeman. Her broad medical affairs experience will be especially valuable as we continue to establish and communicate the scientific body of evidence in support of our investigational once-nightly FT218. Jennifer is an accomplished medical leader and is joining Avadel at a critical juncture as we expand Avadel's focus to include the scientific, clinical and market preparation activities for FT218," said Greg Divis, Chief Executive Officer of Avadel.

"It is a pleasure to join Avadel at this exciting time in the Company's history, with the pending submission of the FT218 NDA to the FDA planned for this month," said Dr. Gudeman. "I am proud to be part of a team that is working towards bringing an innovative once-nightly therapy to an underserved patient population. The need for such a therapy is highlighted by recent research that shows a majority of sodium oxybate-eligible patients are not going on currently available therapies, with twice-nightly dosing being the primary reason cited."

Dr. Gudeman brings approximately 20 years of pharmaceutical industry-specific, medical and clinical affairs experience to Avadel. During this time, she has led or contributed to six commercial product launches and three clinical development programs. Dr. Gudeman has also led interactions with medical societies and patient advocacy organizations to help ensure that commercial medications fulfill their clinically proven therapeutic benefits to patients and providers. Prior to joining Avadel, Dr. Gudeman was Vice President, Medical Affairs at AMAG Pharmaceuticals, overseeing a team of medical science liaisons and scientific communications. Prior to her time at AMAG Pharmaceuticals, she was Director of Medical Affairs at Lumara Health. Additionally, she began her industry career at Mallinckrodt Pharmaceuticals. Dr. Gudeman has published numerous peer-reviewed papers and provided domestic and international presentations on partnership with industry for drug development in high-risk pregnancies. In 2017, Dr. Gudeman received the Healthcare Businesswomen's "Rising Star" award. Dr. Gudeman graduated summa cum laude with a bachelor's degree in pharmacy and magna cum laude with a doctorate in pharmacy from St. Louis College of Pharmacy in 1999 and 2000, respectively.

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 patients with narcolepsy. For more information, please visit www.avadel.com.

Footnote: 1. Annualized Xyrem revenues from the Jazz Pharmaceuticals third quarter and year to date results reported in their press release dated November 2, 2020.

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 planned submission of the FT218 NDA to the FDA 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 we do not file the NDA for FT218 on a timely basis or at all, the risk that the FDA does accept such NDA, the risk that such NDA is not approved by the FDA or such approval is delayed, the risk that the RESTORE study, the open-label extension/switch study of FT218, may be delayed or may not be completed at all, 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 Bursey
LifeSci Communications, LLC
Phone: (646) 970-4688
Email: pbursey@lifescicomms.com

Source: Avadel Pharmaceuticals plc