Avadel Pharmaceuticals Announces First Patient Dosed in Open-Label Extension/Switch Study of Investigational Once-Nightly FT218 as a Potential Treatment for Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy

July 13, 2020

- *Clinical study to enroll 250 patients from sites that participated in the REST-ON study*
- *Study to examine the long-term safety and maintenance of efficacy in patients, and evaluate dosing and preference for patients switching from twice-nightly sodium oxybate to once-nightly FT218*

DUBLIN, Ireland, July 13, 2020 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate, today announced that the first patient has been dosed at a Florida Research Institute initiating an open-label extension (OLE)/switch study of FT218 as a potential treatment for excessive daytime sleepiness and cataplexy in patients with narcolepsy.

“Narcolepsy is a rare neurological sleep disorder with limited treatment options. We were encouraged by the positive Phase 3 data from the REST-ON study that evaluated FT218 as a potential treatment for excessive daytime sleepiness and cataplexy in patients with narcolepsy, so we are enrolling our patients in the open-label extension/switch study. We are pleased to be the first site participating in the study advancing clinical research on narcolepsy to potentially provide our patients more treatment options,” said Akinyemi Ajayi, M.D., principal investigator and Sleep Disorder Specialist.

Jordan Dubow, M.D., Chief Medical Officer of Avadel, added, “The initiation of the OLE/switch study of FT218 underscores the need for more treatment options for people living with narcolepsy. This is an important milestone for FT218, as we start to generate dosing and preference data for narcolepsy patients switching from twice-nightly sodium oxybate to once-nightly FT218. If approved, FT218 could potentially address the key symptoms of narcolepsy, excessive daytime sleepiness and cataplexy, in one nightly dose.”

The OLE/switch study will examine the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218 regardless if they participated in REST-ON or not. The study will enroll about 250 patients at most of the North American clinical trial sites that participated in the REST-ON study.

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 has completed a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. For more information, please visit www.avadel.com.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The Company recently 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.

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 i) the potential benefits of FT218 including the long-term safety and maintenance of efficacy of FT218, and ii) the anticipated enrollment for the OLE/switch study. 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 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 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

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