Avadel to Present New Data from its Pivotal REST-ON Phase 3 Study of FT218 at the American Academy of Neurology Annual Meeting 2021

April 8, 2021

DUBLIN, Ireland, April 08, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating excessive daytime sleepiness and cataplexy in adults with narcolepsy, today announced that it is scheduled to present new secondary endpoint data from its pivotal REST-ON Phase 3 trial at the 2021 American Academy of Neurology (AAN) Annual Meeting, which is being held virtually from April 17-22, 2021.

Abstracts selected for presentation are summarized below.

Poster Presentations
Title: Polysomnographic Measures of Sleep Continuity in Patients with Narcolepsy: Results From the REST-ON Trial, a Pivotal Phase 3 Study of FT218, a Once-Nightly Sodium Oxybate Formulation
Presenter: Yves Dauvilliers, M.D., Ph.D., University of Montpellier
Available: April 17, 2021

Title: Daytime Sleepiness, Sleep Quality, Hallucinations, and Sleep Paralysis in Patients with Narcolepsy: Results From the REST-ON Trial, a Pivotal Phase 3 Study of FT218, a Once-Nightly Sodium Oxybate Formulation
Presenter: Michael J. Thorpy, M.D., Albert Einstein College of Medicine
Available: April 17, 2021

To register, visit AAN's website: www.aan.com/conferences-community/annual-meeting.

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, extended-release formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. For more information, please visit www.avadel.com.

About FT218
FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release (CR) technology. 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. 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. The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021. 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.

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