Avadel to Present New Efficacy and Safety Data from Pivotal Phase 3 REST-ON Trial of FT218 at SLEEP 2021

June 3, 2021

DUBLIN, Ireland, June 03, 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 it will present primary and secondary endpoint data, including new post hoc analyses, from the pivotal Phase 3 REST-ON clinical trial at SLEEP 2021, at the 35th Annual Meeting of the Associated Professional Sleep Societies (APSS). This joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society is being held virtually from June 10-13, 2021.

Avadel will present FT218 efficacy and safety data from six abstracts, which have been published in an online supplement in the journal *Sleep*. Details of the presentations are as follows:

Oral Presentation

Abstract #: 488
Title: REST-ON: Efficacy of FT218 for Daytime Sleepiness, Sleep Quality, Hallucinations and Sleep Paralysis in Patients with Narcolepsy
Presenter: Michael J. Thorpy, M.D., Albert Einstein College of Medicine
Session: O-14: Innovation in the Assessment and Management of Central Hypersomnia
Date and Time: Sunday, June 13, 2021 at 1:03-1:14 p.m. EDT

The oral presentation will also be available as a poster.

Poster Presentations

Abstract #: 491
Title: Efficacy of FT218, a Once-Nightly Sodium Oxybate Formulation, by Narcolepsy Subtype: A Post Hoc Analysis from the REST-ON Study
Presenter: Asim Roy, M.D., Ohio Sleep Medicine Institute

Abstract #: 492
Title: Efficacy of FT218, a Once-Nightly Sodium Oxybate Formulation, by Stimulant Use: A Post Hoc Analysis from the REST-ON Study
Presenter: Asim Roy, M.D., Ohio Sleep Medicine Institute

Abstract #: 493
Title: Weight Loss with FT218, a Once-Nightly Sodium Oxybate Formulation for the Treatment of Narcolepsy: Post Hoc Analysis from REST-ON
Presenter: Anne Marie Morse, D.O., Geisinger Medical Center, Janet Weis Children's Hospital

Abstract #: 489
Title: Pivotal Phase 3 Study of FT218, a Once-Nightly Sodium Oxybate Formulation, in Patients with Narcolepsy: REST-ON Primary Results
Presenter: Clete Kushida M.D., Ph.D., Stanford Sleep Medicine Center

Abstract #: 490
Title: Efficacy of FT218 on Polysomnographic Measures of Sleep Continuity in Patients with Narcolepsy: Results from the REST-ON Trial
Presenter: Yves Dauvilliers, M.D., Ph.D., Sleep and Wake Disorders Centre, Department of Neurology, Gui de Chauliac Hospital

For registered meeting attendees, posters will be available from June 11 to November 30, 2021, in the e-Poster gallery on the SLEEP 2021 website at https://www.sleepmeeting.org/. Posters also will be housed in Avadel's virtual medical booth, with the three posters covering pre-specified primary and secondary endpoints featured in an interactive format with commentary from Dr. Roy, medical director of the Ohio Sleep Medicine Institute. The booth will also include more detailed information about the Company and its ongoing research and publications.

In addition to Avadel's virtual medical booth, the Company will support a symposium titled "How Narcolepsy Management Is Evolving: Expert Panel Discussion." The symposium will be moderated by Dr. Thorpy, director of the Sleep-Wake Disorders Center at Montefiore and professor of neurology at Albert Einstein College of Medicine, and will be available on-demand on the SLEEP 2021 website and in the Company's virtual medical booth until November 30, 2021.

About FT218
FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release 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 NDA to the 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 PDUFA target action date of October 15, 2021. FT218 has been granted Orphan Drug Designation from the 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 U.S. Food and Drug Administration (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**.

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