Avadel to Present Clinical Data for FT218 at SLEEP 2022

May 19, 2022

DUBLIN, Ireland, May 19, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today announced the presentation of clinical data for FT218 in nine posters at the 36th Annual Meeting of the Associated Professional Sleep Societies (APSS), the joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society being held from June 4-8, 2022 in Charlotte, NC. FT218 is the Company's lead drug candidate, an investigational formulation of sodium oxybate designed to be taken once at bedtime for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.

The presentations will highlight new interim data related to dosing and titration from the ongoing RESTORE open-label extension/switch study of FT218. Encore posters featuring updated results from patient preference and nocturnal adverse event questionnaires from the RESTORE study, post hoc analyses from the completed pivotal Phase 3 REST-ON clinical trial of FT218 and results from a discrete choice experiment designed to characterize and quantify drivers of preferences for attributes associated with oxybate treatments for narcolepsy will also be presented. Posters will be on display during a reception each evening June 5-7, 5:15-7:15 p.m. EDT in the poster hall, and all abstracts have been published in an online supplement in the journal *Sleep*.

About Narcolepsy
Narcolepsy is a chronic neurological condition that impairs the brain's ability to regulate the sleep-wake cycle. The condition affects approximately one in 2,000 people in the United States with the cardinal symptom of EDS. Additional symptoms can vary by person and may include DNS, a sudden loss of muscle tone usually triggered by strong emotion (cataplexy), sleep paralysis and hypnagogic and hypnopompic hallucinations.

About FT218
FT218 is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of EDS or cataplexy in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of FT218 in adults with narcolepsy. Among the three co-primary endpoints, FT218 demonstrated statistically significant and clinically meaningful results in EDS, the clinician's overall assessment of the patient's functioning, and reduction in cataplexy attacks for all three evaluated doses compared to placebo.

In January 2018, the FDA granted FT218 Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for those with narcolepsy due to the consequences of middle-of-the-night dosing of the approved product. A marketing application for FT218 is currently under review by the FDA.

Avadel is currently evaluating the long-term safety and tolerability of FT218 in the open-label RESTORE clinical study. For more information, visit: www.restore-narcolepsy-study.com.

About Avadel Pharmaceuticals plc
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company focused on transforming medicines to transform lives. Our approach includes applying innovative solutions to the development of medications that address the challenges patients face with current treatment options. Our current lead drug candidate, FT218, is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of EDS and cataplexy in adults with narcolepsy. For more information, please visit www.avadel.com.

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Source: Avadel Pharmaceuticals plc