Avadel to Present New Clinical Data at World Sleep 2022

March 1, 2022

- *Eight abstracts accepted for poster presentation featuring new data from the Phase 3 REST-ON clinical trial of FT218 and the RESTORE open-label extension/switch study of FT218 in addition to discrete choice experiment results*
- *Company supporting Satellite Symposium focused on patient needs in narcolepsy*

DUBLIN, Ireland, March 01, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, announced today it will present eight posters at World Sleep 2022, taking place March 11-16 in Rome, Italy. The presentations will feature new data from the completed pivotal Phase 3 REST-ON clinical trial of FT218 and the ongoing RESTORE open-label extension/switch study of FT218. Results from discrete choice experiments designed to understand patient and healthcare provider preferences associated with oxybate treatments for narcolepsy and perspectives on narcolepsy disease burden, treatment approaches and satisfaction with current narcolepsy treatment options will also be presented. FT218, also known as ON-SXB, 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. FT218 is currently under review at the U.S. Food and Drug Administration.

Details of Avadel's poster presentations are below:

Title: Patient and Healthcare Provider Surveys of Narcolepsy Disease Burden and Oxybate Treatment Experience
Presenter: Anne Marie Morse, D.O., director of child neurology and pediatric sleep medicine at Geisinger Medical Center at Janet Weis Children's Hospital
Date and Time: Tuesday, March 15 at 5:30 p.m. CET (Poster Group A)

Title: Patient and Provider Preferences for Oxybate Treatment for Narcolepsy: A Discrete Choice Experiment
Presenter: Anne Marie Morse, D.O., director of child neurology and pediatric sleep medicine at Geisinger Medical Center at Janet Weis Children's Hospital
Date and Time: Tuesday, March 15 at 5:30 p.m. CET (Poster Group A)

Title: Long-Term Safety of Once-Nightly Sodium Oxybate: Interim Data From RESTORE
Presenter: David Seiden, MD, FAASM, Senior Medical Director, Clinical Development & Medical Affairs · Avadel Pharmaceuticals
Date and Time: Tuesday, March 15 at 5:30 p.m. CET (Poster Group A)

Title: Efficacy of Once-Nightly Sodium Oxybate (ON-SXB; FT218) By Narcolepsy Type: Post-hoc Analyses From the REST-ON Trial
Presenter: Yves Dauvilliers, M.D., Ph.D., director of the Sleep and Wake Disorders Centre in the Department of Neurology at the Gui de Chauliac Hospital in Montpellier, France
Date and Time: Monday, March 14 at 6:15 p.m. CET (Poster Group B)

Title: Early Efficacy With Once-Nightly Sodium Oxybate (ON-SXB; FT218): Post-hoc Analyses From REST-ON
Presenter: Lois Krahn, MD, Mayo Clinic Center for Sleep Medicine
Date and Time: Monday, March 14 at 5:30 p.m. CET (Poster Group A)

Title: Efficacy of Once-Nightly Sodium Oxybate (ON-SXB; FT218) Across Stimulant Use Subgroups: Post-hoc Analyses From the REST-ON Trial
Presenter: Michael J. Thorpy, M.D., director of the Sleep-Wake Disorders Center at Montefiore and professor of neurology at Albert Einstein College of Medicine
Date and Time: Tuesday, March 15 at 5:30 p.m. CET (Poster Group A)

Title: Efficacy of FT218, a Once-Nightly Sodium Oxybate Formulation, in Patients With Narcolepsy: Post-hoc Sensitivity Analyses From the REST-ON Trial
Presenter: Clete Kushida, M.D., Ph.D., division chief and medical director of Stanford Sleep Medicine, neurologist and professor in the department of psychiatry and behavioral sciences at Stanford University Medical Center and director of the Stanford Center for Human Sleep Research at Stanford University
Date and Time: Monday, March 14 at 5:30 p.m. CET (Poster Group A)

Title: Efficacy of Once-nightly Sodium Oxybate (ON-SXB; FT218) for Excessive Daytime Sleepiness and Cataplexy: Post-hoc Number Needed to Treat and Effect Size Analyses From REST-ON
Presenter: Michael J. Thorpy, M.D., director of the Sleep-Wake Disorders Center at Montefiore and professor of neurology at Albert Einstein College of Medicine
Date and Time: Monday, March 14 at 6:15 p.m. CET (Poster Group B)

In addition to Avadel's poster presentations, the Company will support a Satellite Symposium titled "Avadel Pharmaceuticals: Addressing patient needs in the advancement of narcolepsy treatment" on Tuesday, March 15 from 12:30 – 2:00 p.m. CET. The symposium will feature panel presentations from Yves Dauvilliers, M.D., Ph.D., director of the Sleep and Wake Disorders Centre in the Department of Neurology at the Gui de Chauliac Hospital in Montpellier, France; Michael J. Thorpy, M.D., director of the Sleep-Wake Disorders Center at Montefiore and professor of neurology at Albert Einstein College of Medicine; Clete Kushida, M.D., Ph.D., division chief and medical director of Stanford Sleep Medicine, neurologist and professor in the department of psychiatry and behavioral sciences at Stanford University Medical Center and director of the Stanford

Center for Human Sleep Research at Stanford University; and Anne Marie Morse, D.O., director of child neurology and pediatric sleep medicine at Geisinger Medical Center at Janet Weis Children's Hospital.

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 excessive daytime sleepiness. Additional symptoms can vary by person and may include disrupted nighttime sleep, a sudden loss of muscle tone usually triggered by strong emotion (cataplexy), sleep paralysis and hypnagogic 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 excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON study, 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 does when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (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. FT218 is currently under review by the FDA.

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 excessive daytime sleepiness and cataplexy in adults with narcolepsy. For more information, please visit www.avadel.com.

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