



Avadel Recognizes World Narcolepsy Day and Announces New Data Presentations from Pivotal Phase 3 REST-ON Trial of FT218 at Upcoming Conference

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DUBLIN, Ireland, Sept. 20, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, today announced its support of the third annual World Narcolepsy Day on Wednesday, September 22. FT218 is the Company's current lead drug candidate, an investigational formulation of sodium oxybate designed to be taken once at bedtime for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. FT218 is currently under review at the U.S. Food and Drug Administration with a Prescription Drug User Fee Act target date of October 15, 2021.

[World Narcolepsy Day](#) was established by 28 patient advocacy organizations across six continents to raise global awareness and improve outcomes for people with narcolepsy. As part of Avadel's support of World Narcolepsy Day, the Company recently launched [Narcolepsy Disrupts](#), a narcolepsy awareness campaign for patients, their loved ones and healthcare providers about the importance of prioritizing more natural sleep patterns. The campaign, which was created based on insights from the patient community, provides educational resources such as lifestyle changes and coping strategies to help those with narcolepsy achieve better sleep.

"Excessive daytime sleepiness is my most bothersome symptom during the day, but I also have hallucinations at night, which are very frightening – so managing my condition 24/7 is challenging," said Diana, a person with narcolepsy type 2. "If I don't nap on the weekends, I cannot keep up with my husband and my 3-year-old son and if I stay up late on weeknights, I can hardly keep up with my job because of difficulty concentrating due to brain fog. I appreciate the effort behind World Narcolepsy Day to help spread awareness and educate people about what it's like to live with narcolepsy so that we can reduce delays in diagnosis."

Narcolepsy is a chronic neurological condition that impairs the brain's ability to regulate the sleep-wake cycle and affects approximately three million people globally. According to the National Institute of Neurological Disorders and Stroke, symptoms often start in childhood, adolescence or young adulthood (ages 7 to 25) but can occur at any time in life. Symptoms can vary by person but may include excessive daytime sleepiness, disturbed nighttime sleep, a sudden loss of muscle tone usually triggered by strong emotion (cataplexy), sleep paralysis, and hypnagogic hallucinations. Narcolepsy that occurs with cataplexy is called type 1 narcolepsy. Narcolepsy that occurs without cataplexy is known as type 2 narcolepsy.

"For people living with narcolepsy, the unpredictability of their symptoms can leave them feeling ashamed, stigmatized socially and scared to engage in activities they enjoy," said Dr. Akinyemi O. Ajayi, Sleep Specialist, Medical Director, Florida Pediatric Research Institute. "Compounding the problem is that narcolepsy is often undiagnosed or misdiagnosed, leaving those who suffer from it without any options to manage their symptoms. World Narcolepsy Day is a much needed awareness campaign to help educate the public of the burdensome symptoms of narcolepsy and the need for improved treatment options."

"At Avadel, we have been longstanding supporters of the narcolepsy community and are proud to reinforce our unwavering commitment this World Narcolepsy Day by raising awareness and elevating patient challenges," said Greg Divis, Chief Executive Officer of Avadel. "We understand that the relentless daytime and nighttime symptoms of narcolepsy have a significant impact on patients' personal, professional and social lives. World Narcolepsy Day is a much needed public awareness campaign, helping to reduce stigma and increase visibility for those living with narcolepsy around the world."

In addition to supporting World Narcolepsy Day, Avadel is also participating in upcoming patient and medical conferences, including:

- The annual Narcolepsy Network conference, taking place virtually October 2-3 where the Company is sponsoring a virtual exhibit booth and presenting patient and clinician perspectives on how to manage the disruption of narcolepsy.
- The American College of Chest Physicians annual meeting, taking place virtually October 17 - 20 where new data will be shared in three poster presentations.
- The annual meeting of the American Neurological Association, taking place virtually October 17 - 19 where encore posters featuring post hoc analyses from the REST-ON trial will be presented.

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) and 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 doses 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 with a Prescription Drug User Fee Act target date of October 15, 2021.

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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