Avadel Presents New Data Supporting Clinical Benefit with Once-at-Bedtime FT218 and Preference for Once-Nightly Dosing in Patients with Narcolepsy at CHEST 2021

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- Post-hoc responder analyses demonstrated a significantly greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo -

- Discrete choice experiment demonstrated that the strongest relative driver of overall product choice was number of doses with once-nightly preferred versus twice-nightly dosing regimen between sodium oxybate -

DUBLIN, Oct. 19, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, today announced new data from the completed pivotal Phase 3 REST-ON clinical trial of FT218, also known as ON-SXB. The post-hoc data are being presented in as two separate posters at the American College of Chest Physicians (CHEST) annual meeting, taking place virtually October 17 – 20, 2021, along with the results of a discrete choice experiment (DCE) to understand patient preference. 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. FT218 is currently under review at the U.S. Food and Drug Administration.

"The new post-hoc responder analyses demonstrating that ON-SXB improved EDS provide further confidence in ON-SXB for people with narcolepsy. We believe this is critical for a patient population whose quality of life is severely impacted by EDS," said John Winkelman, M.D., Ph.D., presenting author, professor of Psychiatry at Harvard Medical School and chief of the Sleep Disorders Clinical Research Program in the Department of Psychiatry at Massachusetts General Hospital. "These ON-SXB data represent a compelling way to set expectations for patients receiving therapy. I believe that ON-SXB, a once-nightly treatment option that has demonstrated clinical benefit in a randomized controlled trial, is a meaningful advance in treatment and, if approved, will be a welcome option for patients and physicians alike."

Highlights from the poster presentations are outlined below.

Sleep Latency Response with FT218, a Once-Nightly Sodium Oxybate (ON-SXB): Post-Hoc Responder Analyses from the Phase 3 REST-ON Clinical Trial

- ON-SXB (FT218) treatment was associated with statistically significant improvements compared to placebo on mean sleep latency, as shown by the results of the Maintenance of Wakefulness Test, a measure of EDS, in the pivotal Phase 3 REST-ON clinical trial:
    - A significantly greater proportion of participants who received ON-SXB compared to placebo experienced increased mean sleep latency change from baseline ranging from ≥5 minutes to 30 minutes
    - Improvement was evident as early as week 3 at the 6-g dose and increased with the 7.5-g dose at week 8 and the 9-g dose at week 13
    - The most common adverse drug reactions (≥5%) with ON-SXB 9 g were enuresis (9.1%), dizziness (5.2%), and vomiting (5.2%)

Cataplexy Response with FT218, a Once-Nightly Sodium Oxybate (ON-SXB): Post-Hoc Responder Analyses from the Phase 3 REST-ON Clinical Trial

- ON-SXB (FT218) treatment was associated with statistically significant improvements compared to placebo on the number of weekly cataplexy episodes, as shown by the results of the pivotal Phase 3 REST-ON clinical trial:
    - A significantly greater proportion of participants treated with ON-SXB compared to placebo experienced 25%, 50% and 75% reductions in the number of weekly cataplexy episodes with once-at-bedtime doses of 6, 7.5, and 9 g
    - Of participants taking the two highest doses (7.5 and 9 g) of ON-SXB, approximately 10% had complete elimination of their cataplexy, while approximately half had a 50% reduction and one-third had a 75% reduction in their weekly cataplexy episodes
    - The most common adverse drug reactions (≥5%) with ON-SXB 9 g were enuresis (9.1%), dizziness (5.2%), and vomiting (5.2%)

The Utility of Discrete Choice Experiment in Evaluating Treatment Preferences Among Patients with Narcolepsy

- A discrete choice experiment evaluated drivers of patient preference for sodium oxybate and demonstrated that dosing frequency was the single most important attribute of a narcolepsy treatment, with once-nightly dosing significantly more preferred than twice-nightly dosing ($P<0.001$).
- The number of nightly doses was also the most important driver observed of "taking the medication exactly as directed" and "reduced anxiety/stress", with once-nightly dosing preferred over twice-nightly dosing.

“Avadel is focused on transforming medicines to transform lives, and FT218, if approved, has the potential to be an innovative solution for patients living with the chronic condition of narcolepsy,” said Jennifer Gudeman, PharmD, Vice President of Medical and Clinical Affairs at Avadel. “FT218 has demonstrated meaningful improvement in cataplexy attacks and measurements of EDS with a dosing regimen preferred by patients. We believe in listening to patients to deliver solutions that improve their symptoms and look forward to our ongoing partnership with the narcolepsy community as we strive to make FT218 available to patients and prescribers.”

Avadel also presented encore posters featuring post hoc analyses from the REST-ON trial at the annual meeting of the American Neurological Association, taking place virtually October 17 – 19, 2021, which affirmed the clinical benefit of FT218 on EDS, regardless of narcolepsy subtype (NT1, with cataplexy and NT2, without cataplexy) and with or without concomitant stimulant use, while also demonstrating a modest reduction in weight and body mass index over the 13-week trial.

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.

Cautionary Disclosure Regarding Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, our expectations of the therapeutic benefits of FT218, the timing of the FDA’s review of our NDA for FT218, the sufficiency of data supporting our NDA for FT218, the commercial launch of FT218 (if approved), and the market acceptance of FT218 (if approved). In some cases, forward-looking statements can be identified by the use of words such as “will,” “may,” “could,” “believe,” “expect,” “look forward,” “on track,” “guidance,” “anticipate,” “estimate,” “project,” “next steps” and similar expressions, and the negatives thereof (if applicable).

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in our forward-looking statements include the risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, which we filed with the Securities and Exchange Commission on March 9, 2021 and subsequent SEC filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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