Avadel Pharmaceuticals Announces Ongoing FDA Review of NDA for FT218 for Patients with Narcolepsy

October 15, 2021

DUBLIN, Ireland, Oct. 15, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, announced today that the U.S. Food and Drug Administration (FDA) notified the company that the review of the New Drug Application (NDA) for FT218 is still ongoing, and action will likely not be taken in October. The FDA informed the company that there are no information requests at this time and a new target action date will be provided as soon as possible.

"We have addressed all questions received to date and remain confident that the package we have submitted satisfies all of the FDA's requests. We have not been informed of any deficiencies in our application and remain fully committed to work closely with the FDA for the duration of its review of our NDA for FT218," said Greg Divis, Chief Executive Officer of Avadel. "Once-at-bedtime FT218 has the potential to truly impact the way people with narcolepsy are able to live their lives and we are dedicated to making this important therapy available to patients as quickly as possible."

In February 2021, the FDA accepted Avadel's NDA for FT218 and assigned a target action date of October 15, 2021. The NDA submission is supported by positive data from the pivotal Phase 3 REST-ON study, which was completed under a Special Protocol Assessment (SPA) agreement with the FDA.

About FT218
FT218 is an investigational formulation of sodium oxybate leveraging Avadel's 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 patients 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 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 or 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 the Company's future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, expectations regarding the timing of the FDA's review of the NDA for FT218 and the sufficiency of data supporting the NDA for FT218. 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).

The Company's 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, the Company's business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the Company's 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 the Company's forward-looking statements include the risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 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. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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