



Avadel Pharmaceuticals Provides Comment on Recent Trading Activity

April 26, 2022

DUBLIN, Ireland, April 26, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today provided a statement in response to the trading volatility and subsequent brief trading halt of its shares that occurred yesterday.

"The company is not aware of any new information, including regarding the ongoing review of the FT218 NDA, that caused yesterday's share price movement and brief trading halt," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are advancing our launch preparations, and look forward to bringing this important treatment to people with narcolepsy."

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 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 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 safer than the twice-nightly formulation of sodium oxybate already approved by the FDA due to the ramifications associated with dosing regimen of that 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 EDS 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, expectations regarding the FDA's review of the 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).

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, 2021, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2022, 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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