Avadel Pharmaceuticals Provides Corporate Update

June 29, 2022

- *Pursuing strategies to accelerate final approval of FT218 NDA*
- *Optimizing cost structure to fund strategic priorities and extend cash runway*
- *Continuing key activities to accelerate launch timing of FT218, targeting multi-billion-dollar narcolepsy market opportunity*
- *Management to host a conference call tomorrow, June 30 at 8:00 a.m. ET*

DUBLIN, Ireland, June 29, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today announced the steps it is taking to explore every available pathway to accelerate the decision by the U.S. Food and Drug Administration (FDA) to grant final approval of its lead drug candidate, FT218, prior to June 2023. Concurrent with this strategy, Avadel has received and agreed upon what is expected to be a final label and is completing the last edits of the Risk Evaluation and Mitigation Strategy ("REMS") with FDA and expects to receive tentative approval of FT218.

"We believe the receipt of a tentative approval for the FT218 New Drug Application (NDA) will validate the clinical efficacy and safety profile of FT218 for people living with narcolepsy and will provide clarity on the timing and pathway to a potential final approval and subsequent commercial launch. Nearly every day we hear from disappointed patients who are waiting for a once at bedtime oxybate treatment option. We believe FT218 has a clear and meaningful place in the multi-billion-dollar narcolepsy market and will continue to pursue every potential option to make it available as soon as possible to all eligible patients whose lives it has the potential to improve," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "As part of these efforts, we are optimizing our cost structure by focusing our existing resources on our most important priorities, thus extending our cash runway and subsequent financial bridge to a potential final approval in June 2023 or sooner."

Avadel, in alignment with our most important priorities, is taking the following actions, including those that can potentially accelerate FDA's final approval decision and shorten the timeline between approval and launch of FT218:

- Submitted a Paragraph IV patent certification and expects to receive a tentative approval.
- Filed a motion in the U.S. District Court of Delaware to delist US Patent No. 8,731,963 (the "REMS patent"), from FDA's Orange Book. A court order requiring the patent holder to delist the REMS patent from the Orange Book could provide a pathway for a final approval of FT218 prior to June 2023.
- Preparing for a claim construction hearing ("Markman hearing") in the existing patent litigation in the U.S. District Court of Delaware which is scheduled for August 31, 2022. The Court has previously stated this claim construction hearing needs to take place prior to ruling on the motion to delist the REMS patent from the Orange Book.
- Investing in patient and physician education including the Company's disease state program, www.narcolepsydisrupts.com, which has resulted in over 5,000 narcolepsy patient enrollments in the first half of 2022.
- Continuing key activities in anticipation of a final approval on or before June 2023, including planning for the final preparation of the FT218 REMS program and the continued manufacturing of commercial supply.
- Optimizing the cost structure to reduce total quarterly cash operating expenses to $12.0 to $14.0 million, excluding inventory purchases. A restructuring charge of between $3.0 - $4.0 million, comprised primarily of severance related costs associated with a nearly 50% reduction in workforce, is expected to be recorded in the second quarter of 2022. The Company expects to report greater than $100.0 million of cash, cash equivalents and marketable securities as of June 30, 2022.

Based on extensive market research and comprehensive claims data analytics, Avadel estimates the total patient population could be in the range of approximately 30,000-35,000 and expects FT218, if approved, to be the treatment of choice for patients suffering from narcolepsy-related excessive daytime sleepiness (EDS) or cataplexy. The current twice-nightly U.S. narcolepsy oxybate market is estimated at $1.8 billion comprised of approximately 16,000 patients. In addition, Avadel estimates that in the last three years, 10,000 – 15,000 patients have discontinued their twice-nightly oxybate use, many due to the complications associated with the middle of the night dosing. Furthermore, based on an analysis of U.S. claims data, the Company believes that each year approximately 3,000 patients initiate oxybate treatment for the first time and expects this to grow by 25-50% over time with the introduction of FT218. Based on the estimated total patient population, the potential market opportunity could be in excess of $3.0 billion annually.

Conference Call
To access the conference call, investors are invited to dial (844) 388-0559 (U.S. and Canada) or (216) 562-0393 (International). The conference ID number is 4176205. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.avadel.com. A replay of the webcast will be archived on Avadel's website for 90 days following the event.

About FT218
FT218 is an investigational formulation of sodium oxybate leveraging the Company's proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of EDS or cataplexy in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON trial, 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 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. The NDA for FT218 is currently under review by the FDA.

Avadel is currently evaluating the long-term safety and tolerability of FT218 in the open-label RESTORE clinical study. For more information, visit: www.restore-narcolepsy-study.com.

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. Avadel's current lead drug candidate, FT218, is an investigational formulation of sodium oxybate leveraging its 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 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 FDA's tentative and/or full approval of the FT218 NDA; the commercial launch of FT218, if approved; the potential therapeutic benefit of FT218; the timing and results of the Company's cost structure optimization efforts; the estimated charges and costs expected to be incurred in connection with such cost structure optimization efforts; the projected cost savings resulting from the Company's cost structure optimization efforts; and, if approved, the potential market opportunity 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).

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, 2021, which we filed with the Securities and Exchange Commission 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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