Avadel Pharmaceuticals Announces Appointment of Jordan Dubow, M.D., as Chief Medical Officer

April 29, 2019

DUBLIN, Ireland, April 29, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for sleep disorders, today announced that it has appointed Jordan Dubow, M.D., as Chief Medical Officer. Dr. Dubow brings extensive experience leading clinical development programs in sleep and neurological disorders to Avadel, where he will lead the development of FT218 for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy.

“Dr. Dubow’s experience in a wide range of neurological disorders, especially sleep, will be invaluable to Avadel as we continue advancing FT218 toward approval and commercialization,” said Geoff Glass, Chairman of Avadel Pharmaceuticals. “His appointment is a critical step as we pivot the Company’s focus to assuring FT218 has the best possible chance of being the first approved once-nightly option for narcolepsy patients.”

“Jordan will help us refine our clinical development and regulatory plans based on the review of our REST-ON program that we initiated in the first quarter with the objective of preparing a solid clinical data package to gain FDA approval and differentiated market positioning to drive FT218’s future commercial success,” said Greg Divis, Interim Chief Executive Officer of Avadel Pharmaceuticals.

Dr. Dubow has both depth and breadth of experience in managing clinical development, medical affairs, business development and regulatory affairs, including multiple successful NDA submissions to the U.S. Food and Drug Administration, across a wide range of neurological diseases including sleep disorders such as narcolepsy. Prior to joining Avadel, Dr. Dubow served as Vice President, CNS Therapeutic Strategy with Esteve, a pharmaceutical company headquartered in Barcelona, Spain, where he was responsible for evaluating in-licensing candidates and provided regulatory and clinical support for the Company’s entire development pipeline. Prior to Esteve, Dr. Dubow served as Vice President of Clinical & Medical Affairs at Clintrex, a strategic advisory firm to the pharmaceutical industry, where he provided clinical, regulatory and business development support in the field of neurological diseases. Earlier positions included Chief Medical Officer at Marathon Pharmaceuticals, a biopharmaceutical company focused on developing and commercializing therapies for neurological disorders, Vice President, Medical Affairs at Cynapsus Therapeutics, and Medical Director, Neuroscience Clinical Development at AbbVie. Dr. Dubow is a board-certified neurologist who received his M.D. from the Northwestern University Feinberg School of Medicine. He has numerous peer-reviewed publications in neurological disorders and has served as a reviewer for various neurological journals.

“I was attracted to Avadel by the therapeutic and commercial potential of FT218,” said Dr. Dubow. “The standard-of-care in narcolepsy, though efficacious, is limited by an inconvenient dosing schedule. Despite that, its sales exceeded $1.4 billion in 2018 indicating both the need and opportunity for new treatment options. I believe a differentiated and highly efficacious therapy will be well positioned for success for treating this condition. I look forward to contributing a meaningful role in bringing FT218 to patients who could benefit from it.”

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. The Company’s primary focus is on the development and potential FDA approval for FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel markets three sterile injectable drugs used in the hospital setting, which were developed under the Company’s “unapproved marketed drug” (UMD) program. Avadel is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. 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. In some cases, forward-looking statements can be identified by the use of words or phrases such as “will,” “as we continue,” “objective,” “future success,” “potential, “opportunity” 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 of our research, development and commercialization activities 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 (i) the risk that we could experience failure or delay in completing the Phase III clinical trial for our FT218 “Rest-On” product, or that if the FDA ultimately approves such product, the approval may not include any period of market exclusivity; (ii) the risk that the review of our FT218 “Rest-On” program that we initiated in the first quarter could result in changes that increase the cost of the program and further delay its completion; (iii) the risk that, even if we successfully complete the development of FT218 and begin its commercialization, it may not receive market acceptance, or new, announced alternative products in development may be approved and may be viewed as more effective than FT218 or otherwise receive greater market acceptance; (iv) the risk that servicing our $143.75 million Exchangeable Senior Notes due 2023 may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of such 2023 Notes in cash, repay the 2023 Notes at maturity, or repurchase the 2023 Notes as required following a “fundamental change” event described in the indenture governing the 2023 Notes; and (v) the other 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, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

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 the forward-looking statements contained in this press release.

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