Avadel Pharmaceuticals Appoints Richard Kim as Chief Commercial Officer to Lead the Commercial Launch of Once-Nightly FT218

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DUBLIN, Ireland, Feb. 17, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy, today announced the appointment of Richard Kim to the newly formed role of Chief Commercial Officer. In this role his responsibilities will include leading all aspects of the U.S. commercial launch of the company's lead program, once-nightly FT218, pending regulatory approval.

"Richard joins our team at an important point in the company's history," said Greg Divis, Chief Executive Officer of Avadel. "Richard has over 25 years of biopharmaceutical commercial experience with direct leadership of successful product launches in the U.S. and around the world to treat specialty and orphan diseases. His hands-on experience in building world-class teams, capabilities and infrastructure to support the commercial launches of those innovative new drugs will play a critical role at Avadel as we accelerate our commercialization strategy for once-nightly FT218, in preparation for the highly anticipated U.S. regulatory approval."

"I was drawn to Avadel because of the potential its investigational, once-nightly FT218 product offers as a game changing therapy for patients living with narcolepsy," said Mr. Kim. "I am excited to have the opportunity to work alongside the amazing Avadel team and build upon the positive momentum they have already established for the once-nightly FT218 program, including completion of the pivotal phase 3 study, submission of the NDA to the FDA at the end of last year, and the ongoing preparation for a successful commercial launch."

"It isn't often that a new product has the potential to offer such a significant advancement in patient care for an established multi-billion dollar market. If approved, I believe FT218 will be the preferred choice for sodium oxybate drug therapy and provide a potentially life-changing option for narcolepsy patients, while creating value for our shareholders," concluded Mr. Kim.

Mr. Kim has over 25 years of commercialization, marketing, development and managerial experience in the biopharmaceutical industry in the U.S. and abroad. Prior to joining Avadel, he was at Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), where he most recently served as the President of U.S. Commercial & Strategic Marketing. During his time there he helped to successfully launch OCALIVA™ (obeticholic acid), the first new treatment in nearly 20 years in an orphan disease, Primary Billiary Cholangitis, and led the launch strategy for obeticholic acid for the treatment of NASH. Prior to joining Intercept, Mr. Kim worked at Bristol-Myers Squibb, where he served as General Manager, Hepatitis C Worldwide Commercialization where he led the successful worldwide launch of DAKLINZA™ (daclatasvir) for hepatitis C. Prior to this, Mr. Kim held a number of roles of increasing responsibility leading sales, operational and strategic marketing teams at Bristol-Myers Squibb, including Vice President, SPRYCEL™ Brand Lead, Oncology Global Marketing; Vice President, U.S. In-Line Oncology and Global Marketing; and Vice President, East Area Sales, Cardiovascular and Metabolics. Prior to his time at Bristol-Myers Squibb, Mr. Kim held a range of senior positions in the U.S., Canada and Australia at Schering-Plough, which was acquired by Merck & Co., Inc.

About FT218
FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release (CR) technology. In December 2020, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company primarily focused on the development and FDA approval of FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat 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, the FDA's review of the NDA for FT218, the benefits of Orphan Drug Exclusivity for FT218, if granted by the FDA, the commercial launch of FT218, if approved, and 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 risk that the FDA does not approve the NDA for FT218 or such approval is delayed, the risk that FT218 (if approved) may not receive a 7-year Orphan Drug Exclusivity,

the risk that commercial launch of FT218 (if approved) is delayed, the risk that the potential market performance for FT218 (if approved) may differ materially from projections, and the risk that the impact of the current COVID-19 pandemic on our financial results and results of operations could be greater than we anticipate and 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, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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