Avadel Pharmaceuticals Announces Restructuring to Focus on FT218 Clinical Development Program

February 7, 2019

- Company cost structure expected to be reduced by $70 to $75 million in 2019 –

- Approximately $100 million in cash and marketable securities at December 31, 2018 –

DUBLIN, Ireland, Feb. 07, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), today announced a corporate restructuring to assure the financial health required to maximize the value of FT218, currently in Phase III development for the treatment of excessive daytime sleepiness (EDS) and Cataplexy in patients suffering from Narcolepsy. Avadel expects to realize $70 to $75 million in cost reductions in 2019 as compared to 2018 as a result of the restructuring plan, driven primarily by exiting NOCTIVA ™ .

“It is clear that FT218, an investigational, once-nightly formulation of sodium oxybate, is the Company’s most promising and commercially-attractive asset targeting a large orphan market with an estimated value of nearly $1.5 billion in 2018,” said Greg Divis, interim Chief Executive Officer of Avadel. “If approved, we believe FT218, with once-nightly dosing, will provide a significant improvement for patients over the current standard-of-care. Our focus going forward is to direct our resources toward this development program. As part of our review of the Company’s operations, we have engaged third-party experts to evaluate the ongoing clinical development program of FT218, including the REST-ON Phase III clinical trial, with the objectives of accelerating enrollment and assuring NDA filing readiness. To date, 149 patients have been randomized in the study, 56% of the overall enrollment goal.”

Geoffrey Glass, Chairman of Avadel’s Board of Directors added, “following recently-announced management and board changes, we undertook a comprehensive review of our existing businesses and corporate strategy. The restructuring plan announced today marks an important step toward restoring Avadel’s financial health and creating a pathway to enhance shareholder value. This plan simplifies Avadel’s business, preserves capital, and creates needed focus and clarity. While the restructuring unfortunately affects a majority of our employees, this action is required to enable the Company to maximize the value of FT218 for the treatment of narcolepsy.”

Avadel expects that the restructuring and other cost-saving actions will result in $70 to $75 million in cost reductions during 2019 as compared to 2018, of which $55 to $60 million is expected to result from the exit of NOCTIVA. NOCTIVA’s performance since launch has been highly disappointing despite a substantial investment of resources. It no longer warrants such a level of support, and Avadel will be better positioned for the future by exiting the business entirely. Once fully implemented, the plan will lower the Company’s cost structure by $80 to $90 million in 2020 and beyond when compared to 2018. Avadel estimates it will incur approximately $10 to $15 million of one-time pre-tax charges for severance and other costs related to the restructuring, primarily during the first half of 2019. The Company’s cash and marketable securities balance as of December 31, 2018 was approximately $100 million.

The Company’s workforce will be downsized by more than 50% as part of the restructuring. The focus of the remaining company and corresponding resources include FT218 and hospital products related capabilities and functions. Separately, Avadel Specialty Pharmaceuticals, LLC, a subsidiary, responsible solely for the sales, marketing and distribution of NOCTIVA, has made a voluntary filing under Chapter 11 of the United States Bankruptcy Code. This action is not expected to materially impact any other aspect of the Company’s business, including the ability to operate its sterile injectables hospital business and complete the FT218 Phase III clinical trial. As part of this action, Avadel expects to record in the fourth quarter of 2018 a pre-tax non-cash impairment charge of approximately $66 million related to NOCTIVA intangible assets.

Avadel will host a conference call and live webcast in early March to report financial results for the fourth quarter and full year ended December 31, 2018 and provide a corporate update. The Company will announce the exact date and time of the call later this month.

About Avadel Pharmaceuticals plc

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a specialty pharmaceutical company that seeks to develop differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, by utilizing its proprietary drug delivery technology and through in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. Avadel’s current portfolio of products and product candidates focuses on the central nervous system (CNS) / sleep, and hospital markets. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: *This press release may include 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. The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and related or similar words and expressions, and (as applicable) the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on estimates and assumptions made within the bounds of our knowledge of our business and operations, 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. These risks include: (a) risks relating to our restructuring actions described in this presentation, including the risks that (i) such actions may not result in the full the cost savings we have described in this presentation; and (ii) we may incur a greater amount of one-time costs as a result of such actions than the amount we describe in this presentation; (b) risks relating to the development of our investigational “FT218” sodium oxybate product, including the risks that (i) we may not have adequate capital to complete the development of FT218, we may need to obtain additional capital for such purpose, and such additional capital may not be available on attractive terms*

or at all; (ii) we may be unsuccessful in accelerating the pace of our clinical trial enrollment for the Phase 3 REST-ON clinical trial, or we could experience delay or failure in completing that clinical trial; and (iii) we could be unsuccessful in marketing the FT218 product in the event we obtain FDA approval for it; and (c) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2017, and our quarterly reports on Form 10-Q for the periods ended June 30, 2018 and September 30, 2018, in particular disclosures that may be set forth in under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®,Vazculep® and Akovaz® products, which are not patent protected, could continue to face substantial and increased competition resulting in a further loss of market share and/or forcing us to further reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery technologies and other products; and our dependence on key personnel to execute our business plan. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.

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