Avadel Pharmaceuticals Receives Orphan Drug Designation from FDA for FT 218 for the Treatment of Narcolepsy

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DUBLIN, Ireland, Jan. 10, 2018 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL), “Avadel” or “the Company,” today announced that FT 218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. FT 218, a once-nightly formulation of sodium oxybate using Avadel’s proprietary Micropump® technology, is currently undergoing testing in a Phase III clinical trial for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. The designation has been granted on the plausible hypothesis that FT 218 may be clinically superior to the same drug already approved for the same indication because FT 218 may be safer due to ramifications associated with the dosing regimen of the previously-approved product.

Mike Anderson, Avadel’s Chief Executive Officer, said, “Receipt of Orphan Drug Designation for FT 218 is meaningful for both Avadel and patients suffering from Narcolepsy. Narcolepsy is a debilitating and rare sleep disorder for which limited treatment options exist. We look forward to completing our REST-ON Phase III trial this year and are hopeful that FT 218 can provide meaningful benefit to patients and their quality of life over other standards of care.”

Orphan Drug status is intended to advance drug development for rare diseases. The FDA provides Orphan Drug Designation to drugs and biologics that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in the U.S. The designation can provide development and commercial incentives for designated compounds and medicines, including eligibility for a seven-year period of market exclusivity in the U.S. after product approval, FDA assistance in clinical trial design and an exemption from FDA user fees.

About REST-ON Phase III Clinical Trial

REST-ON is a double-blind, randomized, placebo controlled study of 264 patients to assess the efficacy and safety of a once nightly formulation of sodium oxybate for extended-release oral suspension for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. For more information, please visit www.rethinknarcolepsy.com.

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 in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri, United States 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 similar expressions, and 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 reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: (i) the risks that we may not achieve our goals for 2018, including to (A) achieve a full-scale commercial launch of Noctiva, (B) complete patient enrollment for our REST-ON clinical trial and file an NDA for FT218, (C) file an NDA for a fourth UMD product (AV001), (D) maintain a leading position in our three hospital products, (E) improve the effectiveness and efficiency of our pediatric operations, (F) enhance our portfolio through M&A activity and (G) generate revenues of between $110 million and $130 million; (ii) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including that our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (the “Drug”) or we may not effectively exploit such market opportunity, that significant safety or drug interaction problems could arise with respect to the Drug, that we may not successfully increase awareness of nocturia and the potential benefits of the Drug, and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (iii) 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, 2016, in particular 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 face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline 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 platforms and other products; and our dependence on key personnel to execute our business plan. Except as may be required by law, we disclaim any obligation to publicly update*

any forward-looking statements to reflect events after the date of this press release.

Contacts:

Michael F. Kanan
Chief Financial Officer
Phone: (636) 449-1844
Email: mkanan@avadel.com

Lauren Stival
Sr. Director, Investor Relations & Corporate Communications
Phone: (636) 449-5866
Email: lstival@avadel.com

Primary Logo

Avadel Pharmaceuticals plc