Avadel Pharmaceuticals Enters into Exclusive Negotiations with Serenity Pharmaceuticals for Noctiva™

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DUBLIN, Ireland, Aug. 17, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL) (“Avadel”), today announced that it has entered into an agreement for the right to exclusively negotiate with Serenity Pharmaceuticals, LLC (“Serenity”), for the sole rights to commercialize and further develop Noctiva in the United States and Canada.

Noctiva is a proprietary low-dose formulation of, and delivery system for, the drug desmopressin acetate. It was specifically developed to meet the needs of nocturia patients and was approved by the U.S. Food and Drug Administration (“FDA”) on March 3, 2017. Noctiva is the first and only drug approved for the treatment of nocturia due to nocturnal polyuria in adults ages 18 and over who awaken two or more times per night to void. Nocturia is a condition that affects as many as 40 million adults in the United States[1]. Noctiva is a metered dose intranasal formulation administered as a single spray in one nostril 30 minutes before bedtime and is approved in two dose forms of 0.83 mcg and 1.66 mcg (Full Prescribing Information available here).

The exclusive negotiation period is expected to close on or before September 7, 2017. If Avadel terminates negotiations without cause, Avadel must pay $10 million to Serenity; and if Serenity terminates negotiations without cause, Serenity must pay $10 million to Avadel.

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (NASDAQ:AVDL) is a specialty pharmaceutical company that seeks to commercialize 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 and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: *This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Avadel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: (i) inability to finalize terms or otherwise fail to meet expectations regarding the timing and completion of the definitive license agreement with Serenity under circumstances requiring us to pay a termination fee of $10,000,000 to Serenity; (ii) the amount of the costs, fees, expenses and charges related to the negotiation of a definitive license agreement; (iii) risks related to the need for management to divert attention from the Company's ongoing business operations due to the negotiation of the definitive license agreement; and (iv) 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 (all of which filings are also available on the Company's website), 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; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; 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. Avadel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.*

[1]Sources: (1) US census data 2016 estimates (2) Lee, L. K., et al. "Potential benefits of diagnosis and treatment…” International journal of clinical practice 70.1 (2016): 66-81.

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