



Avadel Pharmaceuticals Announces Acceptance of Late-Breaker Presentation for NOCTIVA™ at the 2018 American Urological Association

April 3, 2018

DUBLIN, Ireland, April 03, 2018 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq:AVDL), "Avadel" or the "Company," today announced that new data from NOCTIVA's pivotal Phase III clinical trials will be presented at the American Urological Association (AUA) 2018 annual meeting in San Francisco as a late-breaking presentation feature in the Next Frontiers plenary session. The presentation will share new data on extending the time to first uninterrupted sleep in elderly patients with nocturia following treatment with AV002 (NOCTIVA).

Mike Anderson, Avadel's Chief Executive Officer, said, "As the first and only US approved nocturia therapy, NOCTIVA continues to demonstrate clinical benefit to a wide variety of patients in efficacy, safety and quality of life. We are pleased that the American Urology Association has recognized the importance of this critical information for the medical community and their patients."

"Nocturia is a highly prevalent, under-recognized condition associated with disrupted sleep, which results in reduced productivity and negatively impacts health and quality of life^{1,[2],[3],[4],[5],[6],[7],[8]}. Achieving 3-4 hours of uninterrupted sleep is a critical threshold for productivity⁹. Along with my co-authors, I look forward to sharing with my colleagues the exciting new findings in the elderly population, a particular group that disproportionately suffers from frequent nighttime urination," said Dr. Benjamin Brucker MD, Assistant Professor of Urology and Obstetrics and Gynecology at New York University Langone Medical Center. "NOCTIVA has the potential to shift the current treatment paradigm for nocturia for the benefit of countless patients."

NOCTIVA is the first and only product approved to treat nocturia due to nocturnal polyuria. Nocturnal polyuria is the overproduction of urine at night and can lead to nocturia, which causes a person to wake two or more times per night to void. It is estimated that nocturia impacts approximately 40 million Americans.¹⁰

Details of the presentation:

Title: Extended First Uninterrupted Sleep Period in Elderly Patients Following Treatment with AV002, an Emulsified Low Dose Vasopressin Analog for Nocturia

Date and Time: Sunday, May 20, 2018 from 4:15 p.m. PDT

Track: Plenary: Next Frontier

Location: Room MCC NORTH, Hall E

Presenter: Dr. Benjamin Brucker, Asst. Prof. of Urology and Obstetrics and Gynecology at New York University Langone Medical Center

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. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

About NOCTIVA™

NOCTIVA (desmopressin acetate) is an emulsified low dose vasopressin analog, approved by the FDA for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It is administered through a preservative-free intranasal delivery system as a single spray in one nostril approximately 30 minutes before bedtime. NOCTIVA is approved in two dosage forms of 0.83 mcg and 1.66 mcg. For more information, please visit www.noctiva.com.

Important Safety Information and Indication for NOCTIVA (desmopressin acetate)

WARNING: HYPONATREMIA

- **NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.**
- **NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.**
- **Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.**

- If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.

For full prescribing information, please click [here](#).

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) risks that we may not achieve our goals of becoming a leading specialty pharma company, including by continuing to grow and broaden our offering of new and differentiated products, launch NOCTIVA, complete our REST-ON Phase III clinical trial, transform our company and drive long-term value creation; and (ii) 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, in particular disclosures that may be set forth 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; numerous risks related to our efforts to successfully commercialize our new NOCTIVA™ product; the possibility that our Bloxiverz®, Vazculep® and Akovaz® products, which are not patent protected, could face increased competition resulting in a further 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 technologies and other products; and our dependence on key personnel to execute our business plan.*

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Source: Avadel Pharmaceuticals plc