# Avadel Launches NOCTIVA™, the First and Only FDA-Approved Treatment for Nocturia Due to Nocturnal Polyuria

May 1, 2018

**Innovative product now available in the United States for condition that interrupts sleep for over 40 million Americans**

DUBLIN, Ireland, May 01, 2018 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq:AVDL) today announced the launch of NOCTIVA ™ (desmopressin acetate), an emulsified microdose Nasal Spray. NOCTIVA is the first and only FDA-approved treatment proven to help adults with nocturia due to nocturnal polyuria, a condition which causes the kidneys to overproduce urine at night.[1] NOCTIVA safely and effectively treats a condition that causes more than 40 million Americans[2] to wake two or more times per night to use the bathroom, and prevents them from getting a good night's sleep.

NOCTIVA's innovative formulation works in the kidneys to lessen nighttime urine production. The nasal spray is a proprietary emulsified microdose of desmopressin combined with a permeation enhancer that increases the transport of NOCTIVA across the nasal mucosa. Delivered via a unique spray pattern, NOCTIVA's breakthrough formulation substantially increases the bioavailability of the active drug, allowing for microdosing, rapid absorption and consistency from dose to dose.

NOCTIVA was studied in two clinical trials in patients who experienced on average two or more nighttime awakenings to urinate. Study patients received either 1.66 mcg or 0.83 mcg of NOCTIVA or a placebo for 12 weeks. Those using NOCTIVA were able to stay in bed an average of four hours or more before having to wake up to urinate (on average, an improvement greater than 50% relative to placebo vs 2.4-hour baseline). In fact, NOCTIVA responders using 1.66 mcg were able to stay in bed more than five hours before experiencing a nocturic episode.[3]

"Having a safe, effective medication to treat my patients suffering from nocturia due to nocturnal polyuria is a game changer for their quality of life," said Dr. Steven A. Kaplan, Professor of Urology at the Icahn School of Medicine at Mount Sinai and Director of the Benign Urologic Diseases and Men's Health Program at Mount Sinai Health System. "Nocturia is not only highly bothersome, but has been underreported and understudied in terms of its long- and short-term health consequences, including increased risk of falls, fractures and depression."

As part of the clinical development of NOCTIVA, a novel instrument was developed in collaboration with the FDA to evaluate the daytime and nighttime impacts of nocturia. Patients' quality of life was assessed in one of the two clinical trials using the "Impact of Nighttime Urination (INTU)" Questionnaire, which evaluated 10 daytime and nighttime consequences of nocturia. Patients rated their bother in terms of concentration, tiredness, irritability and insufficient sleep using a 0-100 scale. The higher the score, the greater the impact. At the end of the clinical trial, patients taking 1.66 mcg of NOCTIVA demonstrated a 45% improvement in their quality of life score when compared to their baseline measure.

"We're committed to getting patients the help they need to improve their quality of life," Avadel CEO Michael Anderson said. "We're working with specialists to provide a safe and effective treatment option to patients who suffer from nocturia due to nocturnal polyuria."

Avadel is committed to making this innovative, patient-focused product widely accessible and affordable to those diagnosed with nocturia due to nocturnal polyuria. With the NOCTIVA Care+ program available at launch, patients will pay no more than $40 for the prescription.[4]

**Please see Important Safety Information below and Full Prescribing Information at www.Noctiva.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 through in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. The Avadel portfolio of products and product candidates focuses on the urology, central nervous systems 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.

**About NOCTIVA ™**

NOCTIVA is an emulsified microdose desmopressin, 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 microdoses 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.**

**Please see the full Prescribing Information for NOCTIVA at www.Noctiva.com/prescribing-information.**

_____

1. Weiss JP. Nocturia: focus on etiology and consequences. Rev Urol. 2012;14(3-4):48-55.

2. Bosch JLH, Weiss JP. The prevalence and causes of nocturia. J Urol. 2010;184(2):440-446.

3. Data on file.

4. Terms and conditions apply.

**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, 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.*

**Contacts:**

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

**Cara Knox**
**FleishmanHillard for Avadel**
Phone: (314) 982-8744
Email: cara.knox@fleishman.com

Source: Avadel Pharmaceuticals plc