Avadel Pharmaceuticals Announces Data Presentation for Noctiva™ at The American Urogynecologic Society's Annual Scientific Meeting

October 5, 2017

DUBLIN, Ireland, Oct. 05, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL), announced that data for the clinical evaluation of Noctiva (previously "SER120") for the treatment of patients with nocturia due to nocturnal polyuria with concomitant overactive bladder (OAB) will be presented in an oral poster presentation at Pelvic Floor Disorders (PFD) Week 2017, the American Urogynecologic Society's annual scientific meeting.

Douglas Van Drie, M.D., who specializes in urogynecology and reconstructive pelvic surgery, will present oral poster 127, "Evaluation of SER120 for the Treatment of Patients with Nocturia due to Nocturnal Polyuria with Concomitant Overactive Bladder," authored by Van Drie, D., Lepor, H., Nitti, V., Cheng, M., Cheng, L., Fein, S., on Friday, Oct. 6 at 5:11 p.m. EST at the Rhode Island Convention Center in Providence, R.I.

"Nocturia is a medical condition that affects approximately 40 million people in the United States and represents an unmet medical need among my urogynecological patients," commented Van Drie. "The condition results in frequent nighttime urination, which prevents patients from experiencing a normal, restful sleep cycle and can lead to a number of complex and costly co-morbidities and health-related consequences, such as nighttime falls and fractures, impaired daytime functioning and productivity, and compromised quality of life."

In an subset analysis of Noctiva's Phase III pivotal studies, 207 patients suffering from nocturia due to nocturnal polyuria with concomitant overactive bladder were evaluated. Patients on Noctiva demonstrated both a significant reduction in mean number of nocturic episodes, a significant improvement to their overall quality of life and a substantial increase in the time from bedtime to first nocturic void compared to placebo.

Noctiva at doses of 1.66 and 0.83 mcg is effective for the treatment of patients with nocturia due to nocturnal polyuria with concomitant OAB. Highlights of Dr. Van Drie's presentation at Friday's event will include:

• The reduction in mean nocturic episodes/night for the 1.66 mcg dose was 2 times that of placebo (P=.0010) and almost 2 times that of placebo for the 0.83 mcg dose (P=.0076)

• The percentage of patients who achieved ≥50% reduction in mean nocturic nocturic episodes/night for the 1.66 mcg dose was more than 3 times greater than placebo (P=.0007) and 0.83 mcg dose was >2.5 times that of placebo (P=.0096)

• The validated QoL Questionnaire (INTU) completed by the patients demonstrated an almost 6 times greater improvement in the QoL for the 1.66 mcg dose and approximately 5 times greater improvement for the 0.83 mcg dose compared to placebo. These results documented that decreasing nocturic episodes correlated with clinically meaningful improvements in how these patients felt and functioned

• The length of time from bedtime to first nocturic void was 2.4 times greater than placebo for the 1.66 mcg dose (P=.0136) and 2.8 times great than placebo for the 0.83 mcg dose (P=.0036)

About Noctiva™
Noctiva is the first and only formulation of desmopressin acetate, a 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 a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected preservative-free intranasal delivery system. Its nasal administration provides targeted absorption, a consistent pharmacokinetic profile and excellent bioavailability.* Noctiva is dosed as a single spray in one nostril 30 minutes before bedtime, and is approved in two dosage forms of 0.83 mcg and 1.66 mcg. Noctiva is expected to become available to patients in the second quarter of 2018. (Full Prescribing Information available here).

Important Safety Information and Indication for Noctiva (desmopressin acetate)

*Data on file

WARNING: HYPONATREMIA
Call 1-877-622-2320 for a complete list of warnings.

• **NOCTIVA can cause hyponatremia, which is a condition that occurs when you do not have enough sodium in your blood.**

• **Your doctor should monitor the sodium levels in your blood before you start and while you are using NOCTIVA. Mild cases of hyponatremia may not have any symptoms, but signs can include nausea, vomiting, fatigue, dizziness, headache, confusion, muscle cramps, feeling restless, and in severe cases, seizures and coma. It may be life-threatening if severe.**

• **Some people should not take NOCTIVA because of a higher risk of severe hyponatremia. You should not take NOCTIVA if you have a lot of fluid intake, have an illness that can cause fluid or electrolyte imbalances, or use loop diuretics (water pills like bumetanide or ethacrynic acid) or systemic or inhaled glucocorticoids (steroids like cortisone or prednisone).**

• **You may need to temporarily or permanently stop taking NOCTIVA if you get hyponatremia.**

What is NOCTIVA used for?
NOCTIVA is a prescription medicine nasal (nose) spray used in adults who wake up two or more times during the night to urinate due to a condition called nocturnal polyuria. Nocturnal polyuria is a condition where your body makes too much urine at night. There are other conditions that could cause you to wake up during the night to urinate. NOCTIVA is only approved for the treatment of nocturnal polyuria. Your doctor should have you measure your urine and the times that you urinate for 24 hours to determine if you have nocturnal polyuria if you have not already done this.

NOCTIVA is not intended for use in children. It has not been studied in adults less than 50 years old, so it is unknown whether NOCTIVA is safe or effective in people below this age.

Who should not take NOCTIVA?
You should not take NOCTIVA if you:

• have or have had low salt levels in your blood

• are thirsty much of the time and drink large amounts of fluids (polydipsia)

• wet the bed while sleeping at night

• are taking a type of water-pill called a loop-diuretic

• are taking a glucocorticoid (steroid) medicine, including an inhaled glucocorticoid (steroid) medicine

• have moderate to severe kidney problems

• have or may have a condition called syndrome of inappropriate antidiuretic hormone (SIADH) secretion

• have an illness that can cause you to have low levels of fluid or electrolytes in your blood, such as vomiting, diarrhea, an infection, or a kidney problem that causes you to lose too much salt

• have symptoms from a heart problem called congestive heart failure

• have high blood pressure that is not controlled

Ask your doctor if you are not sure you have any of these conditions or take any of the types of medicines listed.

What is the most important information you should know about NOCTIVA?

NOCTIVA can cause hyponatremia (low levels of sodium in the blood). Severe cases can lead to seizures, coma, or death. It can cause fluid retention (water weight gain), which can be a particular problem for people with congestive heart failure or uncontrolled high blood pressure.

Call your doctor if you have any of the following symptoms of low salt levels in your blood:

• headache

• nausea or vomiting

• drowsiness

• dizziness

• muscle cramps

• feeling restless

• fatigue

• change in your mental condition, such as confusion, or decreased awareness or alertness

Low salt levels in the blood happen more often in people treated with NOCTIVA who are 65 years old or older than in people treated with NOCTIVA who are younger than 65 years old. Your doctor should check the salt levels in your blood before you start or re-start taking NOCTIVA, during treatment with NOCTIVA, and before increasing your dose.

Ask your doctor if you should temporarily discontinue NOCTIVA if you have allergies or a cold that makes your nose runny or stuffed up, as having such symptoms could affect how your body absorbs the medicine in NOCTIVA.

What should you tell your health care provider?

Before using NOCTIVA, tell your health care provider about all of your medical conditions, including if you:

• have vomiting, diarrhea, fever, or infection

• have kidney or heart problems

• have diabetes mellitus

• have had a head injury

• have a heart problem called congestive heart failure

• have a history of not being able to empty your bladder all of the way (urinary retention)

• have any nose problems, such as blockage, stuffy nose, runny nose, or drainage

• are pregnant or plan to become pregnant. It is not known if NOCTIVA can harm your unborn baby.

• Are breastfeeding or plan to breastfeed. Desmopressin, and ingredient in NOCTIVA, passes into breast milk. Talk to your doctor about the best way to feed your baby if you use NOCTIVA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using NOCTIVA with certain other medicines may cause serious side effects. Do not start taking any new medicines until you talk to your doctor.

Especially tell your doctor if you take a:

• water pill (diuretic)

• glucocorticoid (steroid) medicine, including an inhaled glucocorticoid (steroid) medicine

- Your doctor should stop your treatment with NOCTIVA for a period of time while you are taking and after you stop taking an oral or inhaled glucocorticoid (steroid) medicine.

• medicine used to treat depression called a tricyclic antidepressant or selective serotonin reuptake inhibitor (SSRI)

• medicine used to treat mood disorders, such as schizophrenia or bipolar disorder called chlorpromazine

• medicine used to treat seizures, nerve pain, or bipolar disorder called carbamazepine

• non-steroidal anti-inflammatory medicine (NSAID)

• medicine that you use in your nose

There have not been any studies done to see if other medicines might interact with NOCTIVA. **Ask your doctor or pharmacist if you are not sure if your medicine is one of the types listed above,** or if you are unsure whether any of the medicines you already take might put you at increased risk of side effects.

How should you take NOCTIVA?
You should use NOCTIVA exactly as instructed by your health care professional. Your doctor has prescribed the strength that is best for you, and you should not use more than 1 spray of the prescribed dose at a time, even if you missed a prior dose.

What are the side effects of NOCTIVA?
NOCTIVA may cause serious side effects, including hyponatremia, which may lead to serious or life-threatening conditons, including seizure, coma, trouble breathing, or death if not treated early. NOCTIVA may also cause your body to hold too much water (fluid retention).
The most common side effects of NOCTIVA include:

• nose discomfort

• pain or swelling (inflammation) in your nose or throat

• stuffy nose

• sneezing

• high blood pressure

• back pain

• nosebleed

• inflammation of the lining of the bronchial tubes that carry air to and from your lungs that causes a cough (bronchitis)

• dizziness

These are not all of the possible side effects of NOCTIVA. You are encouraged to call your doctor for medical advice about side effects, and you can also report them to the FDA.

To report SUSPECTED SIDE EFFECTS, contact Avadel Specialty Pharmaceuticals, LLC, at 1-877-622-2320 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please be aware that this is not a complete listing of all safety information associated with NOCTIVA. For more information, call 1-877-622-2320.

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 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 relating to our license agreement with Serenity Pharmaceuticals, LLC including that our internal analyses may overstate the market opportunity in the United States and Canada 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 (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, 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.

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