Avadel Pharmaceuticals Enters into Exclusive License Agreement for Noctiva™

September 5, 2017

Noctiva is the only FDA-approved product indicated for the treatment of nocturia

DUBLIN, Ireland, Sept. 05, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL) ("Avadel"), today announced that it has entered into a license agreement with Serenity Pharmaceuticals, LLC ("Serenity"). The agreement grants Avadel the sole right to commercialize and further develop Noctiva in the United States and Canada. Noctiva is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected intranasal delivery system. It is the first and only product approved by the U.S. Food and Drug Administration ("FDA") for the treatment of nocturia due to nocturnal polyuria.

Key Highlights:

- **Deal Includes $50 million upfront payment; funded by cash on hand, and a near term expected improvement in the Company's effective tax rate.**
- **Current nocturia-treated patient pool estimated at over $2B with no FDA approved treatment options until now, and market growth potential[1].**
- **Long-term growth opportunity with current intellectual property through mid-2030, and potential opportunities to extend patent life.**
- **Balance sheet remains strong with no bank debt, and adequate cash to fund ongoing operations, including completion of the Company's REST-ON Phase III trial.**

Nocturia is a medical condition that affects approximately 40 million[2] people in the United States, and represents a high unmet medical need. Nocturia results in frequent nighttime urination, which may prevent patients from experiencing a normal, restful sleep cycle. Nocturia is associated with a number of co-morbidities and health-related consequences, including an increase in the risk of nighttime falls and fractures, loss of sleep, decreased work productivity, impaired daytime functioning and compromised quality of life[3].

Mike Anderson, Avadel's Chief Executive Officer, said, "Licensing Noctiva is an important step in our strategic growth plan and positions Avadel as a fully-integrated specialty pharmaceutical company, with a profitable base and a significant ongoing Phase III trial. Noctiva is the first and only FDA approved product to treat nocturia due to nocturnal polyuria, and aligns with our mission of offering patients unique and differentiated branded products. Noctiva has the potential to deliver significant value to Avadel, the large, underserved patient population who suffer from nocturia and our shareholders."

Dr. Samuel Herschkowitz, Chief Executive Officer of Serenity, said, "Approximately $200 million has been invested in order to develop and gain FDA approval for Noctiva, which is the first drug therapy shown to be safe and effective for the treatment of nocturia. The clinical program for Noctiva included four Phase 3 studies and two long-term safety trials and demonstrated significant reductions in the mean number of nocturic episodes, and improved quality of life[4]. We believe Avadel is the right partner with the experience, capability and commitment to bring Noctiva to market for the benefit of patients, providers and payors."

Terms of the final agreement, which can be found in detail on Avadel's 8-K filed with the S.E.C. on September 5, 2017, include an upfront payment of $50 million, $20 million due at the earlier of full scale commercial launch or June 30, 2018, performance-based milestones tied to specific Noctiva net sales thresholds and a tiered royalty rate structure based upon achievement of annual net sales. As a result of the licensing agreement, the Company expects an improvement in its effective tax rate, as expenses associated with the launch will partially offset U.S. taxable income. Avadel's strong balance sheet, with $173 million in cash and marketable securities and no bank debt at June 30, 2017, means the Company is able to self-fund the licensing acquisition of Noctiva and subsequent near-term commercialization plans.

The transaction is set to close upon expiration of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. T.R. Winston & Company, LLC, served as financial and strategic advisor to Serenity.

Conference Call:
Avadel will host a conference call and live audio webcast on Wednesday, September 6, 2017 at 8:30 am EDT to discuss this transaction. Interested parties may access the conference call by dialing (844) 388-0559 (U.S. & Canada) or (216) 562-0393 (International) and entering Conference ID# 79911607. The live audio webcast and slide presentation may be accessed via the Investors section of the Avadel Pharmaceuticals website at www.avadel.com. A replay of the webcast will be available on the website for 90 days.

[1] Data on file.

[2] 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.

[3] Data on file.

[4] New Drug Application for Noctiva. Data on file.

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.

About Noctiva™:
Noctiva is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Noctiva™ is a preservative-free intranasal formulation of desmopressin, administered 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. (Full Prescribing Information available here).

Important Safety Information and Indication for Noctiva (desmopressin acetate)

WARNING: HYPONATREMIA:

- Noctiva can cause hyponatremia, which may be life-threatening if severe.
- Noctiva is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, with illnesses that cause fluid or electrolyte imbalances, or those using loop diuretics or systemic or inhaled glucocorticoids.
- Ensure serum sodium is normal before starting or resuming Noctiva. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age or older and in patients at increased risk of hyponatremia.
- If hyponatremia occurs, Noctiva may need to be temporarily or permanently discontinued.

Noctiva should not be used in patients with symptomatic congestive heart failure or uncontrolled hypertension because fluid retention can worsen these underlying conditions. Use of Noctiva should be discontinued temporarily in patients with certain nasal conditions such as colds or allergies until those conditions have resolved.

Noctiva is also not recommended for the treatment of nocturia in pregnant women. Nocturia is usually related to normal physiologic changes in pregnancy that do not require treatment with Noctiva. Noctiva should not be used in children.

The most common side effects of Noctiva in clinical trials included nasal discomfort, cold symptoms (nasopharyngitis), nasal congestion, sneezing, high or increased blood pressure, back pain, nose bleeds, bronchitis and dizziness.

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," "potentially," "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 the following: (i) our internal analyses may overstate the market opportunity in the United States and Canada for the drug desmopressin acetate (the "Drug"), which we have licensed from Serenity Pharmaceuticals, LLC, or we may not effectively exploit such market opportunity; (ii) significant safety or drug interaction problems could arise with respect to the Drug; (iii) we may not successfully increase awareness of nocturia and the potential benefits of the Drug; (iv) we may encounter problems with the manufacture or supply of the Drug; (v) patents and proprietary rights associated with the Drug may not provide adequate protection; (vi) our costs to complete the commercialization of the Drug could be more than planned and/or may not provide the intended positive financial results; (vii) the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (viii) 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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