



UroGen Pharma Announces First Patient Enrolled in Allergan Phase 2 Clinical Trial of RTGel™ in Combination with BOTOX® for the Treatment of Overactive Bladder

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RAANANA, Israel and NEW YORK, Nov. 06, 2017 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (NASDAQ:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, today announced the enrollment of the first patient in a Phase 2 clinical trial of RTGel™ in combination with BOTOX® (onabotulinumtoxinA) for the treatment of overactive bladder. The Phase 2 trial is being conducted by Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, under the terms of a license agreement with UroGen Pharma. RTGel™ is UroGen Pharma's proprietary sustained release, hydrogel-based formulation technology designed to enable longer exposure of the urinary tract tissue to active pharmaceutical ingredients with which it may be combined, including BOTOX®. BOTOX® injection into the bladder is approved as a pharmacologic therapy for the treatment of overactive bladder.

"The enrollment of the first patient in the Phase 2 clinical trial marks another important milestone in our collaboration with Allergan and further demonstrates Allergan's continued commitment to this program," said Ron Bentsur, Chief Executive Officer of UroGen Pharma. "We believe that the innovative RTGel™/BOTOX® combination has the potential to provide an additional treatment option for the many patients suffering from overactive bladder."

In October 2016, UroGen Pharma granted an exclusive worldwide license to Allergan to research, develop, manufacture and commercialize pharmaceutical products that contain UroGen Pharma's proprietary RTGel™ and clostridial toxins, including BOTOX®. Under the terms of the license agreement, UroGen Pharma is eligible to receive additional payments from Allergan related to the achievement of certain development, regulatory and commercial milestones, in addition to royalties on potential net sales.

About the Phase 2 Clinical Trial

The trial is a multi-center, randomized, double-blind, placebo-controlled, single-treatment, two-stage, dose-finding clinical trial on patients with overactive bladder with urgency urinary incontinence who have an inadequate response to or are intolerant to pharmacologic therapy. The first stage of the trial is a placebo-controlled, dose escalation design, followed by the second stage, a randomized, placebo-controlled design. Up to 335 patients are expected to be enrolled. Patients will receive a single bladder instillation of RTGel™ in combination with BOTOX®. The primary efficacy endpoint is the improvement of overactive bladder symptoms as measured by the reduction in urinary incontinence episodes per day.

Learn more about the trial at <http://www.clinicaltrials.gov>.

About Overactive Bladder and RTGel™

Overactive Bladder (OAB) is a common, often disabling condition associated with considerable negative impact on quality of life. OAB results in an uncontrolled urge to urinate, frequent urination, and, in many patients, uncontrollable leakage of urine. Standard first-line pharmacologic treatment for OAB is anticholinergic pills. However, the majority of patients stop taking the pills within one year due to an inadequate response to, or intolerance of, the medication. BOTOX® injection into the bladder is approved as a therapy for OAB.

Over 30 million people in the United States alone and 200 million people worldwide suffer from this burdensome disease.

RTGel™ has thermo-sensitive properties that enable it to convert from a liquid state when cold, into a gel once it reaches body temperature. This allows increased residence time of drugs when mixed with the gel and instilled in the bladder.

About UroGen Pharma Ltd.

UroGen Pharma Ltd. (NASDAQ:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. The Company has developed RTGel™, a proprietary sustained release, hydrogel-based formulation for potentially improving therapeutic profiles of existing drugs. UroGen Pharma's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. UroGen Pharma's lead product candidates, MitoGel and VesiGel, are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade UTUC and bladder cancer. UroGen Pharma is headquartered in Israel and also maintains a corporate office in New York City.

Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to the clinical development of RTGel™ in combination with BOTOX® for the treatment of overactive bladder and other product candidates in UroGen Pharma's pipeline, the potential of the RTGel™/BOTOX® combination to treat patients with overactive bladder, and the potential utility and applicability of the RTGel™ technology beyond uro-oncology and overactive bladder, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential complications thereof; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing a product candidate; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; the maintenance of any applicable collaborations; and the ability to achieve business development transactions on favorable terms to the Company, if at all. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of the final prospectus for UroGen Pharma's initial public offering of securities in the United States filed with the SEC on May 5, 2017 and other filings that UroGen Pharma makes with the SEC from time to time (which are available at <http://www.sec.gov/edgar>), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen Pharma's actual results could differ materially and adversely from those anticipated or implied thereby.

Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen Pharma as of the date of this release.

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