



Investigational New Drug Application for RTGel™ in Combination with BOTOX® for the Treatment of Overactive Bladder Submitted to FDA by Allergan

July 19, 2017

RAANANA, Israel, and NEW YORK, July 19, 2017 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (NASDAQ:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, with a focus on uro-oncology, today announced that it will receive a milestone payment of \$7.5 million under its exclusive worldwide licensing agreement with Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, resulting from Allergan's submission of an Investigational New Drug (IND) application for RTGel in combination with BOTOX for the treatment of overactive bladder to the U.S. Food and Drug Administration (FDA).

"Our licensing agreement with Allergan for the use of our RTGel in combination with BOTOX® continues to be productive with the recent achievement of this important IND submission," said Ron Bentsur, Chief Executive Officer of UroGen. "We are excited about the potential of the RTGel/BOTOX® combination to become an important additional treatment option for patients suffering from overactive bladder."

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

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 treatment for OAB is anticholinergic pills, however, the majority of the 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 second line therapy for OAB and is considered an effective therapeutic option.

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 (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 VesGel, 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, including with respect to the development potential of RTGel/BOTOX®, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials; 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; and the maintenance of any applicable collaborations. In light of these risks, uncertainties and assumptions, the events and circumstances discussed in such forward-looking may not occur, and UroGen Pharma's actual results could differ materially and adversely from those anticipated or implied thereby.

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