UroGen Pharma Announces Oral Presentation at Society of Urologic Oncology (SUO) Annual Meeting

November 27, 2017

Principal Investigator Seth Lerner, M.D., to present design overview of ongoing Phase 3 OLYMPUS trial of MitoGel™ for the treatment of Low-Grade UTUC and data highlights from recently completed compassionate use program

RA'ANANA, Israel and NEW YORK, Nov. 27, 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 Seth Lerner, M.D., principal investigator for the Company's ongoing pivotal Phase 3 OLYMPUS trial of MitoGel™ for the treatment of low-grade upper tract urothelial carcinoma (UTUC), will conduct an oral presentation during a plenary session at the 18th annual meeting of the Society of Urologic Oncology (SUO), taking place November 29-December 1, 2017, in Washington, D.C.

Dr. Lerner will provide an overview of the design of the Phase 3 OLYMPUS trial, including metrics of success and basic patient inclusion and exclusion criteria. In addition, Dr. Lerner will present key data highlights from the Company's recently completed compassionate use program with MitoGel™ for the treatment of UTUC. Topline data from the Phase 3 OLYMPUS trial are expected to be available in the second quarter of 2018.

Details of the presentation are as follows:

Title: Thermo Reversible Hydrogel Based Delivery of Mitomycin C (MitoGel) for Treatment of Upper Tract Urothelial Carcinoma
Presenter: Seth Paul Lerner, M.D., FACS, Professor of Urology at Baylor College of Medicine
Time: Thursday, November 30, 2017, 1:30 p.m. EST
Location: Renaissance Washington DC Downtown Hotel, Washington, D.C.

About the Phase 3 OLYMPUS Trial
OLYMPUS (**O**ptimized De**L**ivery of **M**itomycin for **P**rimary **U**TUC **S**tudy) is an open-label, single-arm Phase 3 clinical trial of MitoGel to evaluate the safety, tolerability and tumor ablative effect of MitoGel in low grade UTUC patients. The trial, designed to be a single pivotal study for the approval of MitoGel in low-grade UTUC, is anticipated to enroll approximately 70 patients at clinical sites across the U.S. and Europe. The trial will also evaluate the durability of the tumor ablative effect of MitoGel.

About UTUC
Non-muscle invasive upper tract urothelial carcinoma (UTUC) has an estimated annual incidence in the United States of up to 7,500 cases – about 5% to 10% of all new cases of urothelial cancer. There are approximately 2,500 new cases of low-grade UTUC in the U.S. with a prevalence of approximately 14,500. UTUC refers to cancer of the upper tract, which connects the bladder to the kidney, and the renal pelvis. The current standard of care for this cancer is complete or partial surgical removal of the involved kidney and upper tract. For patients with a bilateral disease, an anatomic or functionally solitary kidney, medical comorbidities or low-grade disease that present with a limited number of tumors, a kidney-conserving alternative is considered, if possible. However, due to the specific anatomy and physiology of the upper tract and renal pelvis, the performance of organ-sparing endoscopic resection and instillation of neoadjuvant or adjuvant chemotherapy are often challenging, leading to high rates of recurrence. Continuous urine flow, the inability of the upper tract to retain a liquid volume under normal circumstances and the effects of systemic peristalsis result in short exposure time of active agents in the target area. This leads to poor efficacy and limited use of standard chemoablative agents in patients with UTUC. No drugs are currently FDA-approved for the treatment of UTUC.

About MitoGel ™
Utilizing RTGel ™, UroGen's proprietary sustained release, hydrogel-based formulation, MitoGel is designed to enable longer exposure of Mitomycin C to the urinary tract tissue, thereby potentially enabling the treatment of tumors by non-surgical means. MitoGel is administered to patients using standard intravesical catheters. The U.S. Food and Drug Administration (FDA) has granted both Orphan Drug and Fast Track designations to MitoGel for the treatment of low-grade UTUC.

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 severa forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma and bladder cancer. UroGen Pharma is headquartered in Ra'anana, Israel and 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 and commercial prospects of MitoGel™, and the other product candidates in UroGen Pharma's pipeline, patient enrollment in the OLYMPUS trial, 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 ability of the Company to maintain a strong management team and board of directors; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen Pharma's product candidates; and the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies. 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 https://www.sec.gov), 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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