



UroGen Pharma Announces Presentation of Results from Interim Analysis of Pivotal Phase 3 OLYMPUS Trial of UGN-101 (MitoGel™) for Non-Surgical Treatment of Upper Tract Urothelial Cancer (UTUC)

April 3, 2018

RA'ANANA, Israel and NEW YORK, April 03, 2018 (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 a new data presentation from an interim analysis of the ongoing pivotal Phase 3 OLYMPUS clinical trial of UGN-101 (MitoGel™), an investigational mitomycin formulation for the non-surgical treatment of low-grade upper tract urothelial cancer (UTUC). The full interim analysis will be presented on Monday, May 21, 2018 in an oral presentation during the plenary session at the 113th American Urological Association's (AUA) Annual Meeting in San Francisco. The text for the abstract is available online through the [Journal of Urology](#) website.

Details of AUA Oral Presentation

Abstract #: LBA-25

Session: Plenary, Next Frontier

Title: Non-Surgical Management of Low Grade Upper Tract Urothelial Cancer: An Interim Analysis of the International Multicenter OLYMPUS Trial

Presenter: Seth Paul Lerner, M.D., FACS, Professor of Urology, Baylor College of Medicine

Time: Monday, May 21, 2018, 10:40-10:50 AM PDT

Location: MCC NORTH, Hall E, The Moscone Center

"We look forward to presenting data from the OLYMPUS trial of our lead product candidate, UGN-101, for the treatment of patients with low-grade UTUC," said Ron Bentsur, Chief Executive Officer of UroGen. "With UGN-101, we hope to change the treatment paradigm for low-grade UTUC and potentially reduce the high recurrence rate characteristic of UTUC, while eliminating the need for surgery and the risks associated with surgery. Our goal is for UGN-101 to become the first-ever approved treatment for low-grade UTUC."

The OLYMPUS trial continues to enroll patients, and top-line results are expected in the third quarter of 2018.

About the Phase 3 OLYMPUS Trial

OLYMPUS (Optimized DeDelivery of Mitomycin for Primary UTUC Study) is an open-label, single-arm Phase 3 clinical trial of UGN-101 (MitoGel) to evaluate the safety, tolerability and tumor ablativ effect of UGN-101, an investigational formulation of mitomycin, in patients with low-grade UTUC. The trial, designed to be a single pivotal study for the approval of UGN-101 for the treatment of low-grade UTUC, is anticipated to enroll approximately 70 patients at clinical sites across the United States and Europe. Study participants are treated with six weekly instillations of UGN-101 administered via a standard catheter. Four to six weeks following the last instillation, they undergo primary disease evaluation, which involves a ureteroscopy and wash cytology, a standard microscopic test of cells washed from the urine or bladder to detect cancer. All study participants will be followed for a minimum of 12 months following primary disease evaluation to determine the durability of disease control with UGN-101.

About Upper Tract Urothelial Cancer (UTUC)

Upper tract urothelial cancer (UTUC) involves the upper urinary tract, which connects the bladder to the kidney and renal pelvis. In the United States, there are approximately 7,500 new cases of UTUC each year. Of these, about 2,500 cases are low-grade UTUC. Approximately 14,500 people are currently living with low-grade UTUC.

The current standard of care for UTUC is complete or partial surgical removal of the involved kidney and upper urinary tract. For patients with a bilateral disease, an anatomic or functionally solitary kidney, medical comorbidities or low-grade disease who 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 urinary tract and renal pelvis, organ-sparing endoscopic resection and instillation of neoadjuvant or adjuvant chemotherapy is often challenging, leading to high rates of recurrence. Additionally, continuous urine flow, the inability of the upper urinary tract to retain a liquid volume under normal circumstances, and the effects of peristalsis, or muscle contraction, result in short exposure time of active agents in the target area. This leads to poor efficacy and limited use of standard therapeutic agents in the treatment of UTUC.

About UGN-101 (MitoGel™)

UGN-101 is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade UTUC. Utilizing RTGel™, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-101 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. UGN-101 is delivered to patients using standard intravesical catheters.

The U.S. Food and Drug Administration (FDA) has granted both Orphan Drug and Fast Track designations to UGN-101 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 platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen'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's lead product candidates, UGN-101 (MitoGel™, also known as mitomycin urothelial gel) and UGN-102 (VesiGel™, also known as mitomycin intravesical gel), are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma and bladder cancer, respectively. UroGen is headquartered in Ra'anana, Israel with U.S. headquarters in New York.

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 timing and results of clinical development and commercial prospects of the product candidates in UroGen's pipeline, including UGN-101 (MitoGel) and UGN-102 (VesiGel), the scope and development of UroGen's product candidate pipeline, enrollment in the OLYMPUS trial, timing and expectations of results from the OLYMPUS trial, UroGen's expectations regarding its ability to fund its operations, and the ability of UroGen to become a leader in the field of uro-oncology, particularly in the treatment of low-grade UTUC, 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, including with respect to enrollment; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen'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 our annual report for the year ended December 31, 2017 filed with the SEC on March 15, 2018 and other filings that UroGen makes with the SEC from time to time (which are available at <http://www.sec.gov>), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen'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 as of the date of this release.

UROGEN CONTACTS:

Kate Bechtold
Director, Corporate Communications & Investor Relations
KateB@urogen.com
914-552-0456



UroGen Pharma Ltd.