UroGen Pharma Announces Presentation of Analysis from Phase 3 OLYMPUS Trial of UGN-101 for Patients with Low-Grade Upper Tract Urothelial Cancer

April 5, 2019

NEW YORK--(BUSINESS WIRE)--Apr. 5, 2019-- UroGen Pharma Ltd. (Nasdaq: URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in uro-oncology, today announced a new presentation from the pivotal Phase 3 OLYMPUS trial of UGN-101 (mitomycin gel) for instillation, an investigational formulation for the primary non-surgical treatment of patients with low-grade upper tract urothelial cancer (LG UTUC). The analysis, which discusses the minimally invasive chemoablation approach of UGN-101 to potentially treat LG UTUC tumors, including those that are unresectable, will be presented on Sunday, May 5, 2019 in an oral presentation during the plenary session at the 114thAmerican Urological Association (AUA) Annual Meeting in Chicago. The text for the abstract is available online through the Journal of Urology website.

Details of AUA Oral Presentation
Abstract #: LBA-16
Session: Plenary Session, Next Frontier
Title: Nephron-sparing Management of Low Grade (LG) UTUC With UGN-101 (mitomycin gel) for Instillation: The Olympus Trial Experience
Presenter: Seth Paul Lerner, M.D., FACS, Professor of Urology, Baylor College of Medicine
Date and Time: Sunday, May 5, 2019; 3:17 – 3:26 PM CDT
Location: MCP: W375d

“The treatment of LG UTUC remains a technical challenge for urologists, given the anatomical complexity of the kidney and the physical limits of endoscopic instrumentation,” said Mark P. Schoenberg, M.D., Chief Medical Officer of UroGen. “UroGen is committed to raising the standard of care for this typically elderly patient population whose current options consist of repetitive endoscopic surgical intervention or complete loss of a kidney. We look forward to presenting this UGN-101 analysis that further underscores the unmet need in patients with new and recurrent LG UTUC.”

About UGN-101

UGN-101 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade upper tract urothelial cancer (LG UTUC). Utilizing the RTGel™ technology platform, UroGen’s proprietary sustained release, hydrogel-based formulation, UGN-101 is designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard ureteral catheters. The Company initiated its rolling submission of the UGN-101 New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG 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. UroGen 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 investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to potentially ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and bladder cancer, respectively. UroGen is headquartered in New York, NY with operations in Los Angeles, CA and Israel.

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 potential of UGN-101 to be the first non-surgical therapy for LG UTUC, the completion of the rolling NDA for UGN-101, approval, launch and adoption of UGN-101, the potential of UroGen’s proprietary RTGel™ technology platform, and the potential of UGN-102, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the Olympus pivotal Phase 3 trial and potential safety and other 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 UroGen Pharma’s product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; and UroGen Pharma’s ability to attract or retain key management, members of the board of directors and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen Pharma’s most recent Form 10-K filed with the SEC and other filings that UroGen Pharma 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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190405005223/en/

Source: UroGen Pharma Ltd.

UROGEN:
Kate Bechtold
Director, Corporate Communications & Investor Relations

Kate.Bechtold@urogen.com
914-552-0456