The Journal of Urology Publishes Peer-Reviewed Article Highlighting UGN-102 Data in Non-Surgical Treatment for Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

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-- Phase 3 ATLAS Clinical Trial Shows UGN-102 Demonstrated Superiority to TURBT with a 55% Reduction of Risk for Recurrence, Progression or Death in Patients who Received UGN-102 --

PRINCETON, N.J.--(BUSINESS WIRE)--Aug. 8, 2023-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, today announced that *The Journal of Urology* published data from the Phase 3 ATLAS trial for investigational agent UGN-102 (mitomycin) for intravesical solution in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC), that demonstrated superiority to transurethral resection of bladder tumor surgery (TURBT) with a 55% reduction of risk for recurrence, progression, or death in patients who received UGN-102. Tumor-free complete response rate at three months was 65% for patients who only received UGN-102, compared to a 64% complete response rate at three months for patients who underwent TURBT. TURBT is the current standard of care for patients with this type of cancer.

"The publication of our ATLAS data in *The Journal of Urology* adds another chapter to our understanding of the potential of UGN-102 as a treatment for patients with LG-IR-NMIBC, who often face multiple surgeries due to the recurring nature of this cancer," said Mark Schoenberg, M.D., Chief Medical Officer at UroGen. "Our hope is that one day urologists may have an effective, non-surgical therapy option beyond TURBT that can be used to address this large patient population."

The Phase 3 ATLAS clinical trial, which met its primary endpoint, evaluated the efficacy, durability, and safety of UGN-102 with or without TURBT vs. TURBT alone in 282 patients with LG-IR-NMIBC. UroGen recently announced positive topline data from ATLAS and the Phase 3 ENVISION trial. The ENVISION trial evaluated the efficacy and safety of UGN-102 as a primary chemoablative therapy in 240 patients with LG-IR-NMIBC and met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of complete response at 3-months following the initial treatment.

The Journal of Urology publication includes the following findings from ATLAS:

- Tumor-free complete response 3 months after initial treatment was achieved by 92 patients (65%) who received UGN-102 and 89 patients (64%) treated by TURBT.
- UGN-102 was generally well tolerated, with a side effect profile similar to that of previous clinical trials.

The estimated probability of remaining event free 15 months after randomization was 72% for UGN-102 ± TURBT and 50% for TURBT monotherapy [hazard ratio 0.45].

"While TURBT is the standard treatment for bladder cancer, the recurrent nature of LG-IR-NMIBC means that patients will undergo multiple surgeries that come with risks for this older patient population," says Sandip Prasad, M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Medical Center/Atlantic Health System, NJ, and Chief Investigator in the ATLAS trial. "It is exciting to consider what a potential non-surgical therapeutic alternative could mean for both patients and doctors who are eager for additional options."

Additional data evaluating the secondary endpoint of the ENVISION trial, Duration of Response, is expected in 2024. Assuming positive findings, a New Drug Application (NDA) is anticipated to be submitted to the U.S. Food and Drug Administration (FDA) in the same year.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of LG-IR-NMIBC. Utilizing UroGen's proprietary RTGel ® technology, a sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter in an outpatient setting. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024. If approved, UGN-102 would be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries.

About ATLAS

ATLAS is a global, open-label, randomized controlled Phase 3 trial designed to assess the efficacy and safety of UGN-102, with or without TURBT, vs. TURBT alone in patients diagnosed with LG-IR-NMIBC. The trial enrolled 282 patients in clinical sites in the U.S., Europe and Israel. Patients were randomized 1:1 to either UGN-102 or TURBT. Patients in the UGN-102 arm were treated with six weekly intravesical instillations of UGN-102. At the 3-month time point, patients were assessed for response. Patients who demonstrated a complete response to either UGN-102 or TURBT, were assessed for long-term follow-up for evidence of recurrence. Patients who demonstrated presence of persistent disease at 3-months, in either arm, underwent a TURBT and continued for long-term follow-up for evidence of recurrence. The primary endpoint of the study is disease-free survival. Learn more about the ATLAS trial at www.clinicaltrials.gov (NCT04688931).

About UroGen Pharma Ltd.

UroGen is a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers because patients deserve better options. UroGen has developed RTGel® reverse-thermal hydrogel, 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. JELMYTO® (mitomycin) for

pyelocalyceal solution and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit www.urogen.com to learn more or follow us on Twitter, @UroGenPharma.

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, without limitation, statements regarding: the potential for UGN-102 to be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries; the expected timing for additional data evaluating the secondary endpoint of duration of response from ENVISION; the anticipated submission of an NDA for UGN-102 in 2024; and the potential of UroGen's proprietary RTGel technology to improve therapeutic profiles of existing drugs and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen'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; UroGen's ability to attract or retain key management, members of the board of directors and personnel; UroGen's RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; UroGen's financial condition and need for additional capital in the future. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 filed with the SEC in May 11, 2023 (which is 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.

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