New Patient-Reported Outcomes from UGN-102 Clinical Trials Show the Investigational Treatment Did Not Adversely Affect Functionality, Symptom Burden, and Quality of Life in Patients with LG-IR-NMIBC

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- New analysis of patient-reported outcomes from the OPTIMA II, ATLAS and ENVISION studies of UGN-102 presented at the American Urological Association (AUA) 2025 Annual Meeting in Las Vegas, Nevada

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 27, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced patient-reported outcomes following treatment of patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) that showed investigational drug UGN-102 (mitomycin) for intravesical solution achieved robust and durable complete response (CR) rates without negatively impacting quality of life. The data (Moderated Poster - MP15) were presented at the AUA 2025 Annual Meeting in Las Vegas, Nevada.

“Patient reported quality of life outcomes are critical in evaluating the usefulness of investigational drugs, particularly when delivered in the bladder which frequently causes urinary symptoms,” said Charles Peyton, M.D., Assistant Professor, University of Alabama, Department of Urology, Heersink School of Medicine and study investigator. “Aggregated quality of life data across three robust clinical trials suggests that UGN-102 is quite tolerable without negatively impacting symptom burden, patient function or quality of life compared to baseline. UGN-102, if approved, is a promising alternative intravesical treatment for patients with LG-IR-NMIBC.”

In the OPTIMA II, ATLAS, and ENVISION late-phase studies, most patients (≥91% in ATLAS, ≥94% in ENVISION) completed the questionnaires at baseline, three months, and 12 months or study end. Baseline scores indicated high levels of functioning and low symptom burden prior to treatment. UGN-102 did not cause sustained declines in functioning or symptom burden, and no measured domains or items exceeded the threshold for clinically significant worsening at three or 12 months, suggesting no negative impact on quality of life.

“The patient-reported outcomes data showed that UGN-102 did not adversely impact quality of life while achieving high response rates in LG-IR-NMIBC patients,” said Mark Schoenberg M.D., Chief Medical Officer, UroGen. “We’re pleased to hear directly from patients, as their experiences highlight the importance of advancing treatment options that have the potential to reduce the burden of this challenging disease. These findings reinforce our commitment to developing solutions that make a meaningful difference in patients' lives.”

In the Phase 2b OPTIMA II and Phase 3 ENVISION studies, patients received UGN-102, while in the Phase 3 ATLAS trial, patients were randomized to UGN-102 or trans-urethral resection of bladder tumor (TURBT); this analysis includes only data from UGN-102-treated patients. Each study featured a six-week UGN-102 treatment period, a CR assessment at three months, and follow-up ranging from nine to 63 months after three-month CR. Patient-reported symptoms and health status were evaluated using the EORTC-QLQ-NMIBC24 at baseline, three months, and 12 months or study end. Scores, ranging from one (not at all) to four (very much), were transformed to a 0-100 scale, with higher scores indicating greater symptom burden. Descriptive statistics were used to summarize baseline scores and changes, with positive changes reflecting symptom worsening.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of recurrent 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 by a trained healthcare professional. UroGen completed the submission of the rolling new drug application (NDA) for UGN-102 in August 2024, ahead of schedule. The FDA accepted the NDA for UGN-102 and assigned a Prescription Drug User Free Act (PDUFA) goal date of June 13, 2025.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

LG-IR-NMIBC affects around 82,000 people in the U.S. every year, and of those, an estimated 59,000 are recurrent. Bladder cancer primarily affects older populations with increased risk of comorbidities, with the median age of diagnosis being 73 years. Guideline recommendations for the management of NMIBC include TURBT as the standard of care. Up to 70 percent of NMIBC patients experience at least one recurrence and LG-IR-NMIBC patients are even more likely to recur and face repeated TURBT procedures.

About ENVISION

The Phase 3 ENVISION trial is a single-arm, multinational, multicenter pivotal study evaluating the efficacy and safety of UGN-102 (mitomycin) for intravesical solution as a chemoablative therapy in patients with LG-IR-NMIBC. The Phase 3 ENVISION trial completed target enrollment with 240 patients across 56 sites. Study participants received six once-weekly intravesical instillations of UGN-102. The primary endpoint evaluated the CR rate at the three-month assessment after the first instillation, and the key secondary endpoint evaluated durability over time in patients who achieved a CR at the three-month assessment. Learn more about the Phase 3 ENVISION trial at www.clinicaltrials.gov (NCT05243550).

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 the 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. Our first product to treat low-grade upper tract urothelial cancer and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with LG-IR-NMIBC 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 X (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: conclusions from the OPTIMA II, ATLAS and ENVISION data; the estimated patient population and demographics for LG-IR-NMIBC, and the significance of the unmet needs; the potential benefits to patients and opportunities for UGN-102, if approved; the potential for UGN-102 to deliver robust CR rates and duration of response in patients with LG-IR-NMIBC, without significant negative effects on symptom burden, patient function, or quality of life; statements related to UroGen's NDA submission and the expected PDUFA goal date for UGN-102; 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. Words such as "anticipate," "indicate," "potential," "promise," "suggest," or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. 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; the types, severity and treatability of TEAs that occur during clinical trials; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; even though the NDA for UGN-102 has been accepted for filing by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; the PDUFA goal date may be delayed due to various factors outside UroGen's control; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; the ability to obtain and 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 other personnel; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; and UroGen's *RTGel* technology may not perform as expected. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Annual Report on Form 10-K for the year ending December 31, 2024, filed with the SEC on March 10, 2025. 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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