UroGen Announces Updated 18-Month Duration of Response (DOR) of 80.6% from the Phase 3 ENVISION Trial of UGN-102, an Investigational Treatment for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

April 26, 2025

- 18-month DOR of 80.6% by Kaplan-Meier estimate was attained in patients who achieved a complete response (CR) at three months (79.6%)
- Data unveiled during a Podium Presentation at the American Urological Association (AUA) 2025 Annual Meeting in Las Vegas, Nevada

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 26, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced an updated 18-month DOR of 80.6% (95% CI: 74.0, 85.7), by Kaplan-Meier estimate, from the Phase 3 ENVISION trial of UGN-102 (mitomycin) for intravesical solution, an investigational treatment for recurrent LG-IR-NMIBC. These data were featured today in an Oral Presentation Session (Abstract ID: PD12) at the AUA 2025 Annual Meeting in Las Vegas, Nevada.

“This new update from the pivotal ENVISION trial of UGN-102 demonstrated a compelling probability of remaining in complete response of 80.6% at 18 months in patients who achieved a complete response (CR) at three months (79.6%)," said Sandip Prasad M.D., M.Phil., Director of Genitourinary Surgical Oncology, Vice Chair of Urology at Morristown Medical Center/Atlantic Health System, NJ, and Principal Investigator of the ENVISION trial. “Low-grade bladder cancer is a persistent cancer that frequently recurs and comes with its own risks. There is a significant unmet need in finding treatment options for patients with recurrent low-grade bladder cancer.”

The existing standard of care for LG-IR-NMIBC is an invasive surgical procedure requiring anesthesia called transurethral resection of bladder tumor (TURBT). Repeated TURBT procedures can impact patients’ physical health and quality of life and are even associated with an increased risk in mortality. Due to high recurrence rates, LG-IR-NMIBC patients, who are typically elderly with comorbidities, will likely need multiple TURBTs under general anesthesia over the course of their lifetime. An estimated 59,000 patients with LG-IR-NMIBC recur annually and face the burden and risks of repeat surgeries that often provide limited value.

Mark Schoenberg, M.D., Chief Medical Officer of UroGen, stated, "The duration of response data from the ENVISION trial further underscores UGN-102’s potential to positively impact the treatment landscape for patients with recurrent LG-IR-NMIBC. Many of these patients are elderly and face the burden of repeated surgeries under general anesthesia, highlighting the urgent need for innovative treatment options. If approved, we believe UGN-102’s potential to deliver durable complete responses, reduce recurrence rates, and extend treatment-free intervals would represent a significant advancement in the management of recurrent LG-IR-NMIBC."

The most common treatment-emergent adverse events (TEAEs) in the ENVISION trial were dysuria, hematuria, urinary tract infection, pollakiuria, fatigue, and urinary retention. The TEAEs were typically mild-to-moderate in severity and either resolved or were resolving. The ENVISION trial demonstrated a similar safety profile to that observed in other studies of UGN-102. Median follow-up time at 18 months was 18.7 months after the three-month CR.

UroGen completed the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for UGN-102 as a treatment for LG-IR-NMIBC ahead of schedule, and the FDA accepted the NDA for UGN-102 with a Prescription Drug User Free Act (PDUFA) goal date of June 13, 2025.

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 NDA for UGN-102 in August 2024, ahead of schedule. The FDA accepted the NDA for UGN-102 and assigned a 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 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, including the potential to deliver durable complete responses, reduce recurrence rates, and extend treatment-free intervals; 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 "believe," "potential," "will," "would," 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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