UroGen Announces Data at ASCO 2025 Annual Meeting on UGN-102, an Investigational Treatment for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

June 2, 2025

- Presents 18-month duration of response (DOR) data from the ENVISION study
- Analyzes the impact of tumor burden or focality in recurrent LG-IR-NMIBC, a substudy from ENVISION
- Reports ENVISION and ATLAS complete response and DOR data

PRINCETON, N.J.--(BUSINESS WIRE)--Jun. 2, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced results from the ENVISION and ATLAS clinical studies exploring investigational therapy UGN-102 (mitomycin) for intravesical solution for the treatment for recurrent low-grade intermediate-risk non-muscle invasive bladder cancer. The data are featured at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

UGN-102 data featured at ASCO:

- Duration of Response (DOR) Following Treatment with UGN-102 in Patients with Recurrent, Low-Grade, Intermediate-Risk, Non-Muscle Invasive, Bladder Cancer: 18-Month DOR Data from the Phase 3 ENVISION Trial: Abstract #4598, Poster #398
- Impact of Tumor Burden or Focality in Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer on Response to Treatment with UGN-102: A Substudy of the Phase 3 ENVISION Trial: Abstract #4597, Poster #397
- Treatment of Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer with UGN-102: Results of the Phase 3 ATLAS and ENVISION Studies. Published Abstract 501822

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 administered 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 U.S. Food and Drug Administration (FDA) accepted the NDA for UGN-102 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 13, 2025. On May 21, 2025, an Oncologic Drugs Advisory Committee (ODAC) of the FDA voted 4 to 5 that the benefit/risk of UGN-102 (mitomycin) for intravesical solution was favorable for the treatment of recurrent LG-IR-NMIBC. See "Forward-Looking Statements" below.

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 trans-urethral resection of bladder tumor (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. Learn more about non-muscle invasive bladder cancer at www.BladderCancerAnswers.com.

About ENVISION

The Phase 3 ENVISION trial is an ongoing, single-arm, multinational, multicenter 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 three months after the first instillation, and the key secondary endpoint evaluates 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. UroGen's first product to treat low-grade upper tract urothelial cancer and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with recurrent 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: UroGen's UGN-102 NDA and expected PDUFA target action date; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; the potential benefits to patients and opportunities for UGN-102, if approved; 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 “potential,” “target” 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; 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; an ODAC voted 4 to 5 that the benefit/risk of UGN-102 (mitomycin) for intravesical solution was favorable for the treatment of recurrent LG-IR-NMIBC, and although the FDA is not bound by the ODAC’s recommendation, the recommendation may adversely impact the FDA’s decision on the NDA for UGN-102; the PDUFA target action 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 within the timeframe expected, or at all; complications associated with commercialization activities; labeling limitations; competition in UroGen’s industry; the scope, progress and expansion of developing and commercializing UroGen’s product and 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 or procedures, such as surgery; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 12, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250602560792/en/

INVESTOR CONTACT:
Vincent Perrone
Senior Director, Investor Relations
vincent.perrone@urogen.com
609-460-3588 ext. 1093

MEDIA CONTACT:
Cindy Romano
Director, Communications
cindy.romano@urogen.com
609-460-3583 ext. 1083

Source: UroGen Pharma Ltd.