UroGen Announces Outcome of Oncologic Drugs Advisory Committee for UGN-102 for the Treatment of Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

May 21, 2025

PRINCETON, N.J.--(BUSINESS WIRE)--May 21, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a leading biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, announced the outcome of today's meeting of the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA), which discussed the new drug application (NDA) for investigational drug UGN-102 (mitomycin) for intravesical solution. By a narrow margin, the 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.

"While we are disappointed by today's outcome, we continue to believe our clinical data support UGN-102 for the treatment of recurrent LG-IR-NMIBC, a disease with no FDA-approved therapies," said Liz Barrett, President and CEO of UroGen. "The FDA carefully considers the independent advice from ODAC, and we look forward to working with the FDA as they complete their review of the application for UGN-102."

The ODAC reviewed the body of clinical data supporting the efficacy and safety of UGN-102, including the results from the Phase 3 ENVISION study. "Low-grade intermediate-risk non-muscle invasive bladder cancer is a highly recurrent disease and often requires patients – many of whom are elderly – to undergo repeat surgeries under general anesthesia. This is a disease with high unmet needs, and we believe patients deserve more options," said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. "UroGen remains committed to developing innovative treatment options to people living with recurrent LG-IR-NIMBC."

The most common treatment-emergent adverse events in the ENVISION trial were dysuria, hematuria, urinary tract infection, pollakiuria, fatigue, and urinary retention, which are typically manageable in routine urologic practice. The ENVISION trial demonstrated a similar safety profile to that observed in other studies of UGN-102.

The NDA for UGN-102 is currently under review by the FDA with a Prescription Drug User Fee Act (PDUFA) 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 target action 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 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 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 three months 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. 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: the potential for UGN-102 as the first and only FDA-approved treatment for recurrent LG-IR-NMIBC; statements related to 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 patient benefits 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 "expect," "if," "potential," or other words that convey uncertainty of future events or outcomes 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 ability to obtain regulatory approval within the timeframe expected, or at all; 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's *RTGel* technology may not perform as expected; and UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology. 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/20250521737507/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
908-963-7827

Source: UroGen Pharma Ltd.