# UroGen Announces New Data Presentations at the Society of Urologic Oncology 2024 Annual Meeting Highlighting Urothelial Cancer Portfolio Aimed at Addressing Unmet Needs

December 2, 2024

PRINCETON, N.J.--(BUSINESS WIRE)--Dec. 2, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that new data on UGN-102 (mitomycin) for intravesical solution, JELMYTO (mitomycin) for pyelocalyceal solution, and UGN-301(zalifrelimab intravesical solution) will be presented at the Society of Urologic Oncology (SUO) 2024 annual meeting being held in Dallas, Texas from December 4 – 6.

"We are excited that the SUO has accepted data highlighting the potential of our investigational treatment, UGN-102, in development for patients with low-grade, intermediate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC), as well as the ongoing clinical value of JELMYTO for treating low-grade upper tract urothelial carcinoma (LG-UTUC)," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "These presentations underscore our ongoing commitment to addressing the critical unmet needs of patients with urothelial cancers, as well as our mission to provide innovative treatment options that seek to improve both outcomes and quality of life for those battling these challenging conditions."

Key details of UGN-102, JELMYTO and UGN-301 abstracts accepted by SUO:

| Abstract Title | Schedule | Presenter |
|---|---|---|
| **PRIMARY CHEMOABLATION OF RECURRENT LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE-INVASIVE BLADDER CANCER WITH UGN-102: A SINGLE-ARM, OPEN-LABEL, PHASE 3 TRIAL (ENVISION)** | Poster 121<br>Date: 12/5<br>Time: 2:15-3:15 pm CT | Dr. Max Kates |
| **LONG-TERM OUTCOMES OF PRIMARY CHEMOABLATION OF LOW-GRADE UPPER TRACT UROTHELIAL CARCINOMA (LG-UTUC) WITH UGN-101, A MITOMYCIN REVERSE THERMAL GEL** | Poster 122<br>Date: 12/5<br>Time: 2:15-3:15 pm CT | Dr. Brian Hu |
| **HOME INSTILLATION OF UGN-102 FOR PRIMARY CHEMOABLATION OF RECURRENT LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE-INVASIVE BLADDER CANCER: A SINGLE-ARM, OPEN-LABEL, PHASE 3B TRIAL** | Poster 124<br>Date: 12/5<br>Time: 2:15 – 3:15 pm CT | Dr. Vincent Michael Bivins |
| **A PHASE 1 DOSE-ESCALATION STUDY OF UGN-301 (ZALIFRELIMAB) IN PATIENTS WITH RECURRENT NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)** | Poster 133<br>Date: 12/5<br>Time: 2:15 – 3:15 pm CT | Caretha L. Creasy |
| **A PHASE 1 DOSE-ESCALATION STUDY OF UGN-301 (ZALIFRELIMAB) AS MONOTHERAPY AND IN COMBINATION WITH OTHER AGENTS IN PATIENTS WITH RECURRENT NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)** | Poster 206<br>Date: 12/6<br>Time: 10:00 – 11:00 am CT | Caretha L. Creasy |

For further information about UroGen's ongoing clinical trials and programs, please visit our website at urogen.com to learn more or follow us on X (Twitter), @UroGenPharma.

**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 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 NDA submission in August, ahead of schedule. The FDA accepted the NDA for UGN-102 and assigned a PDUFA goal date of June 13, 2025.

**About JELMYTO**

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel indicated for the treatment of adult patients with LG-UTUC. It is recommended for primary treatment of biopsy-proven LG-UTUC in patients deemed appropriate candidates for renal-sparing therapy. JELMYTO is a viscous liquid when cooled and becomes a semi-solid gel at body temperature. The drug slowly dissolves over four to six hours after instillation and is removed from the urinary tract by normal urine flow and voiding. It is approved for administration in a retrograde manner via ureteral catheter or antegrade through nephrostomy tube. The delivery system allows the initial liquid to coat and conform to the upper urinary tract anatomy. The eventual semisolid gel allows for chemoablative therapy to remain in the collecting system for four to six hours without immediately being diluted or washed away by urine flow.

**UGN-301**

UGN-301 is our investigational, in-licensed, anti-CTLA-4 monoclonal antibody (zalifrelimab), prepared with reverse-thermal hydrogel for intravesical administration into the bladder. Intravesical administration of UGN-301 is designed to increase drug concentrations in the bladder without significant systemic exposure, potentially diminishing the systemic toxicity associated with CTLA-4 blockade. UroGen is evaluating UGN-301 as combination

therapy for the intravesical treatment of high-grade NMIBC.

**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 LG-UTUC 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 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 benefits of UGN-102 and UGN-301; the future development of UGN-301; 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: our development plans for UGN-301 may change for a variety of reasons, including data and other program considerations; 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 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 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 September 30, 2024, filed with the SEC on November 6, 2024 (which is available at 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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