



UroGen Announces Data Presentations at the American Urological Association 2025 Annual Meeting Highlighting Emerging Evidence Supporting Our Portfolio for Urothelial Cancers

April 14, 2025

- 18-month duration of response (DOR) data from ENVISION, and integrated patient-reported outcomes (PROs) from UGN-102-treated patients in OPTIMA II, ATLAS and ENVISION in low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)
- Long-term outcomes from the OPTIMA II Phase 2B study of UGN-102
- Sub-analysis from a long-term follow-up study to the OLYMPUS trial of JELMYTO® (mitomycin) for pyelocalyceal solution
- Results of a Phase 1 dose escalation study for UGN-301

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 14, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that data on investigational drug UGN-102 (mitomycin) for intravesical solution, JELMYTO (mitomycin) for pyelocalyceal solution and UGN-301 (zalifrelimab) will be presented at the American Urological Association (AUA) 2025 Annual Meeting being held in Las Vegas, Nevada from April 26-29.

"We are thrilled to present the 18-month DOR data on UGN-102, along with additional data on JELMYTO and our investigational drug UGN-301 (zalifrelimab) an anti-CTL4 antibody in development for the treatment of recurrent non-muscle invasive bladder cancer, at the AUA Annual Meeting," said Mark Schoenberg, Chief Medical Officer, UroGen. "These data highlight the potential of our portfolio to offer significant advancements in the treatment of urothelial cancers."

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

UGN-102		
Abstract Title	Presentation Details	Presenter
Treatment of recurrent low-grade intermediate-risk non-muscle invasive bladder cancer with UGN-102: ongoing results from a single-arm, open-label, phase 3 trial (ENVISION)	Podium Oral Presentation: Abstract ID: PD12 - Galileo 1001 Saturday, April 26, 2025 3:30 PM - 5:30 PM	Dr. Sandip Prasad
Patient-reported side-effect burden for patients with low-grade intermediate-risk non-muscle invasive bladder cancer receiving treatment with UGN-102 (UGN-102 Integrated PROs)	Moderated Poster - MP15 Marco Polo 703 Sunday, April 27, 2025 9:30 AM - 11:30 AM	Dr. Charles Peyton
Treatment of low-grade intermediate-risk non-muscle invasive bladder cancer with UGN-102: long-term outcomes of the (OPTIMA II LT study)	Moderated Poster - MP15 – Marco Polo 703 Sunday, April 27, 2025 9:30 AM - 11:30 AM	Dr. Neal Shore
JELMYTO		
Long-term outcomes of treatment of recurrent or new-onset low-grade upper tract urothelial carcinoma with UGN-101, a mitomycin reverse thermal gel (OLYMPUS LT)	Interactive poster - IP12 – Casanova 501 Sunday, April 27, 2025 1:00 PM - 3:00 PM (IP12)	Dr. Brian Hu
UGN-301		
Treatment of recurrent non-muscle invasive bladder cancer with UGN-301 (zalifrelimab): results of a phase 1 dose-escalation study (UGN-301-MONO)	Interactive Poster - IP02 – Marco Polo 701 Saturday, April 26, 2025 7:00 AM - 9:00 AM	Dr. Jay Raman

UroGen is a Founders' Circle Sponsor of the AUA Innovation Nexus Conference

UroGen's President and Chief Executive Officer, Liz Barrett, will participate in a Showcase Panel discussion on April 25, alongside exciting urology startups that span the globe and are developing products—devices, artificial intelligence platforms, diagnostic tests, etc.—covering a variety of urologic issues such as prostate and bladder cancer, kidney injuries, fertility testing, nocturnal enuresis, overactive bladder, and interstitial cystitis. Liz will also take part in the Founders' Circle Awards Presentation.

The AUA Innovation Nexus is a powerful forum to advance urologic discovery to solutions that improve patient care and save lives. Register here: <https://auanexus.org/innovation-nexus-conference/registration>

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 *RTGe*® 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 Fee Act (PDUFA) goal date of June 13, 2025.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

In the U.S., bladder cancer is the second most common urologic cancer in men. LG-IR-NMIBC represents approximately 23,000 newly diagnosed bladder cancer patients each year and an estimated 59,000 recurrences annually among patients diagnosed in previous years. 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.

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.

About 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 a monotherapy and as combination therapy for the intravesical treatment of high-grade NMIBC. UroGen is evaluating UGN-301, in a multi-arm Phase 1 study of UGN-301 as monotherapy and in combination with other agents.

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 *RTGe*® 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. To learn more visit www.urogen.com or follow us on X (Twitter), @UroGenPharma.

APPROVED USE FOR JELMYTO

JELMYTO® is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

IMPORTANT SAFETY INFORMATION

You should not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. JELMYTO can harm your unborn baby. You should not become pregnant during treatment with JELMYTO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JELMYTO. **Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with JELMYTO and for 6 months after the last dose. **Males being treated with JELMYTO:** If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO and for 1 week after the last dose.
- **Tell your healthcare provider if you take water pills (diuretic).**

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment.
- You will receive your JELMYTO dose from your healthcare provider 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. Your healthcare provider may recommend up to an additional 11 monthly doses.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 6 hours.
- To urinate, **males and females should sit** on a toilet and flush the toilet several times after you use it. After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.
- Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you

develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.

- **Bone marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.
- **The most common side effects of JELMYTO include:** urinary tract infection, blood in your urine, side pain, nausea, trouble with urination, kidney problems, vomiting, tiredness, stomach (abdomen) pain.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1800FDA1088. You may also report side effects to **UroGen Pharma** at 1-855-987-6436.

Please see JELMYTO Full Prescribing Information, including the Patient Information, for additional information.

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 UroGen's portfolio to offer significant advances in the treatment of urothelial cancers; statements related to UroGen's NDA submission, and expected PDUFA goal date for UGN-102; statements regarding our ongoing clinical studies of UGN-301; [and] the estimated patient population and demographics for LG-IR-NMIBC; the potential of UroGen's proprietary *RTGeI* 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," "potential," "prepare," "will," 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 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; the ability to obtain regulatory approval within 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) for UroGen's product and product candidates 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 personnel; UroGen's *RTGeI* technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGeI* technology; and UroGen's financial condition and need for additional capital in the future. 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250414098016/en/): <https://www.businesswire.com/news/home/20250414098016/en/>

INVESTOR CONTACT:

Vincent Perrone
Senior Director, Investor Relations
vincent.perrone@UroGen.com
609-460-3588 ext. 1093

MEDIA CONTACT:

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

Source: UroGen Pharma Ltd.