# UroGen Reports 94.5% Six-Month Duration of Response in Phase 3 UTOPIA Trial, Advancing UGN-103 Toward Potential Approval in Recurrent Low-Grade Intermediate-Risk NMIBC

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PRINCETON, N.J., May 15, 2026 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotechnology company focused on transforming the treatment of urothelial and specialty cancers, today announced UGN-103 achieved a 94.5% (95% CI: 86.1, 97.9) durability of response (DOR) at six months by Kaplan-Meier estimate, in the ongoing Phase 3 UTOPIA trial of UGN-103 (mitomycin) for intravesical solution in patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The six-month results from UTOPIA are generally consistent with the 91.9% (95% CI: 86.9, 95.0) six-month DOR observed with ZUSDURI™ (mitomycin) for intravesical therapy in its pivotal ENVISION trial. ZUSDURI is the first and only treatment approved by the U.S. Food and Drug Administration (FDA) for adult patients with recurrent LG-IR-NMIBC.

Based on the consistency of UTOPIA data with the results of the ENVISION trial studying ZUSDURI in patients meeting the same eligibility criteria and alignment with the FDA, UroGen remains on track to submit a New Drug Application (NDA) for UGN-103 in the third quarter of 2026.

“The durability of response observed at six months with UGN-103 in the UTOPIA trial is generally consistent with that observed in the pivotal ENVISION trial of ZUSDURI, and highlights the potential to further advance care for adult patients with recurrent LG-IR-NMIBC,” said Abishek Srivastava, MD, Urologic Oncologist at Atlantic Urology Clinics, Myrtle Beach, SC, START Center for Cancer Research, Carolinas and lead investigator of the UTOPIA trial. “UGN-103 builds on a proven therapeutic approach with meaningful innovations that could help enhance how we deliver this therapy in clinical practice.”

UGN-103 is designed to build on the clinical and commercial foundation of ZUSDURI. The benefits of UGN-103 include a more streamlined manufacturing process and simplified reconstitution, while preserving the innovative and proven *RTGel*® technology that enables sustained drug exposure at tumor sites in the bladder.

“These clinical data reinforce the potential of UGN-103 to become a new standard of care for adult patients with recurrent LG-IR-NMIBC,” said Liz Barrett, President and Chief Executive Officer of UroGen. “With FDA alignment on our regulatory path, we are advancing with urgency toward NDA submission. We believe UGN-103 represents a significant opportunity to build on our leadership in uro-oncology, expand our commercial portfolio, and drive long-term growth.”

UroGen holds U.S. patents covering the combination of its proprietary *RTGel* technology with medac’s licensed lyophilized mitomycin formulation, as well as the use of UGN-103 in LG-IR-NMIBC, with intellectual property protection expected to extend into December 2041.

**About UTOPIA**

The UTOPIA trial is a single-arm, multicenter study evaluating the efficacy and safety of UGN-103 in 99 patients across global sites. Enrolled patients received 75 mg of UGN-103 via intravesical instillation in an outpatient setting once weekly for six weeks. The primary endpoint is CR rate at three months, with responders entering a follow-up phase of up to 12 months to assess DOR. For more information on the UTOPIA study, please visit https://clinicaltrials.gov/study/NCT06331299.

**About UGN-103**
In January 2024, UroGen entered into a licensing and supply agreement with medac to develop UGN-103 for recurrent LG-IR-NMIBC. UGN-103 is designed to reinforce and extend the clinical and commercial profile of ZUSDURI, the first and only FDA-approved treatment for adults with recurrent LG-IR-NMIBC. The program maintains UroGen’s innovative and proven *RTGel* technology, enabling sustained mitomycin exposure in the bladder, while incorporating next-generation enhancements, including a more streamlined manufacturing process and simplified reconstitution to support improved ease of use in clinical practice. UroGen holds U.S. patents covering the combination of its proprietary *RTGel* technology with medac’s licensed lyophilized mitomycin formulation, as well as the use of UGN-103 in LG-IR-NMIBC, with intellectual property protection expected to extend into December 2041.

**About ZUSDURI**

ZUSDURI (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin approved for the treatment of adults with recurrent LG-IR-NMIBC. Utilizing UroGen’s proprietary *RTGel* technology (a sustained release, hydrogel-based formulation), ZUSDURI is delivered directly into the bladder by a trained healthcare professional using a urinary catheter in an outpatient setting, thereby enabling the treatment of tumors by non-surgical means.

**About Non-Muscle Invasive Bladder Cancer (NMIBC)**
LG-IR-NMIBC affects around 82,000 people in the United States 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 transurethral 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 NMIBC at **www.BladderCancerAnswers.com**.

**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 is approved to treat low-grade upper tract urothelial cancer, and our second product, ZUSDURI (mitomycin) for intravesical solution, is approved for adult patients with recurrent LG-IR-NMIBC. Both products 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, @UroGenPharma.

**About medac CDMO**
The belief that health is humanity's most valuable resource drives medac group. Since 1970, the mission of medac has been to improve patients' quality of life worldwide by making the best medical treatments available. Since 2000, medac has been dedicated to improving patient outcomes globally by supporting pharmaceutical companies in bringing the best medical treatments to market. As a trusted Contract Development and Manufacturing Organization (CDMO), headquartered in Germany, medac CDMO is specialised in providing customised, high-quality services to customers and worldwide markets.

With a team of over 2,000 highly skilled professionals, medac CDMO offers comprehensive solutions tailored to the needs of clients worldwide. The cutting-edge facilities of medac group in Germany and the Czech Republic are equipped with the latest technologies to ensure precision, efficiency and compliance with the most stringent industry standards. From early-stage development to large-scale commercial production, medac CDMO is committed to foresight, progress, reliability and creative thinking which makes them a solution ahead.

The deep expertise, commitment to quality and flexible manufacturing capabilities enable medac CDMO to serve as a trusted partner for pharmaceutical and biotech companies looking to scale their operations and bring life-changing treatments to patients around the globe.

For more information, please visit www.medac-cdmo.com.

**APPROVED USE FOR ZUSDURI**
ZUSDURI (mitomycin) for intravesical solution is a prescription medicine used to treat adults with a type of cancer of the lining of the bladder called low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) after previously receiving bladder surgery to remove tumor that did not work or is no longer working.

**IMPORTANT SAFETY INFORMATION**

**You should not receive ZUSDURI if you** have a hole or tear (perforation) of your bladder or if you have had an allergic reaction to mitomycin or to any of the ingredients in ZUSDURI.

**Before receiving ZUSDURI, tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems
- are pregnant or plan to become pregnant. ZUSDURI can harm your unborn baby. You should not become pregnant during treatment with ZUSDURI. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZUSDURI.

**Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with ZUSDURI and for 6 months after the last dose.

**Males being treated with ZUSDURI:** You should use effective birth control (contraception) during treatment with ZUSDURI and for 3 months after the last dose.

- are breastfeeding or plan to breastfeed. It is not known if ZUSDURI passes into your breast milk. Do not breastfeed during treatment with ZUSDURI and for 1 week after the last dose.

**How will I receive ZUSDURI?**

- You will receive your ZUSDURI dose from your healthcare provider 1 time a week for 6 weeks into your bladder through a tube called a urinary catheter. It is important that you receive all 6 doses of ZUSDURI according to your healthcare provider's instructions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.
- During treatment with ZUSDURI, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

**After receiving ZUSDURI:**

- ZUSDURI may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 24 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.

**The most common side effects of ZUSDURI include:** increased blood creatinine levels, increased blood potassium levels, trouble with urination, decreased red blood cell counts, increase in certain blood liver tests, increased or decreased white blood cell counts, urinary tract infection, and blood in your urine.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

**Please see ZUSDURI 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 the Phase 3 UTOPIA trial to support an NDA submission for UGN-103 and the planned timing thereof; the potential path toward approval of UGN-103 and potential approval thereof; the potential of UGN-103 to advance care for and provide benefits to adult patients with recurrent LG-IR-NMIBC and become a new standard of care; the potential of UGN-103 to build on UroGen's leadership in uro-oncology, expand its commercial portfolio, and drive long-term growth; the potential benefits of UGN-103 as compared to ZUSDURI, including its streamlined manufacturing and reconstitution processes and expected intellectual property protection; the expected duration of intellectual property protection for UGN-103; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; the potential of UroGen's proprietary

*RTGel* technology to improve therapeutic profiles of existing drugs other than mitomycin; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as "believe," "can," "estimated," "expect," "may," "plan," "potential," 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 clinical results may not be indicative of results that may be observed in the future; potential safety and other complications related to UroGen's products and product candidates; risks related to our and our licensors' ability to protect our respective patents and other intellectual property, including the fact that UroGen's or our licensors' pending patent applications may not be successful, and in such event, the duration of intellectual property protection would be more limited; the ability to maintain regulatory approval; complications associated with commercialization activities; labeling limitations; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's products 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 and UroGen's products and product candidates may not perform as expected; the data from the UTOPIA trial may not be sufficient to support approval of UGN-103; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; and the impacts of general macroeconomic and geopolitical conditions on UroGen's business and financial position. 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, 2026, filed with the SEC on May 6, 2026, 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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