UroGen Reports 77.8% Three-Month Complete Response Rate from Phase 3 UTOPIA Trial of UGN-103 and Receives FDA Agreement on NDA Submission Strategy in Recurrent LG-IR-NMIBC Based on UTOPIA Trial

November 6, 2025

PRINCETON, N.J., Nov. 06, 2025 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced robust preliminary results from its ongoing Phase 3 UTOPIA trial, demonstrating a 77.8% three-month complete response (CR) rate (95% CI, 68.3%, 85.5%) with UGN-103 (mitomycin) for intravesical solution in patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). This result is consistent with the 79.6% three-month CR rate (95% CI, 73.9%, 84.5%) observed following treatment with ZUSDURI in the pivotal ENVISION trial. In addition, the U.S. Food and Drug Administration (FDA) agreed that CR and durability results from the UTOPIA trial can support the submission of a New Drug Application (NDA) for UGN-103 for recurrent LG-IR-NMIBC.

"The robust 77.8% three-month CR rate observed in the UTOPIA trial is highly encouraging and reinforces the potential of UGN-103 to deliver meaningful benefits to patients," said Liz Barrett, President and Chief Executive Officer of UroGen. "In addition, the FDA's agreement that the UTOPIA trial can support the submission of an NDA for UGN-103 represents a significant regulatory milestone and a strong validation of our clinical strategy. Together, these achievements give us significant momentum and a clear path toward potential approval, positioning UGN-103 as a key growth driver and marking an important advancement in expanding our leadership in uro-oncology. We look forward to working closely with the FDA as we complete the UTOPIA trial and prepare for an NDA submission in 2026."

UGN-103 is designed to offer key improvements over ZUSDURI (mitomycin) for intravesical solution, the first and only FDA-approved treatment for adults with recurrent LG-IR-NMIBC. These include a shorter manufacturing process and a simplified reconstitution procedure, while maintaining UroGen's established approach that enables prolonged drug exposure within the bladder. UroGen has two U.S. patents with claims relating to the combination of the Company's *RTGel*® technology combined with medac's licensed proprietary lyophilized mitomycin formulation. These patents cover UGN-103 as well as the use of UGN-103 for the treatment of LG-IR-NMIBC and expire in 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 once weekly for six weeks. The primary endpoint is complete response rate at three months, with responders entering a follow-up phase of up to 12 months to assess durability of response. 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 LG-IR-NMIBC. UGN-103 is an innovative mitomycin formulation that aims to streamline manufacturing and reconstitution processes while providing intellectual property coverage until December 2041. It utilizes UroGen's *RTGel*® technology for prolonged mitomycin exposure.

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 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 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 non-muscle invasive bladder cancer 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 benefits to patients and opportunities for UroGen's product candidates, including the potential of UGN-103 to deliver meaningful benefits to patients, as a key growth driver for UroGen, to streamline manufacturing and reconstitution processes and to offer intellectual protection until December 2041; the expected duration of intellectual property protection for UGN-103; UroGen's ongoing UTOPIA clinical trial of UGN-103; the planned NDA submission for UGN-103 and the timing thereof; the belief that UGN-103, if approved, will offer several

improvements over ZUSDURI; the FDA's agreement that the UTOPIA trial can support the submission of an NDA for UGN-103 representing a significant regulatory milestone, a strong validation of UroGen's clinical strategy and giving UroGen a clear path toward potential approval of 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 "can," "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 June 30, 2025, filed with the SEC on August 7, 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.

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