ZUSDURI™ Clinical Review Published in Reviews in Urology™ Highlights Durable Efficacy and Manageable Safety Profile in Recurrent Low-Grade, Intermediate-Risk Non–Muscle Invasive Bladder Cancer

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PRINCETON, N.J., Oct. 02, 2025 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company focused on developing and commercializing innovative solutions for urothelial and specialty cancers, today announced the publication of a comprehensive review of the clinical development program for ZUSDURI™ (mitomycin) for intravesical solution, formerly known as UGN-102, the first and only FDA-approved medicine for adults with recurrent, low-grade, intermediate-risk non–muscle-invasive bladder cancer (LG-IR-NMIBC). The article titled: "*Review of UGN-102: A Reverse Thermal Gel Containing Mitomycin for the Treatment of Recurrent, Low-Grade, Intermediate-Risk Non-Muscle Invasive Bladder Cancer*" is published in the peer-reviewed journal *Reviews in Urology* ™, the official journal of LUGPA.

"ZUSDURI is an FDA-approved, non-surgical treatment that has consistently demonstrated robust, clinically significant, and durable complete responses in patients with recurrent LG-IR-NMIBC," said publication author and ENVISION principal investigator Sandip Prasad, M.D., M.Phil., Director of Genitourinary Surgical Oncology and Vice Chair of Urology at Morristown Medical Center/Atlantic Health System, NJ. "With an acceptable safety profile manageable in routine urologic practice, ZUSDURI is administered in an outpatient setting without the need for general anesthesia. This review article highlights the clinical evidence supporting ZUSDURI's role as an innovative option for patients with recurrent LG-IR-NMIBC."

Key Highlights from the Review:

- High Complete Response Rates: Across late-stage clinical trials (OPTIMA II, ATLAS, and ENVISION), UGN-102 demonstrated complete response (CR) rates between 64.8% and 79.6% at three months.
- Durable Disease Response: In the ENVISION trial, 80.6% of patients remained disease-free at 18 months following CR. Among the 41 patients who achieved CR in the OPTIMA II study, the median duration of response (DOR) was 24.2 months; among the 17 patients in the long-term follow-up study, the median DOR was 42.1 months. The median follow-up for the 17 patients in the long-term follow-up study was 50.4 months.
- Manageable Safety Profile: Adverse events were primarily localized to the lower urinary tract. The most common (≥10%) adverse reactions (ARs) with ZUSDURI, including laboratory abnormalities, that occurred in patients were dysuria, increased potassium, increased creatinine, decreased hemoglobin, increased eosinophils, increased aspartate aminotransferase, increased alanine aminotransferase, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria. ARs were mainly mild to moderate. Serious ARs occurred in 12% of patients, including urinary retention (0.8%) and urethral stenosis (0.4%).
- No Adverse Impact from Patient-Reported Outcomes: Clinical trials show that ZUSDURI did not adversely affect functionality, symptom burden, and quality of life in patients with LG-IR-NMIBC.

"This comprehensive review clearly explains the body of evidence supporting ZUSDURI as an innovative treatment option for patients with recurrent LG-IR-NMIBC," said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. "By offering a non-surgical and durable solution, ZUSDURI represents a major advance in the way we care for these patients."

The clinical development program for ZUSDURI includes three late-phase clinical trials that investigated the safety and efficacy of ZUSDURI in patients with LG-IR-NMIBC: OPTIMA II, ATLAS, and ENVISION.

The newly diagnosed and recurrent patients with LG-IR-NMIBC included in the ZUSDURI clinical development program tended to be elderly (median ages 67-70 years across the studies). They also had a relatively high disease burden, with 60.3-82.8% having multiple tumors, 18.6-49.3% having aggregate tumor size greater than 3 cm, and 24.6-51.7% having LG recurrence within the year prior to their current diagnosis.

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 ENVISION
The Phase 3 ENVISION trial is a single-arm, multinational, multicenter pivotal study evaluating the efficacy and safety of ZUSDURI (mitomycin) for intravesical solution as a chemoablative therapy in adult patients with recurrent 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 ZUSDURI. The primary endpoint evaluated the CR rate at three months after the first instillation, and the key secondary endpoint evaluates 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 the Phase 2b OPTIMA II Trial

OPTIMA II (OPTimized Instillation of Mitomycin for Bladder Cancer Treatment) was an open-label, single-arm, multi-center Phase 2b clinical trial of ZUSDURI evaluating the safety and efficacy in patients with LG-IR-NMIBC. The trial enrolled 63 patients across 20 sites in the US and Israel. Learn more about the OPTIMA II trial at www.clinicaltrials.gov (NCT03558503).

About ATLAS

ATLAS was a global, open-label, randomized controlled Phase 3 trial designed to assess the efficacy and safety of UGN-102, with or without TURBT, vs. TURBT alone in patients diagnosed with LG-IR-NMIBC. The trial enrolled 282 patients in clinical sites in the U.S., Europe and Israel. UroGen halted patient enrollment in the ATLAS study in November 2021 to shift to an alternative development strategy, primarily focusing on the pivotal ENVISION trial for ZUSDURI. Learn more about the ATLAS trial at www.clinicaltrials.gov (NCT04688931).

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 our first product and ZUSDURI 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.

IMPORTANT SAFETY INFORMATION
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 of ZUSDURI, including as an innovative, outpatient treatment option, its safety profile, its potential to provide durable CRs and clinically meaningful recurrence-free intervals and as a compelling alternative to TURBT; 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," "estimate," "likely," "may," "potential," "up to," "will" 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: clinical results may not be indicative of results that may be observed in the future, including in larger populations; potential safety and other complications related to UroGen's products; risks related to our and our licensors' ability to protect our respective patents and other intellectual property; 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 ZUSDURI may not perform as expected; new data relating to ZUSDURI, including from spontaneous adverse event reports and from the ongoing ENVISION trial, may result in changes to the product label and may adversely effect sales, or result in withdrawal of ZUSDURI from the market; the potential for payors to delay, limit or deny coverage for ZUSDURI; 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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