UroGen Announces Five-Year Long-Term Extension Study of the OPTIMA II Trial Demonstrates Long-Term Durability of Response to ZUSDURI™ in Patients with Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

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- *Findings published in the journal of Clinical Genitourinary Cancer show patients remained event-free for a median of two years after achieving complete response with ZUSDURI (mitomycin) intravesical solution.*
- *Among the 17 patients who achieved complete response and entered a long-term extension study, the median duration of response was 3.5 years by Kaplan-Meier estimate.*

PRINCETON, N.J., July 21, 2025 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions for urothelial and specialty cancers, today announced the publication of results of a five-year long-term extension study of the Phase 2b OPTIMA II trial evaluating ZUSDURI (mitomycin) for intravesical solution in patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) demonstrating durable, long-term complete responses (CRs) in patients who initially achieved a CR following treatment with ZUSDURI. The publication, titled *"Treatment of Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer With UGN-102: Outcomes From the 5-year Long-Term Extension Study of the Single-Arm, Phase 2b OPTIMA II Study"*, is now available online at https://doi.org/10.1016/j.clgc.2025.102392.

"Low-grade intermediate-risk bladder cancer is a chronic, recurring disease that often requires repeated surgical intervention," said Neal D. Shore, MD, FACS Medical Director for the START Carolinas/Carolina Urologic Research Center and lead author of the study. "The long-term data from the extension study of OPTIMA II highlight ZUSDURI's ability to deliver sustained responses in an outpatient setting, which may be especially valuable for recurrent patients and thus for physicians who prefer a different, non-surgical treatment option."

Among the 41 patients who achieved CR at three months post-treatment with ZUSDURI in the OPTIMA II trial, 25 remained in CR at 12 months and 17 entered the long-term follow-up study. For the 41 patients achieving CR at three months, the median Kaplan-Meier estimate of duration of response (DOR) was 24.2 months (95% CI 9.7, 42.1) with a median follow-up of 35.8 months. For the 17 patients in the long-term follow-up study, the median DOR was 42.1 months by Kaplan-Meier estimate (95% CI: 24.2, NE), with a median follow-up of 50.4 months. These results build upon previously published 12-month DOR data, showing ZUSDURI's potential to deliver meaningful, lasting event-free periods.

"These results reflect our continued commitment to bringing forward innovative treatments that give patients and physicians more options," said Mark Schoenberg, MD, Chief Medical Officer, UroGen. "For recurrent patients facing repeated surgeries, it offers a non-surgical approach that can empower patients and providers to choose a path that best fits individual needs and preferences."

Safety data were not collected during the long-term follow-up trial. The most commonly reported treatment emergent adverse events (>10% of patients) from the parent OPTIMA II study were dysuria in 26 (41% of patients); pollakiuria in 13 (21%); hematuria in 10 (16%); urgency to urinate or urinary tract infection, both occurring in 9 (14%); and fatigue in 7 (11%).

The OPTIMA II trial included both newly diagnosed and recurrent adult patients with LG-IR-NMIBC. Of the 17 patients that entered long-term follow up, 16 (94%) were recurrent and 1 (6%) was newly diagnosed. This cohort of patients had a median DOR of 3.5 years by Kaplan-Meier estimate. ZUSDURI is indicated only for the treatment of adults with recurrent LG-IR-NMIBC.

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 in an out-patient procedure by a trained healthcare professional using a urinary catheter to enable the treatment of tumors by non-surgical means. Visit ZUSDURI.com for more information.

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 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. Learn more about non-muscle invasive bladder cancer at www.BladderCancerAnswers.com.

About OPTIMA II

OPTIMA II (OPTimized Instillation of Mitomycin for Bladder Cancer Treatment) was an open-label, single-arm, multi-center Phase 2b clinical trial of ZUSDURI to evaluate its safety and efficacy in patients with LG-IR-NMIBC.

Learn more about the Phase 2b OPTIMA II trial at www.clintrials.gov (NCT03558503).

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

low-grade upper tract urothelial cancer and ZUSDURI (mitomycin) for intravesical solution, our first product to treat recurrent LG-IR-NMIBC are both 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.

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.

ZUSDURI ™ is a trademark and UroGen® is a registered trademark of UroGen Pharma Ltd.

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 to patients; 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," "may," "plan," "potential," "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; the ability to maintain regulatory approval; 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; 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, 2025, filed with the SEC on May 12, 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.

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

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