UroGen Announces Publication of Phase 3b Study Results Demonstrating the Feasibility of Home Instillation of ZUSDURI™ for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer in Reviews in Urology

July 28, 2025

PRINCETON, N.J., July 28, 2025 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative treatments for urothelial and specialty cancers, today announced the publication in *Reviews in Urology* of results from a Phase 3b study evaluating the feasibility of administering ZUSDURI™ (mitomycin) for intravesical solution (formerly known as UGN-102) in the home setting. The study, titled *"Home Instillation of UGN-102 for Primary Chemoablation of Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer: A Single-Arm, Open-Label, Phase 3b Trial,"* demonstrated that trained home health professionals (HHPs) can safely and effectively administer ZUSDURI outside of a traditional clinical setting.

“The ability to deliver this treatment safely and effectively at home has the potential to ease the burden on patients and reduce reliance on hospital or clinic resources,” said David Morris, MD, lead investigator and practicing urologist at Urology Associates, PC, Nashville, TN. “As physicians, we’re always looking for ways to provide effective care with greater comfort and convenience. These findings represent an important step in that direction.”

The study assessed the feasibility, safety, and early efficacy of at-home instillations of ZUSDURI in patients with recurrent LG-IR-NMIBC. Six of eight patients (75%) completed all six scheduled treatments, with five of those six patients indicating they would recommend the home-based approach to others. A 75% complete response (CR) rate was observed at three months (95% CI: 34.9, 96.8), and no new safety concerns were identified. Feasibility questionnaires were completed by patients, and HHPs throughout the study. After each home instillation, patients rated their experience based on comfort, safety, communication, preference compared to office instillation, and overall satisfaction. At study end, they were also asked whether they would recommend home instillation of ZUSDURI to other patients and as an alternative to undergoing TURBT. Investigators assessed the clinical comparability of home versus in-office administration. HHPs provided feedback after each visit and at the study's conclusion, reporting on their comfort with the procedure, perceived difficulty, and adequacy of training and support.

“This patient-centered approach to care reflects our commitment to redefining how urologic cancers are treated, offering patients access to effective and convenient treatment options,” said Mark Schoenberg, MD, Chief Medical Officer, UroGen. “The ability to potentially administer ZUSDURI safely in the home represents a meaningful advancement for patients and caregivers alike, especially those who may face challenges traveling to frequent clinic visits.”

In this study, ZUSDURI was administered via urinary catheter once weekly for six weeks, with the first dose administered in the clinic, followed by five at-home instillations by HHPs. Investigators found no meaningful differences between home and office instillation for most patients. The safety profile was consistent with previous studies, with most adverse events being mild-to-moderate urinary symptoms.

Study limitations include, among others, the small sample size of eight patients, and the open-label and single-arm design.

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. Patients can 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 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. Jelmyto®, 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.

Copyright©2025 UroGen Pharma, Inc. All rights reserved.

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 feasibility of home instillation of ZUSDURI; the potential benefits to patients and opportunities for ZUSDURI, including the potential to administer ZUSDURI at home; the potential benefits of the home instillation of ZUSDURI, including to ease the burden on patients, reduce reliance on hospital or clinic resources and provide effective care with greater comfort and convenience; the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs other than mitomycin; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; 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; potential safety and other complications related to UroGen's products; 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 affect 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 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

Source: UroGen Pharma Ltd.