UroGen Submits NDA for UGN-103, an Investigational Treatment of Recurrent LG-IR-NMIBC

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PRINCETON, N.J., Aug. 17, 2026 (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 the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational drug UGN-103 (mitomycin) for intravesical solution. UGN-103 is a next-generation mitomycin formulation being developed for the treatment of adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). It is built on the clinical and commercial foundation of ZUSDURI (mitomycin) for intravesical solution.

"The NDA submission for UGN-103 marks another important milestone in advancing our vision to redefine the treatment of urothelial cancers," said Liz Barrett, President and CEO of UroGen. "UGN-103 represents the next evolution in our portfolio and is designed to provide a more streamlined manufacturing process, simplified reconstitution and extended shelf-life of the reconstituted product while leveraging our *RTGel*® technology."

The NDA for UGN-103 is supported by the clinical data from the ongoing Phase 3 UTOPIA trial, a single-arm, multicenter study evaluating the efficacy and safety of UGN-103 in adult patients with recurrent LG-IR-NMIBC. UGN-103 demonstrated a 77.8% three-month complete response (CR) rate (95% CI: 68.3%, 85.5%) and a 94.5% six-month duration of response (DOR) by Kaplan-Meier estimate (95% CI: 86.1%, 97.9%). Both the three-month CR rate and the DOR observed at six months with UGN-103 in the UTOPIA trial are consistent with those observed in the pivotal ENVISION trial of ZUSDURI. Because these findings are derived from separate clinical studies, no formal cross-trial comparison was performed.

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 build on the clinical and commercial foundation 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 coverage expected to extend into July 2044.

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 people experiencing recurrence. 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 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 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. UroGen's first product treats low-grade upper tract urothelial cancer and UroGen's second product, ZUSDURI (mitomycin) for intravesical solution, treats adult patients with recurrent LG-IR-NMIBC; both 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 (formerly Twitter), @UroGenPharma.

About medac
At medac group, we believe that health is humanity's most valuable resource. Since 1970, our mission has been to improve patients' quality of life worldwide by making the best medical treatments available. As a globally operating pharmaceutical company headquartered in Germany, we provide high-quality medical treatments for patients worldwide in over 90 countries. With more than 2,000 employees, we are committed to improving human health.

Our products are manufactured in Germany and other European countries to the highest standards, utilizing our own logistics center and production sites, and subsequently distributed worldwide.

We are constantly working to improve authorized medicines and to develop innovative therapies in the fields of rheumatology, urology, hematology, and oncology. Part of our mission is to provide safe, high-quality and innovative original products, as well as generics and biosimilars. In this way, we make vital treatments accessible to those affected.

For more information, please visit **www.medac-group.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 you have previously received bladder surgery to remove tumor and it 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, 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: UGN-103 representing the next evolution in UroGen's portfolio and the potential benefits of UGN-103 as compared to ZUSDURI, including its streamlined manufacturing, reconstitution processes, and extended shelf-life; 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 "can," "estimated," "expect," "may," "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 its 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. These and other risks and uncertainties are described in the

Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the U.S. Securities and Exchange Commission on August 5, 2026. In light of these risks and uncertainties, 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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