UroGen Announces New Data Presentations at the American Urological Association 2024 Annual Meeting Highlighting Clinical Benefits of Our Portfolio for Urothelial Cancers

April 17, 2024

- Subgroup analysis of the UGN-102 ATLAS Trial in patients with new versus recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)
- Three independent long-term real-world analyses of JELMYTO® (mitomycin) for pyelocalyceal solution exploring its use in broad patient types and method of administration

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 17, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that new data on investigational drug UGN-102 (mitomycin) and JELMYTO and will be presented at the American Urological Association (AUA) 2024 Annual Meeting being held in San Antonio, Texas from May 3 – 6.

"We are proud that the AUA selected the ATLAS post-hoc analysis as a podium presentation," said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. "The results highlight UGN-102's potential to help significantly advance treatment for patients with newly diagnosed and recurrent LG-IR-NMIBC, a highly prevalent and recurrent disease. Additionally, we are excited to see additional independent real-world evidence related to JELMYTO treatment of LG-UTUC patients in a diverse patient types."

Key details of UGN-102 and JELMYTO abstracts accepted by AUA:

Abstract Title	Presentation Details	
Response to Primary Chemoablation with UGN-102 in Patients with New or Recurrent LG IR NMIBC: Post-hoc Analysis of the ATLAS Trial	Podium Oral Presentation: Abstract ID 24-6641, Saturday, May 4, 2:20-2:30 PM CDT, Location 304A	Presenter: Dr. William Huang
Longitudinal Follow Up of Multicenter Study of UGN-101 for Upper Tract Urothelial Cancer	Podium Oral Presentation: Abstract ID 24-7470, Sunday, May 5, 11:10-11:20 AM CDT, Location 301A	Presenter: Dr. Yair Lotan
Exploring Recurrence After Initial Response to UGN-101 Induction in Expanded Settings	Podium Oral Presentation: Abstract ID 24-7534, Sunday May 5, 11:20-11:30 AM CDT, Location 301A	Presenter: Dr. Adam Feldman
Mitomycin-containing Reverse Thermal Gel UGN-101 for Upper Tract Urothelial Carcinoma: Retrograde Instillation in Clinic and Outcomes	Video Presentation: Abstract ID 24-7720, Saturday, May 4, 10:50-11:00 AM CDT, Location Video Abstract Theater	Presenter: Dr. Golena Moncaleano

UroGen Sponsors AUA Innovation Nexus

UroGen's President and Chief Executive Officer, Liz Barrett, will participate in a panel discussion about the state of innovation in urology and a reverse pitch on key areas of discovery and collaboration during the AUA Innovation Nexus Conference on May 2. The AUA Innovation Nexus is a powerful forum to advance urologic discovery to solutions that improve patient care and save lives. Register here: https://auanexus.org/innovation-nexus-conference/registration

State of Innovation in Urology	**Reverse Pitch:** 1-2 PM CDT **Showcase Panel:** Thursday May 2 between 2:45-4:45 PM CDT	Liz Barrett, President and CEO, UroGen Pharma & Other Speakers

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of LG-IR-NMIBC. Utilizing UroGen's proprietary RTGel ® technology, a sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter in an outpatient setting. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates completing its new drug application (NDA) submission for UGN-102 in September 2024 with a potential FDA decision as early as the first quarter of 2025.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

In the U.S. bladder cancer is the second most common urologic cancer in men. LG-IR-NMIBC represents approximately 22,000 newly diagnosed bladder cancer patients each year and an estimated existing 60,000 recurrent patients. Bladder cancer primarily affects older populations with the median age of diagnosis 73 years and an increased risk of comorbidities. Guideline recommendations for managing LG-IR-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 repeat TURBT procedures.

About JELMYTO

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC). It is recommended for primary treatment of biopsy-proven LG-UTUC in patients deemed appropriate candidates for renal-sparing therapy. JELMYTO is a viscous liquid when cooled and becomes a semi-solid gel at body temperature. The drug slowly dissolves over four to six hours after instillation and is removed from the urinary tract by normal urine flow and voiding. It is approved for administration in a retrograde manner via ureteral catheter or antegrade through nephrostomy tube. The delivery system allows the initial liquid to coat and conform to the upper urinary tract anatomy. The eventual semisolid gel allows for chemoablative therapy to remain in the collecting system for four to six hours without immediately being diluted or washed away by urine flow.

About Upper Tract Urothelial Cancer

Urothelial cancer is the ninth most common cancer globally and the eighth most lethal neoplasm in men in the U.S. Between five percent and ten percent of primary urothelial cancers originate in the ureter or renal pelvis and are collectively referred to as upper tract urothelial cancers (UTUC). In the U.S., there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often face comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). These treatments can lead to a high rate of recurrence and relapse.

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 LG-UTUC and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. To learn more, visit www.UroGen.com or follow us on X (Twitter), @UroGenPharma.

APPROVED USE FOR JELMYTO

JELMYTO® is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

IMPORTANT SAFETY INFORMATION

You should not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. JELMYTO can harm your unborn baby. You should not become pregnant during treatment with JELMYTO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JELMYTO. **Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with JELMYTO and for 6 months after the last dose. **Males being treated with JELMYTO:** If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO and for 1 week after the last dose.
- **Tell your healthcare provider if you take water pills (diuretic).**

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment.
- You will receive your JELMYTO dose from your healthcare provider 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. Your healthcare provider may recommend up to an additional 11 monthly doses.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 6 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.

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you

develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.

- **Bone marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.
- **The most common side effects of JELMYTO include:** urinary tract infection, blood in your urine, side pain, nausea, trouble with urination, kidney problems, vomiting, tiredness, stomach (abdomen) pain.

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 JELMYTO 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 anticipated submission of an NDA to the FDA for UGN-102 and the timing thereof; the anticipated timing for an FDA decision; the potential of UroGen's proprietary RTGel technology to improve therapeutic profiles of existing drugs; and the potential of UroGen's sustained release technology to make local delivery more effective as compared to other treatment options. Words such as "anticipate," "assume," "could," "plan," "potential," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; findings from the durability of response endpoint from the ENVISION Phase 3 study may not be positive, and in such event, UroGen's NDA pathway could be negatively impacted; even if the durability of response endpoint data from the ENVISION Phase 3 study are positive, there is no guarantee that the current clinical development plan for UGN-102 will ultimately support submission of an NDA; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's product candidates; the size and growth of the market(s) for UroGen's product and product candidates and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's ability to attract or retain key management, members of the board of directors and personnel; UroGen's RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; and UroGen's financial condition and need for additional capital in the future. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 2024 (which is available at www.sec.gov), 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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