Long-Term Follow-up Study to the OLYMPUS Trial Presented at SUO 2024 Reports Median Duration of Response of Four Years in Patients Who Achieved a Complete Response with JELMYTO®

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- Favorable long-term durability data further supports JELMYTO as a primary treatment for low-grade upper tract urothelial cancer

PRINCETON, N.J.--(BUSINESS WIRE)--Dec. 5, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today highlights results from a long-term follow-up study with JELMYTO (mitomycin) for pyelocalyceal solution, which is FDA approved for the treatment of adults with low-grade, upper tract urothelial cancer (LG-UTUC). Among patients from the OLYMPUS trial who achieved a complete response after primary chemoablation with JELMYTO (n=41, 20 of whom entered the long-term follow-up study), the median duration of response was 47.8 months (median follow-up 28.1 months (95% CI 13.1, 57.5). The study results were presented at the Society for Urologic Oncology (SUO) annual meeting in Dallas, Texas, and were recently published online in the Journal of Urology.

“The median duration of response of 47.8 months in patients who achieved a complete response with JELMYTO demonstrates robust long-term control of LG- UTUC,” said Brian Hu, M.D., Associate Professor of Urology, Loma Linda University School of Medicine and study investigator. “With these compelling data showing sustained complete response, JELMYTO provides a valuable treatment option for potentially achieving a long-lasting recurrence-free interval.”

Of the 71 patients enrolled in OLYMPUS, 41 achieved a complete response after treatment with JELMYTO and had a median duration of response of 47.8 months (95% CI 13.0, not estimable), with median follow-up of 28.1 months (95% CI 13.1, 57.5).

“Managing relapse and preserving kidney function are key treatment goals for LG-UTUC, as the risk of disease progression is low,” said Mark Schoenberg, M.D., Chief Medical officer, UroGen. “The study’s findings are compelling, as they support the potential of JELMYTO to offer patients long-lasting benefits, with evidence of an extended response duration that may improve quality of life and reduce the need for more invasive treatments.”

The analysis has certain limitations, including its post-hoc nature and the inherent selection bias of the 20 patients enrolled in the long-term follow-up study.

About JELMYTO

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel approved for the treatment of adult patients with low-grade-UTUC (LG-UTUC). 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 a 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 (UTUC)

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 UTUC. In the U.S., there are approximately 6,000 - 7,000 new or recurrent LG-UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often have multiple comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). Treatment with endoscopic surgery can be associated with 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. Visit www.urogen.com to learn more 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 1800FDA1088. 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 benefits of JELMYTO; the long-term follow up study data supporting the potential of JELMYTO to offer patients long-lasting benefits that may improve quality of life and reduce the need for more invasive treatments; the estimated patient population and demographics for UTUC; the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: prior results may not be indicative of results that may be observed in the future; potential safety and other complications from JELMYTO use in diverse UTUC patient types; and UroGen's *RTGel* technology may not perform as expected and we may not successfully develop and receive regulatory approval of any other product that incorporates UroGen's *RTGel* technology. 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 September 30, 2024, filed with the SEC on November 6, 2024 (which is available at http://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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