UroGen Highlights New Data Presented at AUA that Adds to the Evidence Supporting In-Office Nephrostomy Tube Administration of JELMYTO®, the only Non-Surgical, Kidney-Sparing Treatment for Adults with Low Grade Upper Tract Urothelial Cancer

May 16, 2022

-- Multi-Center Retrospective Study was Presented at the 2022 American Urological Association Annual Meeting in New Orleans --

NEW ORLEANS--(BUSINESS WIRE)--May 16, 2022--

UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to creating novel solutions that treat urothelial and specialty cancers, today highlights new data on real-world experience utilizing the antegrade approach via nephrostomy tube for administration of JELMYTO® (mitomycin) for pyelocalyceal solution. This data adds to a growing body of evidence on the safety and efficacy profile of the antegrade method of administration for JELMYTO. These data were presented during a podium presentation at the 2022 American Urological Association (AUA) annual meeting in New Orleans, Louisiana.

“JELMYTO is efficacious as a chemoablative agent in adult patients with low grade upper tract urothelial cancer, and while it’s FDA approved for both antegrade and retrograde administration, prior reports are limited to the retrograde experience,” said Kyle Rose, MD, Urologic Oncology Fellow at Moffitt Cancer Center in Tampa, Fla., and study investigator. “These data provide additional evidence that instillation via a nephrostomy tube is an effective instillation method with a safety profile that offers an encouraging option to appropriate patients.”

Dr. Rose presented the abstract *Antegrade Administration of Reverse Thermal Mytomycin Gel for Primary Chemoablation of Upper Tract Carcinoma via Percutaneous Nephrostomy Tube: A Multi-Institutional Real-World Experience (Abstract PD58-06)* during a podium presentation at the AUA annual meeting on Monday, May 16.

“All 71 patients in the Phase 3 OLYMPUS trial utilized the retrograde approach to administer JELMYTO, therefore we are pleased to see real-world evidence that supports the utilization of the antegrade approach giving physicians and patients more options to administer JELMYTO based on their preference and experience,” said Mark Schoenberg, MD, Chief Medical Officer, UroGen.

About This Study

The real-world data from this retrospective analysis was pooled from Moffitt Cancer Center, Tampa, FL; University of Missouri School of Medicine, Columbia, MO; The University of Texas MD Anderson Cancer Center, Houston, TX; and Mayo Clinic, Rochester, MN.

Twenty-six patients received nephrostomy tube administration of JELMYTO, six patients (23%) had solitary kidneys. Nine patients (35%) went on to receive at least one dose of maintenance therapy. Ureteral stenosis occurred in four patients (15%). Other adverse events included fatigue (27%), flank pain (19%), urinary tract infection (12%), sepsis (8%) and hematuria (8%). No patients had impaired renal function during follow-up and no deaths occurred.

Thirteen patients (50%) exhibited a complete response at post-induction ureteroscopy while 12 patients (46%) had a partial response. One patient experienced progression to invasive disease and required a nephroureterectomy. At a median follow-up of seven months (IQR 3-9) post-induction, no patients who experienced a complete response recurred.

The limitations of this study include the retrospective nature, small sample size, and pooled reporting of results. There is a need for larger studies with longer follow-up to study more conclusively any potential advantages of antegrade JELMYTO administration when compared to retrograde instillation.

About the Pivotal OLYMPUS Study

OLYMPUS (Optimized DeLiverY of Mitomycin for Primary UTUC Study) was an open-label, single-arm Phase 3 clinical study of UGN-101 JELMYTO (mitomycin) for pyelocalyceal solution, to evaluate the safety, tolerability and tumor ablative effect of JELMYTO in patients with low-grade Upper Tract Urothelial Cancer UTUC (LG UTUC). Seventy-one patients were treated at clinical sites across the United States and Israel. Study participants were treated with six weekly instillations of JELMYTO administered via a standard catheter. Four to six weeks following the last instillation, patients underwent a Primary Disease Evaluation (PDE) to determine Complete Response (CR), the primary endpoint of the study. PDE involved a ureteroscopy and wash cytology, a standard microscopic test of cells obtained from the urine to detect cancer and for cause biopsy. Patients who achieved a CR at the PDE timepoint were eligible for the maintenance phase of the trial, during which they could receive monthly maintenance instillations for up to 12 months and were assessed to determine the durability of response with JELMYTO.

In the OLYMPUS study, data was generated for the retrograde administration of JELMYTO. In that study population ureteric obstruction was reported in 58% (n=41) of patients receiving JELMYTO, including 17% (n=12) of patients who experienced Grade 3 obstruction.

About LG UTUC

LG UTUC is a rare disease managed by endoscopic methods and radical nephroureterectomy. Endoscopic resection and laser ablation attempt to preserve the kidney, though there is a high risk of recurrence that may eventually necessitate removal of the kidney. Although kidney removal is the gold standard for treatment of high-grade UTUC, it may be over-treatment in LG UTUC, as kidney removal offers similar five-year survival as kidney-sparing procedures but is associated with significant morbidity. JELMYTO is efficacious as a primary chemoablative therapy in patients with LG UTUC.

About JELMYTO®

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel indicated for primary chemoablative treatment of LG UTUC in adults. 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.

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 U.S. Food and Drug Administration. 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

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 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 commercial product Jelmyto (mitomycin) for pyelocalyceal solution, 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 Twitter, @UroGenPharma.

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 whether future studies could demonstrate any potential advantages of antegrade administration of JELMYTO as compared to retrograde instillation; optimism regarding the effectiveness of the antegrade approach; RTGel's™ potential to improve the 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: results from initial reports of the antegrade administration of JELMYTO may not be indicative of results that may be observed in the future; potential safety and other complications from the antegrade administration of JELMYTO; the timing and success of clinical trials and potential safety and other complications thereof; the ability to obtain and maintain regulatory approval; the labelling for any approved product; the scope, progress and expansion of developing and commercializing UroGen's 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. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on May 10, 2022 and other filings that UroGen makes with the SEC from time to time (which are 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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