UroGen Pharma Highlights Data Presentations at the 2022 American Urological Association Annual Meeting

May 13, 2022

- *New data on in-office nephrostomy tube administration of JELMYTO® (mitomycin) for pyelocalyceal solution, the only non-surgical, kidney-sparing treatment for adults with low-grade upper tract urothelial cancer*
- *Results from the Phase 2b OPTIMA II trial of UGN-102 and impact of treatment in maintaining health-related quality of life*

PRINCETON, N.J.--(BUSINESS WIRE)--May 13, 2022-- UroGen Pharma Ltd. (Nasdaq: URGN) today highlighted four presentations of interest featuring data on JELMYTO® (mitomycin) for pyelocalyceal solution for patients with low-grade upper tract urothelial cancer (LG-UTUC) and investigational agent UGN-102 (mitomycin) for intravesical solution in Phase 3 clinical development as primary non-surgical therapy for low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) at the upcoming 2022 American Urological Association (AUA) Annual Meeting, May 13-16 in New Orleans, Louisiana. The presentations will be published in the June 2022 issue of *The Journal of Urology*® and will be accessible via the AUA website.

Details on AUA Presentations:

Podium Presentation
Abstract #: PD26-08
Session: Low-grade urothelial carcinoma recurs at a tempo that naturally accelerates from Adagio to Allegro
Presenter: Alex Sankin, M.D., Associate Professor Department of Urology, Albert Einstein College of Medicine
Date and Time: Saturday, May 14, 2022 at 2:10-2:20 PM CT
Location: Room 252

ICU Theater
Session: Chemoablation as primary treatment: Transforming the paradigm for low grade UTUC with JELMYTO
Presenter: Jennifer Linehan, M.D. Associate Professor of Urology and Urologic Oncology at the Saint John's Cancer Institute
Date and Time: Sunday, May 15, 2022 at 12:00-1:00 PM CT
Location: S&T Hall: Booth 1043

Moderated Poster
Abstract #: MP54-06
Session: Longitudinal Health-Related Quality of Life Outcomes in Adults with Non-Muscle-Invasive Bladder Cancer Receiving a Chemoablative Gel as a Primary Treatment (Optima II: Phase 2b, single arm, open-label trial)
Presenter: Angela Smith, M.D., M.S. Associate Professor at the University of North Carolina (UNC) Department of Urology in Chapel Hill, North Carolina
Date and Time: Monday, May 16, 2022 at 8:45-10:00 AM CT
Location: Room 228

Podium Presentation
Abstract #: PD58-06
Session: Antegrade Administration of Reverse Thermal Mitomycin Gel for Primary Chemoablation of Upper Tract Urothelial Carcinoma via Percutaneous Nephrostomy Tube: a Multi-Institutional Real-World Experience
Presenter: Kyle Rose, M.D., Urologic Oncology Fellow at Moffitt Cancer Center in Tampa, Fla.
Date and Time: Monday, May 16, 2022 at 1:50-2:00 PM CT
Location: Room 252

UroGen will be hosting Booth #837 at the Ernest N. Morial Convention Center during AUA 2022.

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. 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.

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