UroGen Pharma Appoints David Lin as New Chief Commercial Officer

June 3, 2024

PRINCETON, N.J.--(BUSINESS WIRE)--Jun. 3, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, today announced that David Lin will join UroGen as its Chief Commercial Officer and member of the Executive Leadership Team. In this role, David will be spearheading UroGen's commercial strategy, including preparation for the potential launch of our lead pipeline candidate UGN-102, if approved, and driving the continued growth and commercialization of JELMYTO® (mitomycin) for pyelocalyceal solution.

David Lin brings to UroGen a wealth of experience garnered from a distinguished career in the pharmaceutical industry. Prior to joining UroGen, David held several key leadership positions at Bristol Myers Squibb, where he played pivotal roles in driving the success of various initiatives. Notably, as Head of U.S. Cell Therapy, David led the successful launch of two CAR T therapies, showcasing his expertise in bringing innovative therapies to market. Additionally, his tenure as Head of Worldwide Cardiovascular contributed significantly to the global cardiovascular franchise, including expansion through the MyoKardia acquisition.

"As we enter the next stage in building a long-term growth company, we are thrilled to welcome David to the UroGen team," said Liz Barrett, President and CEO of UroGen Pharma. "His extensive experience and proven track record of commercial success will be invaluable as we advance our mission of bringing innovative therapies to patients in need. With David's leadership, we are confident in our ability to maximize the commercial potential of JELMYTO and our expanding pipeline."

Before his time at Bristol Myers Squibb, David served as Global Head of Surgery and Perioperative Care at The Medicines Company, demonstrating his diverse experience across different sectors of the healthcare industry. His career journey also includes various leadership roles at Johnson & Johnson, where he made impactful contributions to pharmaceuticals, medical devices, and consumer businesses.

David Lin expressed his enthusiasm about joining UroGen, stating, "I am honored to join UroGen at such an exciting time in the company's evolution. I look forward to working closely with the team to drive commercial success and ultimately make a meaningful difference in the lives of patients with urothelial cancers."

David is an alumnus of Cornell University, where he earned his Bachelor of Arts in Economics, and Duke University, where he completed his Master of Business Administration (MBA). Beyond his professional endeavors, David is actively engaged in mentoring start-up businesses in life sciences as a member of the Canadian Technology Accelerator and serves as a Strategic Advisor to ChroniSense Medical, a clinical-stage medical technology company.

Jeff Bova will be stepping down as Chief Commercial Officer on June 3 as he pursues new opportunities. We are incredibly grateful for the work he did here at UroGen.

For more information about UroGen Pharma and its portfolio of urological solutions, please visit www.urogen.com.

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-UTUC (LG-UTUC). It is approved for adult patients with 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 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 UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer. 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 Q3 2024 with a potential U.S. Food and Drug Administration (FDA) decision as early as the first quarter of 2025.

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 potential approval and launch of UGN-102; expected contributions of executive leadership team members and UroGen's ability to maximize the commercial potential of JELMYTO and its expanding pipeline; the potential benefits of UGN-102; UroGen's ongoing clinical trials, including the ENVISION Phase 3 study; UroGen's plans to submit an NDA to the FDA for UGN-102 and the expected timing thereof and the timing for potential FDA decisions thereon; 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: results from completed clinical trials may not be indicative of results that may be observed in the future; there is no guarantee that the current clinical development plan for UGN-102 will ultimately support the 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; potential safety and other complications from UGN-102; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; 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 the growth of the market(s) for UroGen's product and product candidates, the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's ability to attract or retain key management, members of its board of directors and personnel; UroGen's *RTGel* technology may not perform as expected; and UroGen 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 March 31, 2024, filed with the SEC on May 13, 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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Source: UroGen Pharma Ltd.