UroGen Pharma Announces License and Supply Agreement with Neopharm to Pursue Regulatory Approval and Commercialization for Jelmyto® in Israel

July 28, 2021

- Jelmyto® *granted expedited review in Israel*
- Jelmyto *is the only US FDA approved treatment for low-grade upper tract urothelial cancer*

PRINCETON, N.J.--(BUSINESS WIRE)--Jul. 28, 2021-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases, and Neopharm group ("Neopharm"), today announced an exclusive license for Neopharm to market and sell *Jelmyto*® (mitomycin) for pyelocalyceal solution in Israel, subject to regulatory approval. *Jelmyto* is the first and only U.S. Food and Drug Administration approved medicine for adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

Neopharm will lead the regulatory process in Israel, which is supported by the results from the Phase 3 OLYMPUS trial that showed *Jelmyto* achieved clinically significant disease eradication in adults with LG-UTUC.

"We are excited to work with Neopharm and take the first step in making *Jelmyto* available to patients in Israel," said Liz Barrett, President and Chief Executive Officer of UroGen. "As we begin the process of geographic expansion for *Jelmyto*, it was important for us to prioritize Israel as the first opportunity to bring this innovative treatment to patients outside of the United States. Beyond the fact that our company was founded in Israel, and we continue to have a significant presence there, physicians and patients in Israel played a key role in the pivotal study that supported *Jelmyto's* approval in the United States."

Jelmyto, which received expedited approval in the United States in April 2020, is an innovative therapy utilizing UroGen's proprietary sustained release RTGel™ technology in combination with mitomycin, an established chemotherapy that inhibits DNA synthesis. It has been designed to dwell in the cavity, enabling mitomycin to have longer exposure to and broader coverage of urinary tract tissue, thereby allowing the treatment of tumors by non-surgical means.

"We look forward to working with UroGen to move *Jelmyto* through the regulatory process in Israel and to make this novel, non-surgical treatment available to appropriate patients as quickly as possible," said Efi Shnaidman, general manager of Neopharm Israel. "We are proud to be the first company outside the US to have started the regulatory approval and commercialization process for Jelmyto, demonstrating Israel's importance in geographic expansion. Moreover, it is exciting to work with another company who has deep roots in Israel. I am confident that our well-established expertise and heritage of collaboration with innovative biopharmaceutical companies will make *Jelmyto* a success in Israel."

In addition to Israel, UroGen continues to work with regulators and potential collaborators in key markets to explore opportunities for geographic expansion. UroGen is committed to bringing the promise of *Jelmyto* to as many patients as possible, as quickly as feasible.

About *Jelmyto*®

Jelmyto (mitomycin) for pyelocalyceal solution, is a drug formulation of mitomycin indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC). Utilizing the RTGel™ technology platform, UroGen's proprietary sustained release, hydrogel-based formulation, *Jelmyto* is designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. *Jelmyto* is delivered to patients using standard ureteral catheters or nephrostomy tube. The U.S. FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to *Jelmyto* for the treatment of LG-UTUC. On April 15, 2020, the FDA approved *Jelmyto*, making it the first drug approved for the treatment of LG-UTUC in adult patients.

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.

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 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 biopharmaceutical company dedicated to building novel solutions that treat specialty cancers and urologic diseases 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 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.

About Neopharm

Established in 1941, Neopharm is one of Israel's leading providers of innovative integrated solutions across the pharmaceutical, medical and healthcare markets. Neopharm focuses on the sale and marketing of novel groundbreaking specialty and orphan medications as well as home healthcare services in Israel via partnerships with the world's leading multinational bio-pharma companies. Neopharm is the partner-of-choice and one-stop-shop for multinational bio-pharma companies seeking to enter or expand their business in the Israeli pharmaceutical, medical and biotechnology markets and is proud of its best-in-class platform, reputation and track- record of success for launching and marketing groundbreaking novel therapies in Israel. Neopharm group of companies employs more than 900 employees, has an annual sales turnover in excess of US$450M and sales in 60 countries.

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 regulatory approval and commercialization of *Jelmyto* in Israel; *Jelmyto* being a success in Israel; the potential geographic expansion of *Jelmyto* outside of the United States; and the potential of UroGen's proprietary RTGel technology platform to improve therapeutic profiles of existing drugs. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential safety and other complications thereof; regulatory approval in Israel generally includes all of the risks associated with obtaining FDA approval, the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities, including complications over which we have no or only limited control as a result of our reliance on third parties; the labeling 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; *Jelmyto* may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success as a result of significant competition with competing technologies and other factors; UroGen's ability to attract or retain key

management, members of the board of directors and personnel; and any negative effects on UroGen's business, commercialization and product development plans caused by or associated with COVID-19. 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 13, 2021, 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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INVESTOR CONTACT:
Sara Blum Sherman
Head of Investor Relations
investors@urogen.com

MEDIA CONTACT:
communications@urogen.com

Source: UroGen Pharma Ltd.