UroGen Pharma Reports Strong Preliminary Jelmyto® Sales for Second Quarter 2021

July 14, 2021

- *73% growth in net product revenue over 1Q 2021 to approximately $13.0 million in 2Q 2021*
- *2Q 2021 operating expenses anticipated in the range of $33 to $38 million*
- *Full 2Q 2021 financial results and conference call to be reported on Wednesday, August 4, 2021*

PRINCETON, N.J.--(BUSINESS WIRE)--Jul. 14, 2021-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases, today announced that it expects net product revenue from Jelmyto sales for the second quarter ended June 30, 2021, to be approximately $13.0 million, representing an increase of over 70% compared to the first quarter of 2021 and the highest quarterly sales since Jelmyto was launched in June 2020. Additionally, operating expenses in the second quarter of 2021 are anticipated to be in the range of $33 to $38 million. Cash, cash equivalents and marketable securities as of June 30, 2021, are expected to be approximately $129.0 million.

“Our strong, preliminary top line results for the second quarter of 2021 have validated our belief that increased vaccination rates and the general re-opening of activities throughout the United States would correlate to increased adoption of Jelmyto as an innovative treatment for patients with low-grade upper tract urothelial cancer,” said Liz Barrett, President and Chief Executive Officer of UroGen. “The momentum in Jelmyto sales gives us increased confidence in physician adoption of this paradigm shifting therapy. We are optimistic that this trend will continue as our commercial team actively engages in-person with healthcare providers to activate new sites and increase usage at existing sites. We look forward to reporting our full results for the second quarter of 2021 in early August.”

The Company expects to report full financial results for the second quarter ended June 30, 2021, and host a conference call on Wednesday, August 4, 2021. A press release with the details for the conference call will be issued approximately one week prior to the planned reporting date.

Preliminary Financial Results

The preliminary financial results set forth above are based on management’s initial review of the Company’s results as of and for the quarter ended June 30, 2021, and are subject to revision based upon the Company’s quarter-end closing procedures and the completion of the review by the Company’s external auditors of the Company’s quarter-end financial statements. Actual results may differ materially from these preliminary results as a result of the completion of quarter-end closing procedures, final adjustments, and other developments arising between now and the time that the Company’s financial results are finalized. In addition, these preliminary results are not a comprehensive statement of the Company’s financial results for the quarter ended June 30, 2021, should not be viewed as a substitute for complete financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of the Company’s results for any future period.

2021 Operating Expense Guidance

The Company affirms its previously announced guidance for full-year operating expenses in the range of $155 to $165 million, including non-cash share-based compensation expense of $24 to $28 million, subject to market conditions.

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 takewater 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. UroGen's first commercial product, 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: our expected revenue and other financial results as of and for the quarter ended June 30, 2021; our full-year 2021 operating expense guidance; our belief that physicians will continue to adopt Jelmyto and that the momentum in Jelmyto sales observed over the second quarter of 2021 will continue; our belief that Jelmyto will be a paradigm shifting therapy; 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 risk that our actual revenue or other financial results as of and for the quarter ended June 30, 2021 may differ materially from those set forth in this press release as a result of the completion of quarter-end closing procedures;* the timing and success of clinical trials and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; 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; complications associated with commercialization activities, including complications resulting from the ongoing COVID-19 pandemic; 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; 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.

JELMYTO® and UroGen® are registered trademarks of UroGen Pharma, Ltd.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210714005260/en/

INVESTOR CONTACTS:
Sara Blum Sherman
Head of Investor Relations
investors@urogen.com

Lee Roth
lroth@burnsmc.com
212-213-0006

MEDIA CONTACT:
Eric Van Zanten
Head of Communications
Eric.VanZanten@urogen.com
610-529-6219

Source: UroGen Pharma Ltd.