UroGen Pharma to Host Thought Leader Webinar on UGN-102 and Non-Muscle Invasive Bladder Cancers

October 11, 2022

-- UGN-102 is an Investigational Formulation of the Novel RTGel™ Delivery Technology Combined with Mitomycin in Phase 3 Development for the Treatment of Low-Grade Intermediate Risk NMIBC --

-- Webinar scheduled for Tuesday October 18, 2022 at 9:00 AM ET --

PRINCETON, N.J.--(BUSINESS WIRE)--Oct. 11, 2022-- UroGen Pharma Ltd. (NASDAQ: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that it will host a thought leader webinar on non-muscle-invasive bladder cancers (NMIBC) and the potential role of the Company's investigational product candidate, UGN-102, to treat low-grade intermediate-risk NMIBC (LG-IR-NMIBC) on Tuesday, October 18, 2022 at 9:00 AM Eastern Time.

The webinar will feature presentations from key opinion leaders Gary D. Steinberg, MD, from NYU Grossman School of Medicine, and William C. Huang, MD, from NYU Langone Health, who will discuss the unmet medical need and the current treatment landscape for NMIBC patients.

UroGen leadership will provide insight into their pipeline portfolio, highlighting the Company's Phase 3 clinical program of UGN-102, an investigational therapeutic that utilizes UroGen's innovative technology, RTGel™ reverse-thermal hydrogel, and mitomycin for the potential treatment of LG-IR-NMIBC.

A live Q&A session will follow the formal presentations. To register for the event, please click here.

Dr. Steinberg is Director of the Urology Bladder Cancer Program and Professor in the Department of Urology at the NYU Grossman School of Medicine. He earned his MD from the University of Chicago and completed his Residency in Urology at the Johns Hopkins University School of Medicine. At NYU Langone's Perlmutter Cancer Center, Dr. Steinberg treats people who have muscle-invasive and non-muscle–invasive bladder cancer. He specializes in performing radical cystectomy, a procedure in which the entire bladder and nearby lymph nodes are removed, as well as urinary tract reconstruction after bladder removal surgery. Dr. Steinberg is highly active in clinical research and leads multiple trials that investigate new medications and procedures for the treatment of bladder cancer. He has authored or coauthored more than 200 journal articles as well as many medical textbook chapters. He chairs the scientific advisory board of the Bladder Cancer Advocacy Network and is on the executive committee of the Bladder Cancer Research Network. In addition, he is a member of multiple professional organizations, including the American Society of Clinical Oncology, the Society of Urologic Oncology, and the American Urological Association.

William C. Huang, MD, is a urologic oncologist at NYU Langone Health and the Perlmutter Cancer Institute. He is Professor of Urology and Radiology and Vice Chair (Clinical Affairs) in the Department of Urology at the NYU Grossman School of Medicine. Dr. Huang is also the Chief of Urology at Tisch Hospital and the Co-Director of the Robotic Surgery Center at NYU Langone Health. Dr. Huang has extensive experience in open, robotic, and laparoscopic surgical techniques. His surgical expertise includes the treatment of complex kidney, retroperitoneal, and testicular tumors, along with minimally invasive partial nephrectomy, radical cystectomy, retroperitoneal lymphadenectomy, and prostatectomy. Dr. Huang has published over 200 articles in several high-impact journals including the *Journal of Clinical Oncology (JCO)*, *Lancet Oncology, Journal of the American Medical Association (JAMA)* and the *New England Journal of Medicine (NEJM)*. He has lectured at both national and international meetings, particularly on improving outcomes following kidney cancer surgery. Dr. Huang continues to advance the field of urologic oncology through his research into novel approaches to the diagnosis and management of kidney, testicular cancer, and non-muscle invasive bladder.

About LG-IR-NMIBC

Out of the 80,000 estimated cases of bladder cancer per year in the U.S., approximately 35,000 are low-grade NMIBC patients comprised of both low-risk (approximately 15,000) and intermediate risk (approximately 20,000). These patients face a future of recurrence and additional surgeries. Recurrence in low-grade intermediate-risk NMIBC is pervasive and often underestimated. In patients who recur, approximately 68 percent will experience two or more recurrence episodes throughout the course of their disease, a high and frequent rate in contrast to other non-metastatic cancers. Currently, the only effective primary treatment available is a surgical procedure known as transurethral resection of bladder tumor, or TURBT. Every time TURBT is performed it imposes more burden and serious risks on the patient. Approximately 25 percent of patients are not appropriate for TURBT, whether due to physical factors such as age and comorbidities or an unwillingness to undergo surgery.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade intermediate risk NMIBC. Utilizing RTGel™ Technology, UroGen's proprietary 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. The Company presented results from the Phase 2b OPTIMA II trial in September 2021.

About the Phase 3 ENVISION Trial

The Phase 3 ENVISION trial is a multinational, multicenter single-arm study evaluating the efficacy and safety of UGN-102 (mitomycin) as primary chemoablative therapy in patients with low-grade, intermediate-risk NMIBC. The Phase 3 ENVISION trial is expected to enroll approximately 220 patients across 90 sites and study participants will receive six once-weekly intravesical instillations of UGN-102. The planned primary endpoint will evaluate the complete response rate at three months after the first installation, and the key secondary endpoint will evaluate durability over time in patients who achieve complete response at the three-month assessment. Based on discussions with the FDA, and enrollment expected by the end of 2022, assuming positive findings, UroGen anticipates submitting an NDA for UGN-102 in 2024.

About UroGen Pharma Ltd.

UroGen is 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 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 the enrollment expectations for the single-arm Phase 3 ENVISION study for UGN-102 and the timing thereof; the timing, design and potential success of the ENVISION study; the timing of the planned NDA submission for UGN-102; RTGel's potential to improve the therapeutic profiles of existing drugs; UroGen's sustained release technology making local delivery a potentially more effective treatment option; and the design of UroGen's product and product candidates. Words such as "anticipate," "designed to," "expect," "plan," "potential," "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements necessarily contain these identifying words. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: any negative effects on UroGen's business, commercialization and product development plans caused by or associated with COVID-19; 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; competition in our industry; and the sufficiency of our capital resources. 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 Securities and Exchange Commission (SEC) on August 11, 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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