UroGen Pharma Submits Investigational New Drug (IND) Application for UGN-102 (VesiGel™) for the Treatment of Low-Grade Non-Muscle Invasive Bladder Cancer (LG NMIBC)

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Company Expects to Begin U.S. Phase 2b Clinical Trial in Q3 2018

UGN-102 Has Potential to Become the First Front Line Non-Surgical Therapy for Patients with LG NMIBC

RA'ANANA, Israel and NEW YORK, July 11, 2018 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, with a focus on uro-oncology, today announced that it submitted to the U.S. Food and Drug Administration (FDA) an Investigational New Drug (IND) application for UGN-102 (VesiGel™, mitomycin gel for intravesical instillation) for the treatment of patients with low-grade non-muscle invasive bladder cancer (LG NMIBC) at the end of Q2 2018. If accepted, the Company expects to begin a Phase 2b clinical trial in the United States in Q3 2018.

UGN-102 represents the second product candidate in UroGen's pipeline and addresses an unmet medical need in the treatment of patients with relapsing urothelial cancer of the urinary bladder. The proposed Phase 2b single-arm, open-label, multi-center trial is designed to assess the efficacy and safety of UGN-102 as a potential first-line chemoablation agent in the treatment of patients with LG NMIBC at risk for recurrence. Transurethral resection of bladder tumor (TURBT) followed by adjuvant chemotherapy or immunotherapy is the current standard of care. In 2012, the annual incidence of urothelial bladder cancer was 80,000 in the United States with a prevalence of 700,000[1]. NMIBC accounts for approximately 80% of all new cases of bladder cancer diagnosed in the United States each year, with the majority of patients experiencing life-long, repetitive surgical treatment for cancer recurrence.

"The IND submission of UGN-102 is a significant milestone for our RTGel™ technology platform. With UGN-102, we have a great opportunity to provide the first non-surgical alternative for patients suffering from chronically relapsing LG NMIBC," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "The positive data observed in the Phase 3 trial of our lead product candidate, UGN-101 (MitoGel®), is a strong validation of our platform. We are encouraged by the efficacy and durability data generated in a Phase 2a European study of UGN-102 and if our IND is accepted, look forward to beginning the clinical trial in the United States."

About UGN-102
UGN-102 is a novel formulation of mitomycin that provides slow release of the drug over time by using UroGen's proprietary RTGel™ Technology Platform. It is administered locally via instillation into the bladder and is under investigation as a potential first-line chemoablation agent in the treatment of low-grade bladder cancer. UroGen submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration in Q2 2018, and upon clearance of the IND, the Company intends to conduct a Phase 2b program to further investigate UGN-102 in the treatment of this condition.

About Non-Muscle Invasive Bladder Cancer (NMIBC)[1,2]
Bladder cancer accounts for approximately 90% to 95% of all new cases of urothelial cancer in the United States, with a prevalence of approximately 700,000. Bladder cancers are described as non-muscle invasive (NMIBC, 80% of total incidence and prevalence; 64,000 and 560,000, respectively) or muscle-invasive (MIBC, 20% total incidence and prevalence; 16,000 and 140,000, respectively) based on how far into the wall of the bladder they have invaded. Overall, approximately 70% of patients with NMIBC present with low-grade disease at diagnosis (incidence: 44,800 and prevalence 392,000). The standard of care for treating NMIBC patients is TURBT followed by adjuvant chemotherapy or immunotherapy. TURBT is a surgical operation for tumor removal conducted under anesthesia in a hospital setting and is associated with risks such as bleeding, injury to the bladder and infection. Relapse of disease is common after TURBT (30-40% at one year and up to 70% at five years following surgery); and, it is not unusual for patients to require multiple surgical procedures to control NMIBC over a lifetime making bladder cancer the most costly cancer to treat in the United States. No drugs have been approved for the primary non-surgical management of NMIBC, and only three drugs are approved for adjuvant (post-surgical) use to decrease the likelihood of recurrence.

About UroGen Pharma Ltd.
UroGen Pharma Ltd. (Nasdaq:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. UroGen has developed RTGel™, 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 lead product candidates, UGN-101 (MitoGel®) and UGN-102 (VesiGel™), are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma and bladder cancer, respectively. UroGen is headquartered in Ra'anana, Israel with U.S. headquarters in New York.

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 with respect to the timing and results of clinical development and commercial prospects of the product candidates in UroGen's pipeline, including UGN-102 (VesiGel™) and UGN-101 (MitoGel®), the potential for the FDA to accept the IND application for UGN-102, if accepted, the ability of UroGen to commence the proposed Phase 2b clinical trial of UGN-102 for the treatment of patients with LG NMIBC, and the ability of UroGen to become a leader in the field of uro-oncology, particularly in the treatment of low-grade UTUC, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the potential approval of its first therapy; the potential acceptance by the FDA of UroGen's IND for UGN-102 for the treatment of patients with LG NMIBC; the ability to commence and complete the proposed Phase 2b clinical trial of UGN-102 for the treatment of patients with LG NMIBC; the ability to obtain and maintain regulatory approval; the scope, progress and expansion of developing and commercializing UroGen's product candidates; and UroGen's ability to attract or retain key management and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of our annual report for the year ended December 31, 2017 filed with the SEC on March 15, 2018 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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[1] https://seer.cancer.gov/statfacts/html/urinb.html

[2] Campbell-Walsh Urology 10th Edition 2011

UroGen Pharma Ltd.