UroGen Pharma Announces FDA Acceptance of Investigational New Drug Application for MitoGel, a Novel Sustained Release Formulation of Mitomycin C, for the Treatment of Low-Grade Upper Tract Urothelial Carcinoma

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-Plans to Initiate Single Pivotal, Open-Label, Single-Arm Phase 3 Clinical Trial in First Quarter of 2017-

Ra'anana, Israel, New York, NY, December 12, 2016: UroGen Pharma Ltd., a privately held, clinical stage biopharmaceutical company, today announced the acceptance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for MitoGel™ for the treatment of low-grade upper tract urothelial carcinoma (UTUC). There are currently no FDA-approved drugs for the treatment of UTUC. UroGen plans to initiate a single pivotal, open-label, single-arm Phase 3 clinical trial of MitoGel for the treatment of low-grade UTUC in the first quarter of 2017. The single pivotal, open-label, single-arm Phase 3 clinical trial design is based on preliminary evidence of the safety and efficacy of MitoGel from an ongoing investigator-initiated Compassionate Use program for the treatment of severe, non-resectable, low-grade UTUC.

Utilizing RTGel, a proprietary sustained release, hydrogel-based formulation, MitoGel is designed to enable longer exposure of Mitomycin C to the urinary tract tissue, thereby potentially enabling the treatment of tumors by non-surgical means. MitoGel has been granted Orphan Drug Designation by the FDA for the treatment of UTUC.

Ron Bentsur, Chief Executive Officer of UroGen Pharma, stated, "IND acceptance by the FDA is an important milestone for UroGen and our MitoGel program, and it highlights our commitment to developing new therapies for urological diseases that we believe have high unmet clinical needs. We look forward to commencing the single pivotal, open-label, single-arm Phase 3 clinical trial for MitoGel for the treatment of low-grade UTUC in the first quarter of 2017."

Arie Belldegrun, MD, UroGen Pharma's Chairman, commented, "As we continue to advance our product candidates, we look forward to potentially establishing a leadership position in the treatment of various forms of urothelial cancer for the benefit of patients. Concurrently, we are exploring the broad applicability of the RTGel platform beyond uro-oncology, and our recently announced Allergan collaboration for overactive bladder is one such example."

About UTUC

Upper tract urothelial carcinoma (UTUC) has an estimated annual incidence in the United States of up to 7,500 cases – about 5% to 10% of all new cases of urothelial cancer. UTUC refers to cancer of the upper tract, which connects the bladder to the kidney, and the renal pelvis. The current standard of care for this cancer is complete surgical removal of the involved kidney and upper tract. For patients with a bilateral disease, an anatomic or functionally solitary kidney, medical comorbidities or low-grade disease that present with a limited number of tumors, a kidney-conserving alternative is considered, if possible. However, due to the specific anatomy and physiology of the upper tract and renal pelvis, the performance of organ-sparing endoscopic resection and instillation of neoadjuvant or adjuvant chemotherapy are extremely challenging, leading to high rates of recurrence and risk for progression. Difficulties in administering and maintaining Mitomycin C or any other drug in the upper tract due to low residual duration and short exposure time of the active agent in the treated area results in low treatment efficacy and limited use of chemoablative agents in patients with UTUC. Furthermore, due to the rarity of UTUC, clinical development of UTUC treatments is limited and there are currently no FDA-approved drugs for the treatment of UTUC.

About UroGen Pharma Ltd.

UroGen Pharma is a clinical stage biopharmaceutical company developing advanced non-surgical, local treatments to address unmet needs in the field of urology, with a focus on uro-oncology. The Company has developed RTGel, a proprietary sustained release, hydrogel-based formulation for potentially improving the efficacy and safety profiles of existing drugs. UroGen Pharma'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 Pharma's lead product candidates, MitoGel and 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 UTUC and bladder cancer. Moreover, UroGen Pharma has recently completed a worldwide licensing agreement with Allergan Pharmaceuticals International Limited, a wholly owned subsidiary of Allergan plc, for the use of RTGel with neurotoxins for the treatment of overactive bladder and related conditions. UroGen Pharma is headquartered in Israel and also maintains a corporate office in New York City.

Forward Looking Statements

This press release contains forward-looking statements. All statements contained herein other than statements of historical fact constitute forward-looking statements, including statements regarding UroGen Pharma's anticipated results of operations and financial position, business strategy, clinical development plan and operating plans. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of preclinical studies and clinical trials conducted by or on behalf of UroGen Pharma, including with respect to the efficacy and safety of its product candidates; UroGen Pharma's ability to obtain and maintain regulatory approval of its product candidates, and the labeling for any approved products; the scope, progress, expansion and costs of developing and commercializing UroGen Pharma's product candidates; UroGen Pharma's ability to obtain and maintain intellectual property protection for its product candidates; UroGen Pharma's anticipated growth strategies; UroGen Pharma's expectations regarding competition; the anticipated trends and challenges in UroGen Pharma's business and the markets in which it operates; UroGen Pharma's ability to attract or retain key management and personnel; the size and growth of the potential markets for UroGen Pharma's product candidates and its ability to serve those markets; the rate and degree of market acceptance of UroGen Pharma's product candidates vis-à-vis alternative therapies; UroGen Pharma's expectations regarding regulatory requirements; developments in applicable regulatory regimes; UroGen Pharma's ability to enter into and maintain collaborations; and the manner in which UroGen Pharma intends to use its cash resources and the sufficiency thereof. Moreover, UroGen Pharma operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. It is not possible for UroGen Pharma's management to predict all risks, nor can they assess the impact of all factors on its business or the extent to which any such factor or combination of factors may cause actual results to

differ materially from those contained herein. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur, and UroGen Pharma's actual results could differ materially and adversely from those anticipated or implied by the forward-looking statements contained herein. UroGen Pharma undertakes no obligation to update any such forward-looking statements after the date hereof to conform to actual results or changes in expectations.

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