UroGen Pharma Initiates Rolling Submission of New Drug Application (NDA) for UGN-101 for the Treatment of Low-Grade Upper Tract Urothelial Cancer (LG UTUC)

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UGN-101 Has the Potential to Become the First Drug Ever Approved for LG UTUC

Submission Supported by Pivotal Phase 3 OLYMPUS Study; Topline Results to be Presented in January 2019

Company Expects to Complete NDA Submission by mid-2019, with Potential Approval in 2019

NEW YORK--(BUSINESS WIRE)--Dec. 17, 2018-- UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, today announced that it has initiated the rolling submission with the U.S. Food and Drug Administration (FDA) of the New Drug Application (NDA) for UGN-101 (mitomycin gel) for instillation as a treatment for patients with low-grade upper tract urothelial cancer (LG UTUC). The company expects to complete its NDA submission by mid-2019, with potential approval in 2019.

“This is an important milestone in our mission to bring innovative, non-surgical treatment options to patients with urothelial cancers and potentially eliminate the need for repetitive surgical intervention and kidney removal,” said Ron Bentsur, Chief Executive Officer of UroGen. “UGN-101 has the potential to be the first non-surgical therapy for LG UTUC, and the first drug ever approved in this indication. We are grateful to our UroGen team and clinical investigators who have worked diligently to advance this potentially paradigm-shifting program.”

The NDA submission is supported by clinical data from the Phase 3 OLYMPUS clinical trial of UGN-101 for the non-surgical treatment of LG UTUC. Results from an interim analysis were presented at the American Urologic Association Annual Meeting in May 2018. UroGen plans to present topline data from the OLYMPUS study in January 2019.

The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC.

About UGN-101
UGN-101 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade upper tract urothelial cancer (LG UTUC). Utilizing the RTGel™ technology platform, UroGen’s proprietary sustained release, hydrogel-based formulation, UGN-101 is designed to enable longer exposure of mitomycin to urinary tract tissue, thereby enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard ureteral catheters.

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 and UGN-102, 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 New York, NY with operations in Los Angeles, CA and Israel.

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 of the completion of UroGen Pharma’s NDA submission, the timing of top line results for the Olympus pivotal Phase 3 trial, and the potential of UGN-101 to be the first non-surgical therapy for LG UTUC and the first drug ever approved in this indication, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the Olympus pivotal Phase 3 trial, and potential safety and other complications thereof; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen Pharma’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; and UroGen Pharma’s ability to attract or retain key management, members of the board of directors and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen Pharma’s Form 20-F filed with the SEC on March 15, 2018 and other filings that UroGen Pharma 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 Pharma’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 Pharma as of the date of this release.

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