Following Pre-NDA Meeting with the FDA, UroGen Announces Rolling NDA Submission for UGN-102 to Begin January 2024

October 3, 2023

PRINCETON, N.J.--(BUSINESS WIRE)--Oct. 3, 2023-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on plans for submission of a New Drug Application (NDA) for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of complete response (CR) at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls (CMC) sections of the NDA, which is planned for January 2024. If approved, UGN-102 has the potential to introduce a new non-surgical treatment paradigm for LG-IR-NMIBC, a subset of bladder cancer patients characterized by high recurrence rates and the need for multiple surgeries.

“We are very pleased with the outcome of our pre-NDA meeting where the FDA agreed with our plan to submit our NDA for UGN-102 once all patients reach 12 months post CR. Our dialogue with the FDA during our recent pre-NDA meeting was very constructive and underscores the strength of our clinical program for UGN-102,” said Liz Barrett, President and CEO, UroGen. “With the announcement of positive Phase 3 topline results from the ATLAS and ENVISION studies earlier this year, this meeting was a significant step in defining the path forward for NDA submission and potential approval for UGN-102. UroGen is committed to developing innovative treatments for those battling bladder cancer, one of the most recurrent malignancies, and UGN-102 stands at the forefront of that mission.”

The UGN-102 clinical development plan centers around the Phase 3 ENVISION pivotal trial and is supported by robust clinical data from the ATLAS Phase 3 and OPTIMA Phase 2b trials.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of LG-IR-NMIBC. Utilizing UroGen’s proprietary RTGel ® technology, a 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 in an outpatient setting. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates submitting an NDA for UGN-102 in 2024.

About UroGen Pharma Ltd.

UroGen is a 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. JELMYTO® (mitomycin) for pyelocalyceal solution 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 path forward for a UGN-102 NDA submission; the potential approval of UGN-102; the potential for UGN-102 to introduce a new non-surgical treatment paradigm for LG-IR-NMIBC; the anticipated commencement of a rolling NDA for UGN-102 in January 2024; and the potential of UroGen’s proprietary RTGel technology to improve therapeutic profiles of existing drugs and UroGen’s sustained release technology making local delivery potentially more effective as compared to other treatment options. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; the ability to obtain regulatory approval within the timeframe expected, or at all; there is no guarantee that the current clinical development plan for UGN-102 will ultimately support submission of an NDA, notwithstanding the current agreement with the FDA; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen’s industry; 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; UroGen’s RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; UroGen’s financial condition and need for additional capital in the future. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the SEC in August 10, 2023 (which is 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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