UroGen Pharma Announces Exclusive License Agreement with Agenus Inc to Advance Treatment of Urinary Tract Cancers

November 11, 2019

UroGen to Develop and Commercialize Zalifrelimab (AGEN1884, anti-CTLA-4 antibody) with UGN-201 for High-Grade Non-Muscle Invasive Bladder Cancer

NEW YORK--(BUSINESS WIRE)--Nov. 11, 2019-- UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of uro-oncology, today announced that it has entered into an exclusive worldwide[1] license agreement with Agenus Inc (Nasdaq:AGEN) to develop and commercialize zalifrelimab (AGEN1884, anti-CTLA-4 antibody) via intravesical delivery in combination with UGN-201 for the treatment of urinary tract cancers. This combination is based on encouraging preclinical data utilizing UroGen's proprietary sustained release technology, which is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects. UroGen's initial indication for development will be high-grade non-muscle invasive bladder cancer (HG NMIBC).

Zalifrelimab (AGEN1884, anti-CTLA-4 antibody) is currently being evaluated by Agenus in combination with Agenus' anti-PD-1 antibody balstilimab (AGEN2034) in second line cervical cancer with anticipated BLA filing in 2020. UGN-201 is a TLR-7/8 agonist that is in early stage development at UroGen for HG NMIBC.

"Patients with high-grade forms of non-muscle invasive bladder cancer are at a high risk of progression and we are committed to rapidly advancing our development efforts on their behalf," said Liz Barrett, President and Chief Executive Officer of UroGen. "Together with our pipeline medicines, UGN-101 and UGN-102, that target low-grade upper tract urothelial cancer and low-grade bladder cancer, respectively, the addition of this new medicine targeting high grade urothelial diseases provides UroGen with a complementary pipeline that advances our vision to be a leader in uro-oncology."

Under the terms of the agreement and in exchange for the worldwide[1] exclusive license to AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery, Agenus will receive an upfront payment of $10 million, in addition to up to $115 million for achieving certain clinical development and regulatory milestones, up to $85 million upon achieving certain commercial milestones, as well as royalties on net sales of licensed products in the 14-20% range.

UroGen will be responsible for all development and commercialization activities.

UroGen's lead investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to potentially ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer (LG UTUC) and low-grade non-muscle invasive bladder cancer (LG NMIBC), respectively. UGN-101 has been granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations by the U.S. Food and Drug Administration for the treatment of LG UTUC.

[1] Worldwide license does not include Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions.

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 investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to potentially ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and bladder cancer, respectively. UroGen is headquartered in New York, NY with operations in Los Angeles, CA and Israel.

Forward Looking Statements

Statements in this report that are not strictly historical in nature, including statements regarding the Company's plans and expectations with respect to its planned development of AGEN1884, are forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including risks relating to those inherent in the development of products for the treatment of urological cancer. For a discussion of these and other factors, please refer to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2019 as well as the Company's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof, except as required by law.

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