UroGen Pharma Announces Sponsored Research Agreement with the Johns Hopkins University School of Medicine to Expand Immuno-Oncology Pipeline

March 15, 2021

Exploratory research at the Johns Hopkins University to study checkpoint inhibitors combined with RTGel ™ in Glioblastoma Multiforme

PRINCETON, N.J.--(BUSINESS WIRE)--Mar. 15, 2021-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases, today announced a strategic, exploratory immunotherapy sponsored research agreement with the Johns Hopkins University to study the potential of checkpoint inhibitors combined with RTGel ™ in glioblastoma multiforme, or GBM, an aggressive and difficult to treat brain cancer. Johns Hopkins researchers expect to begin nonclinical research of RTGel combined with a PD-1 and a CTLA-4, respectively, in the second quarter of 2021.

UroGen's proprietary RTGel technology is a reverse-thermal hydrogel that may increase dwell time of current therapies and exposure of active drugs, potentially improving the therapeutic effects of existing products.

"Local delivery of checkpoint inhibitors has the potential to fundamentally change the treatment paradigm for some of the most devastating cancers. We are excited to work with Johns Hopkins investigators on this exciting frontier in immunotherapy," said Dr. Mark Schoenberg, Chief Medical Officer of UroGen Pharma. "This research will be an exciting addition to our current immuno-oncology pipeline, including UGN-302 which combines UGN-201, a toll-like receptor 7/8 agonist, with UGN-301, a CTLA-4 antagonist, for the treatment of high-grade non-muscle invasive bladder cancer. With our expanding programs in this field of research, we look forward to extending the potential of our RTGel platform in immunotherapy."

The goal of this research is to further understand the efficacy of local delivery of immunotherapy to tumor draining lymph nodes, where anti-tumor T cells are primed by antigen presenting cells. Based on research at the Johns Hopkins University, sustained release of immunotherapy such as anti-PD-1 delivered directly to the lymph nodes, may target myeloid cells and T cells with PD-1 expression to enhance proliferation and anti-tumor activity of T cells. Successful use of lymph-node targeting therapies may reduce the toxicities associated with systemic administration of immunotherapy.

GBM is an aggressive malignant brain tumor with a five-year survival rate of less than five percent. GBM is difficult to treat and treatment options today are limited, and typically include surgery followed by radiation and chemotherapy. It is the most common primary brain tumor, with around 12,000 cases diagnosed per year in the United States.

About UroGen Pharma Ltd.

UroGen is a biopharmaceutical company dedicated to building novel solutions that treat specialty cancers and urologic diseases 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. UroGen's first commercial product, 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: the potential of UroGen's proprietary RTGel technology platform to improve therapeutic profiles of existing drugs; the potential to expand the use of the RTGel platform in immunotherapy; the timing of expected initiation of the nonclinical research of RTGel combined with a PD-1 and a CTLA-4; the potential for local delivery of checkpoint inhibitors to fundamentally change the treatment paradigm for some cancers; and the potential for successful use of lymph-node targeting therapies to reduce the toxicities associated with systemic administration of immunotherapy. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities, including complications resulting from the ongoing COVID-19 pandemic; the labeling for any approved product; 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; and any negative effects on UroGen's business, commercialization and product development plans caused by or associated with COVID-19. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on November 9, 2020, 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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