UroGen Pharma to Host UGN-102 Data Event on July 27, 2023

July 6, 2023

-- Program to Highlight Topline Results from the Phase 3 ATLAS and Pivotal ENVISION Clinical Trials --

PRINCETON, N.J.--(BUSINESS WIRE)--Jul. 6, 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 will host a data event on Thursday, July 27th, 2023 at 10:00 a.m. Eastern Time. The event will focus on UGN-102 (mitomycin) for intravesical solution for patients with low-grade, intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) and will highlight topline results from the Phase 3 ATLAS and ENVISION clinical trials.

For ENVISION, UroGen will provide complete response rate (the primary endpoint) from approximately 240 patients who completed the study; and for ATLAS, the predecessor to ENVISION, UroGen will provide disease free survival (the primary endpoint) as well as complete response, durability, and safety data from approximately 280 patients that completed the study. The program will also feature Key Opinion Leaders and a panel discussion on the treatment of LG-IR-NMIBC.

Please register for the webinar under the Events & Presentations section of the Company's Investor Relations site (https://investors.urogen.com/events-and-presentations).

Following the live audio webcast, a replay will be available on the Company's website (https://urogen.com).

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin 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 ENVISION Phase 3 study, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024. If approved, UGN-102 would be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries.

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: plans with respect to a regulatory submission for UGN-102 and the timing thereof; the potential for UGN-102 to be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries; 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; 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 March 31, 2023 filed with the SEC in May 11, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230706821424/en/

INVESTOR CONTACT:
Vincent Perrone
Senior Director, Investor Relations
vincent.perrone@urogen.com
609-460-3588 ext. 1093

MEDIA CONTACT:

Cindy Romano
Director, Corporate Communications
cindy.romano@urogen.com
609-460-3583 ext. 1083

Source: UroGen Pharma Ltd.