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UroGen Pharma announces positive results of UGN-101

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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

A clinical stage pharma company, UroGen Pharma developing treatments to address unmet needs in the field of urology has announced topline results from the ongoing pivotal Phase 3 OLYMPUS clinical trial of UGN-101 (mitomycin gel) for instillation, an investigational mitomycin formulation for the non-surgical treatment of low-grade upper tract urothelial cancer (UTUC).

This analysis showed that on an intent-to-treat basis, 57 percent of patients achieved a complete response (CR) rate at their primary disease evaluation (PDE, or the primary endpoint) which was conducted four to six weeks after completion of UGN-101 treatment. Importantly, all evaluated patients in CR remain disease free at six months.

This international, multi-center trial completed enrollment with 71 patients in December 2018. Of the 71 patients enrolled in the trial, 61 patients have been evaluated for the primary endpoint which was a CR as defined as a negative ureteroscopic evaluation and a negative wash cytology. The remaining 10 patients are awaiting PDE evaluation.

Mark P. Schoenberg, Chief Medical Officer of UroGen said, “We are pleased to report that the CR and durability data remain consistent with the Interim Analysis presented in May 2018. These results continue to validate the potential of UGN-101 to shift the surgical treatment paradigm and benefit patients whose only alternative would be repetitive endoscopic surgical intervention or complete loss of a kidney.”

“The durability observed in the OLYMPUS study provides further evidence that the non-surgical treatment of LG UTUC with UGN-101 may result in clinically-meaningful, recurrence free survival. We are grateful to the patients, their families, and clinical investigators who have made this important study possible”, he added.

Approximately 45 percent of tumors treated were categorized as unresectable by surgery at baseline. Of the patients who achieved CR, UroGen now has six-month durability on half of these patients. Durability is a key secondary endpoint for the trial.

The safety profile of UGN-101 continues to be acceptable with most treatment-emergent adverse events characterized as mild or moderate and transient and in line with ureteral procedures. These included ureteral narrowing and hydronephrosis, urinary tract infection, flank pain and creatinine elevation.

UroGen intends to seek regulatory approval of UGN-101 in LG UTUC based on data from all 71 patients and initiated its rolling submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018.

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.

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.