Urogen has been Granted Orphan Drug Designation from the US FDA for its Innovative Treatment of UTUC

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Urogen Pharma, a clinical stage specialty pharmaceutical company focused on treatment of urological diseases, announced today that MitoGel, a sustained release formulation of Mitomcin C, has been granted orphan-drug designation by the U.S Food and Drug Administration ("FDA") for the treatment of Urinary Upper Tract Urothelial Carcinoma (UTUC).

The novel sustained-release chemotherapy formulation is a non-surgical alternative to current standard treatment involving kidney removal, and sometimes even dialysis. The orphan designation was granted based on extensive preclinical trials showing that MitoGel extends the exposure of upper tract urothelium to the chemotherapeutic agent Mitomycin C. Due to the anatomical constrains of the upper urinary tract and continuous passing of urine through the ureter, local chemotherapy is not an effective treatment option for this type of cancer.

"We are very pleased with the FDA´s recognition of our technology as an orphan product for the treatment of this type of cancer", said Gil Hakim, President of UroGen. "This designation is an important milestone in our overall strategy to be the first company to provide a treatment for patients with UTUC, a disease with no effective non-surgical treatment option."

Prof Arie Belldegrun MD FACS, Chairman of the Board of Directors added: “As an innovative approach that directly impacts the treatment for UTUC, we look forward to future outcomes that potentially could change the landscape of upper tract therapeutics”.

About UTUC

Upper Tract Urothelial Carcinoma (UTUC) is a urinary tract Transitional Cell Carcinoma (TCC) that affects the urothelium that is lining the upper urinary tract.

UTUC affects less than 2:100,000 patients in the US. The standard treatment for UTUC is a complete removal of the implicated kidney and ureter (radical nephroureterectomy – RNU). Mainly due to the inability to retain local treatment (chemotherapy) in the ureter due to continuous urine creation by the kidneys, no adequate, organ-sparing non-surgical alternative exists. Current treatment approach results in high cost that reaches over $400,000 per patient over 5 years.

A non-surgical local treatment of this type of cancer is a highly clinical unmet need