TPS4629 Poster Session

The uTRACT registry: A single-arm, multicenter, prospective, and retrospective registry study to evaluate the real-world use of UGN-101 in participants with upper tract urothelial carcinoma (UTUC) in the United States.

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Background: Upper tract urothelial carcinoma (UTUC) constitutes 5–10% of primary urothelial carcinomas, affecting two in 100,000 people in the US annually. Peak incidence occurs in patients 70–90 years of age.[1–3] Low-Grade (LG) UTUC represents 40% of the total disease burden.[3] Endoscopically-guided ablation is often used to treat LG-UTUC, however recurrence is common, and the long-term surveillance risks potential complications in this elderly patient population. UGN-101 is a reverse thermal hydrogel formulation of mitomycin approved for chemoablative treatment of LG-UTUC, administered as a liquid in a chilled state, which converts to a gel depot at body temperature, resulting in a dwell time of 4–6 hours. In the phase 3 OLYMPUS trial, 42 of the 71 LG-UTUC patients treated with UGN-101 achieved complete response (CR) at 3 months.[4] Among the 41 patients followed after CR, median follow-up was 28.1 months (95% CI, 13.1-57.5), and median duration of response (DoR) was 47.8 months (95% CI, 13.0-not estimable).[5] **Methods:** The uTRACT registry (NCT05874921) is evaluating real-world data from patients administered UGN-101, post-FDA approval(15 Apr 2020). Approximately 400 patients >18 years old with UTUC who received ≥1 dose of UGN-101 will be enrolled at ~20 sites. Retrospective data will be collected from patients that received UGN-101 after approval as well as prospective data from newly eligible patients. UGN-101 is administered as 6 once weekly pyelocalyceal instillations retrograde via ureteral catheter or antegrade via a nephrostomy tube. Instillation volume is based on volumetric measurements, not to exceed 15 mL (60 mg of mitomycin). For participants with a CR 3 months after the first dose, once monthly maintenance instillations may be administered (up to 11 additional doses). Participant history and disease status are collected at baseline (prior to UGN-101 dosing), and dosing information, surveillance endoscopy and imaging results will be captured over a period of 3 years post baseline, at approximately 3, 6, 12, 24, and 36 months after the first instillation. Assessment of response will be based on endoscopic surveillance, imaging, cytology, and/or for-cause biopsy. Data analysis will be performed on the overall cohort (~400 participants) and the LG-UTUC cohort (expected to be ~340 participants). Outcomes collected include no evidence of disease at 3-months, DoR, recurrence free survival, time to recurrence/ progression and adverse events. The uTRACT registry started enrollment in 2023 with 228 patients recruited to date. 1. Siegel RL, et al. CA Cancer J Clin. 2022;72:7-33. 2. Rouprêt M, et al. Eur Urol. 2023;84:49-64. 3. Raman J, Shore ND. Rev Urol. 2020;22:1-8. 4. Kleinmann N, et al. Lancet Oncol. 2020;21:776-785. 5. Pierorazio PM, et al. J Urol. 2024: 101097ju0000000000004331. Clinical trial information: NCT05874921. Research Sponsor: UroGen Pharma.