



LONG-TERM OUTCOMES OF PRIMARY CHEMOABLATION OF LOW-GRADE UPPER TRACT UROTHELIAL CARCINOMA WITH UGN-101, A MITOMYCIN REVERSE THERMAL GEL

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INTRODUCTION

- Low-grade upper tract urothelial carcinoma (LG-UTUC) can be treated with endoscopically guided ablation; however, recurrence is common, requiring lifelong surveillance, associated with complications¹⁻⁴
- In the phase 3 OLYMPUS trial (NCT02793128) **UGN-101**, a reverse thermal gel containing mitomycin (4mg/mL) used as primary treatment for LG-UTUC, resulted in clinically significant disease eradication⁵
- Here we report long-term outcomes of patients with recurrent and new-onset LG-UTUC who achieved complete response (CR) in OLYMPUS (**Figure 1**)
- CR is defined as negative 3-month ureteroscopic evaluation, negative cytology, and negative for-cause biopsy

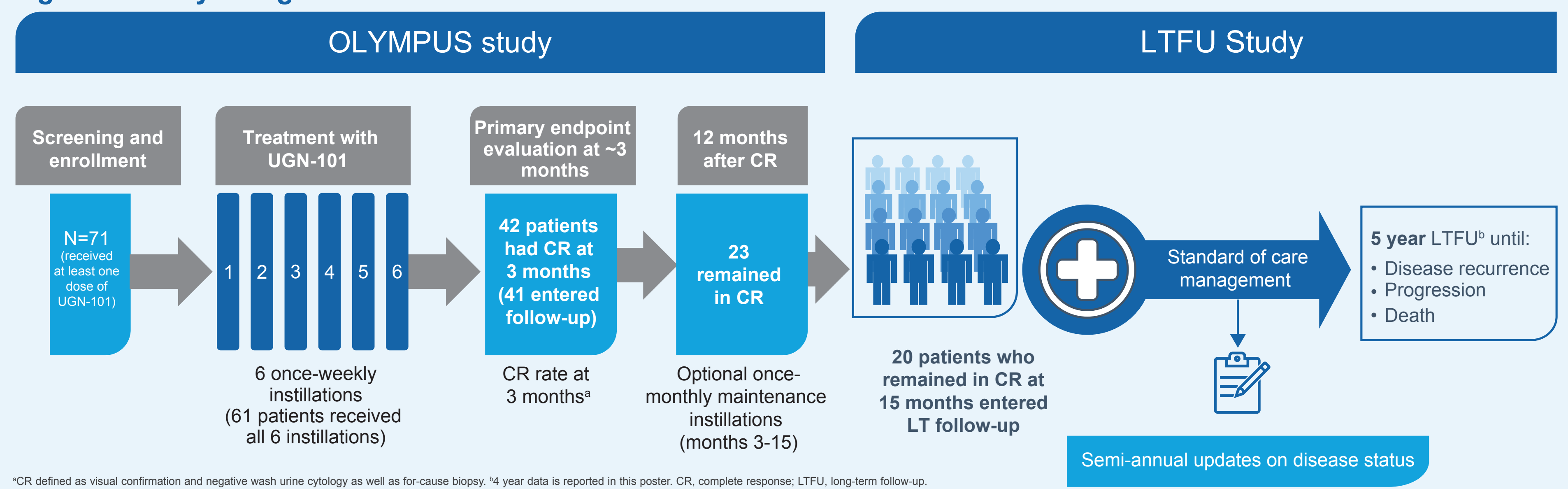
RESULTS

Table 1. Baseline Characteristics

Characteristic	OLYMPUS Trial (N=71)	LTFU (n=20)
Age, median (range), years	71 (42-87)	72 (50-87)
Sex, n (%)		
Male	48 (68)	12 (60)
Female	23 (32)	8 (40)
Race, n (%)		
White	62 (87)	18 (90)
Black	4 (6)	0
Hispanic	3 (4)	2 (10)
Asian	2 (3)	0
Other	0 (0)	0
Two kidneys at enrollment, n (%)	63 (89)	19 (95)
History of UTUC, n (%)	34 (48)	10 (50)

*Percentage was calculated from the overall number of patients in the ITT analysis set. ITT, intention-to-treat; max, maximum; min, minimum; UTUC, upper tract urothelial carcinoma.

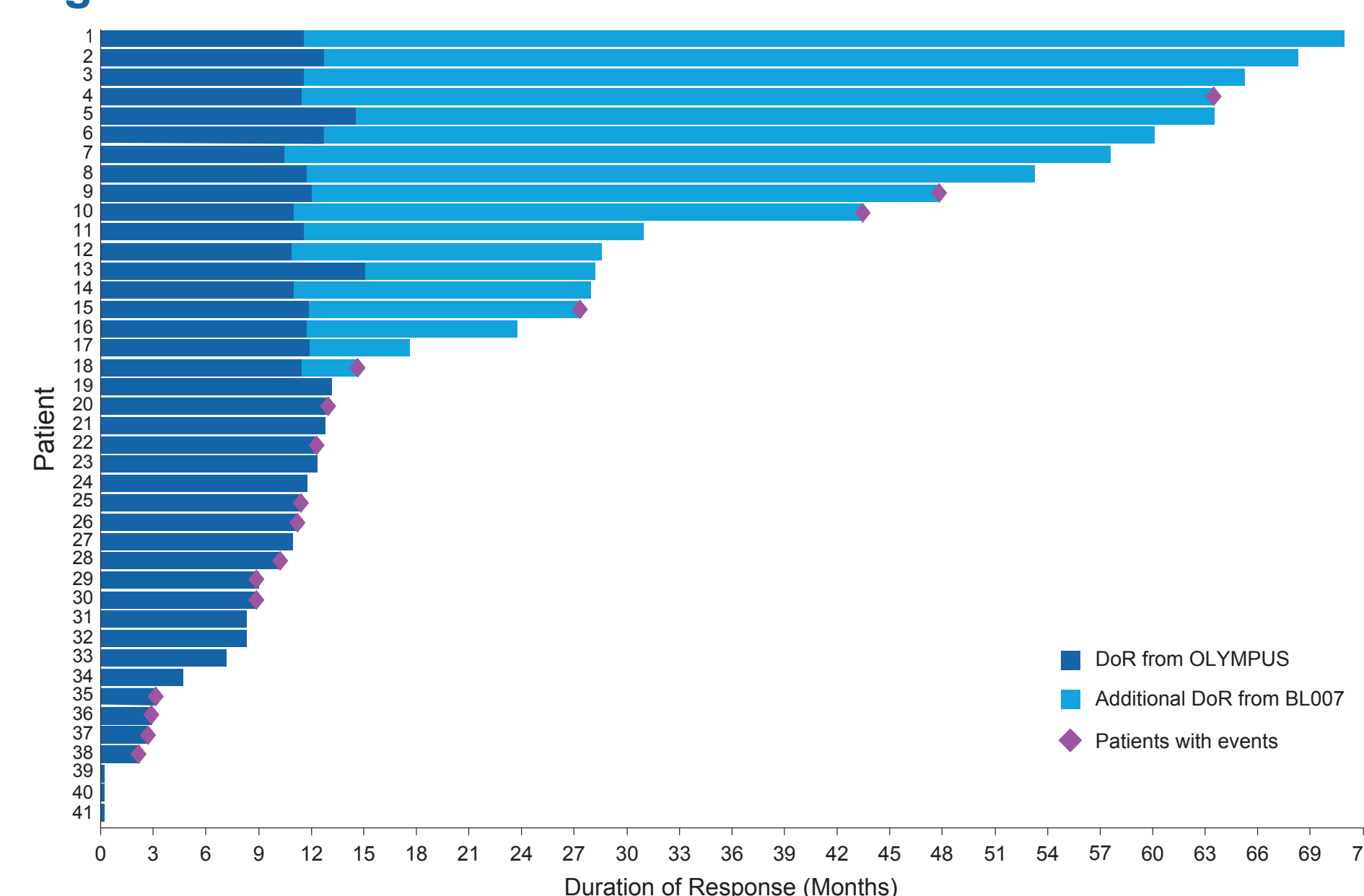
Figure 1. Study Design and Methods



*CR defined as visual confirmation and negative wash urine cytology as well as for-cause biopsy. [†]4 year data is reported in this poster. CR, complete response; LTFU, long-term follow-up.

- 41 patients with CR at 3 months were followed up after initial treatment (**Table 1**) with a median follow-up of 28.1 months (95% Confidence Interval (CI) 13.1, 57.5) and a median duration of response (DoR) of 47.8 months (95% CI 13.0, not estimable [NE]), **Table 2, Figures 2 and 3**
- Of these patients, 21 had new-onset UTUC, and 20 had recurrent UTUC at baseline; there were no significant differences in durability between groups, with 8 patients in each group experiencing recurrence or death

Figure 2. Swimmer Plot of DoR in OLYMPUS and LTFU



DoR, duration of response; LTFU, long-term follow-up

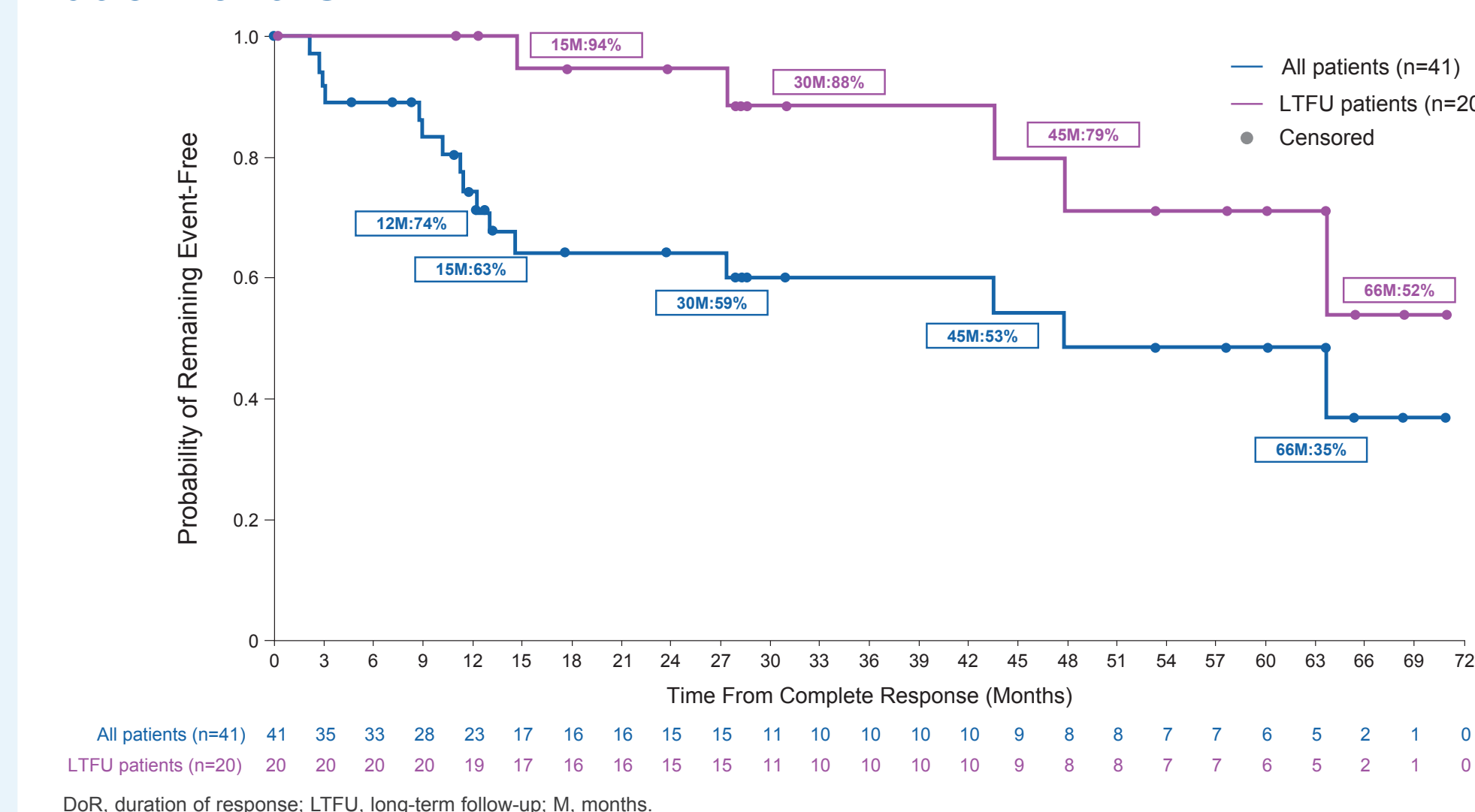
- 20 patients entered LTFU with a median follow-up of 53.3 months (95% CI 27.9, 65.3); median DoR was not estimable (95% CI 43.5, NE) due to the low event rate. Of the 15 patients censored, 9 discontinued and 6 were ongoing at the time of analysis
- Of the 20 patients evaluated in LTFU, 2 (10%) had UC tumor recurrence, and 3 (15%) patients died (2 unknown reasons and 1 septic shock from *E. coli* bacteremia and acute hypoxemic respiratory failure); no deaths were related to study treatment

Table 2. Summary Response in OLYMPUS and LTFU

	OLYMPUS FU (n=41)	LTFU (n=20)
Patients with events, n (%)		
Recurrence of disease	10 (24.4)	2 (10.0)
Death	6 (14.6)	3 (15.0)
Patients censored, n (%)		
Early discontinuation in LTFU	5 (12.2)	9 (45.0)
Ongoing CR	6 (14.6)	6 (30.0)
Median follow-up time, months (95% CI)	28.1 (13.1, 57.5)	53.3 (27.9, 65.3)
Kaplan-Meier estimate of DoR, months (95% CI)	47.8 (13.0, NE)	NE (43.5, NE)

CI, confidence interval; CR, complete response; DoR, duration of response; FU, follow-up; LTFU, long-term follow-up; NE, not estimable.

Figure 3. Kaplan-Meier Estimate of DoR in Patients with CR at 3 Months



All patients (n=41) 41 35 33 28 23 17 16 16 15 15 11 10 10 10 10 9 8 8 7 7 6 5 2 1 0
LTFU patients (n=20) 20 20 20 20 19 17 16 16 15 15 11 10 10 10 10 9 8 8 7 7 6 5 2 1 0
DoR, duration of response; LTFU, long-term follow-up; M, months.

CONCLUSIONS

- Patients with LG-UTUC who achieved CR after receiving treatment with **UGN-101** experienced clinically meaningful long-term response
- The median DoR of all patients achieving CR in OLYMPUS was 47.8 months, irrespective of whether their cancer was new onset or recurrent
- Limitations: this was a *post-hoc* analysis, and patients entering LTFU up may have done so due to good results
- The ongoing uTRACT registry (NCT05874921) will provide an opportunity to collect and evaluate real-world data in a larger sample, to further inform the use of **UGN-101** in UTUC patients

References:
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Disclosures:
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