

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



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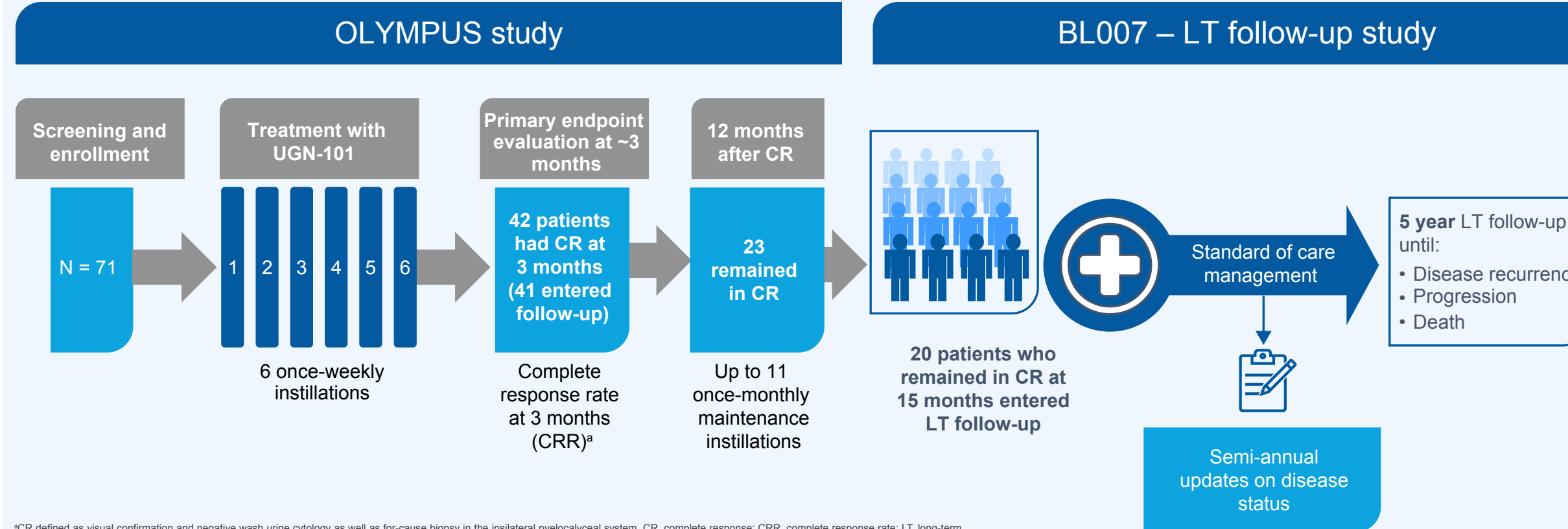
INTRODUCTION

- Low-grade upper tract urothelial carcinoma (LGUTUC) can be treated with endoscopically guided ablation, however, relapse 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 who achieved complete response (CR) in OLYMPUS; defined as negative 3-month ureteroscopic evaluation, negative cytology, and negative for-cause biopsy

RESULTS

- Among the 41 patients followed up after initial CR (1 withdrew consent), median follow-up was 28.1 months (95% confidence interval [CI] 13.1, 57.5); median duration of response (DoR) was 47.8 months (95% CI 13.0–not estimable [NE])
- 20 patients entered long-term follow-up in study BL007: with a median follow-up of 53.3 months [95% CI 27.9, 65.3]); 75% had no evidence of recurrence; median DoR was not estimable (95% CI 43.5, NE) due to the low event rate
- Of the 41 patients with CR in OLYMPUS, 16 (39%) had documented events; 10 (24.4%) had urothelial carcinoma (UC) tumor recurrence and 6 (14.6%) patients died (not treatment-related)
- Of the 20 patients evaluated in BL007, 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

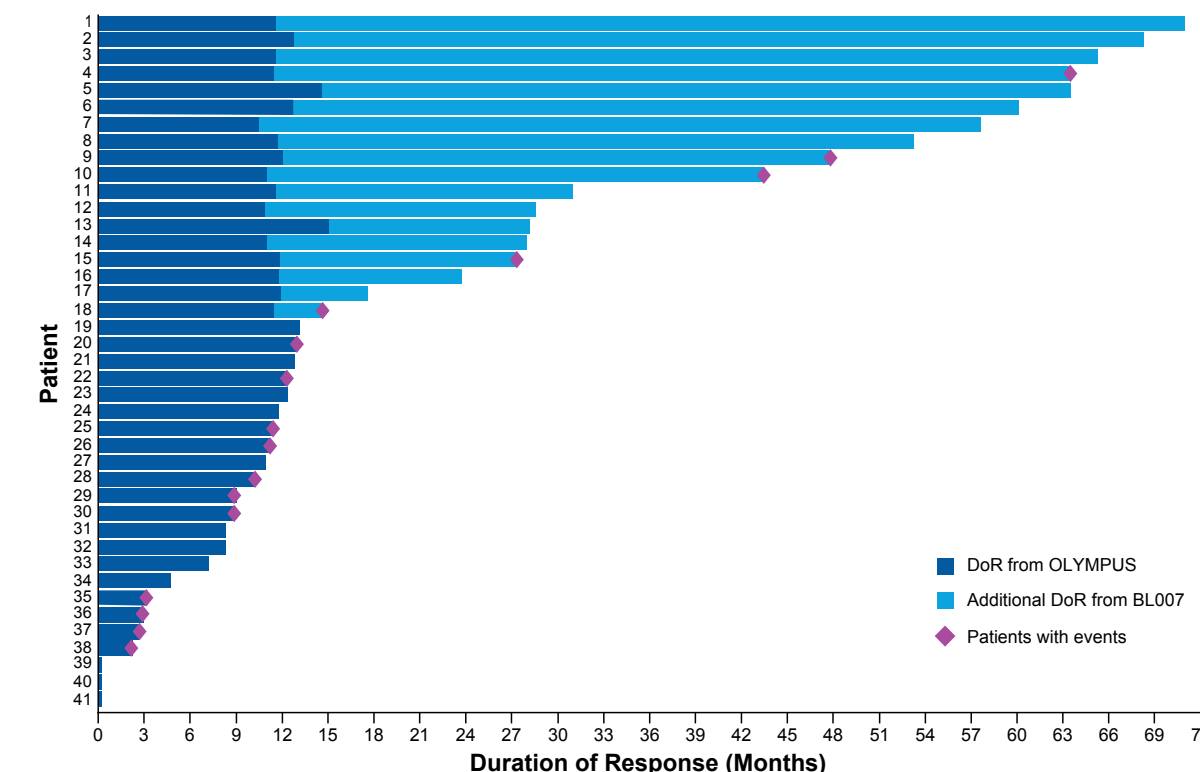
STUDY DESIGN AND METHODS



*CR defined as visual confirmation and negative wash urine cytology as well as for-cause biopsy in the ipsilateral pyelocalyceal system. CR, complete response; CRR, complete response rate; LT, long-term.

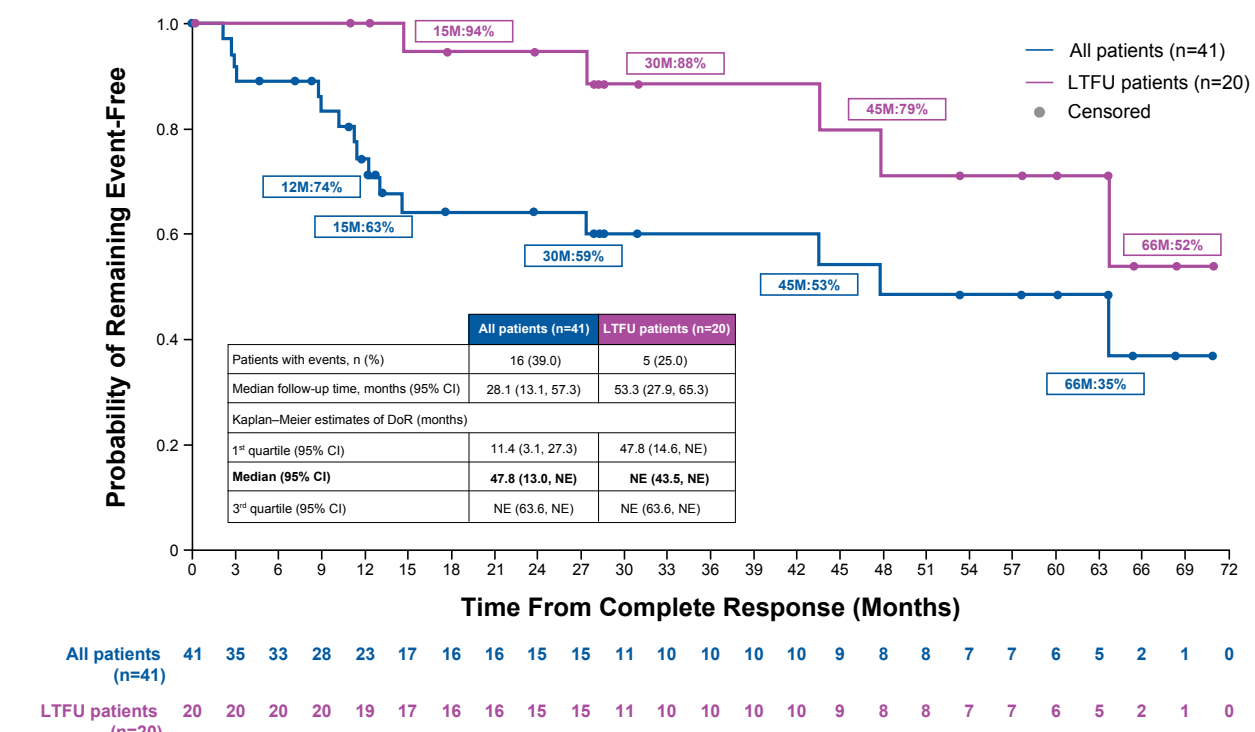
- OLYMPUS was an open-label, single-arm, phase 3 trial. The study design, inclusion/exclusion criteria, and results have been previously reported⁵
- Briefly, 71 patients with LG-UTUC were treated with 6 once-weekly doses of intracavitary **UGN-101**
 - 42 patients achieved a CR, and 41 entered follow-up
 - Of the 23 patients who maintained a CR at the end of the 12-month post-CR follow-up period, 20 entered long-term follow-up in the BL007 study

SWIMMER PLOT FOR DURATION OF RESPONSE IN OLYMPUS (N=41) AND BL007 (N=20)



DoR, duration of response.

KAPLAN-MEIER ESTIMATION OF DURATION OF RESPONSE IN ALL PATIENTS WITH CR IN OLYMPUS (N=41) AND THE SUBSET OF PATIENTS IN BL007 (N=20)



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

BASELINE CHARACTERISTICS (OLYMPUS AND BL007)

Characteristic	OLYMPUS Trial N=71	LT Follow-Up (BL007) n=20
Age (years)		
Median (min, max)	71 (42, 87)	72 (50, 87)
Sex, n (%)^a		
Male	48 (68)	12 (60)
Female	23 (32)	8 (40)
Race, n (%)^a		
White	62 (87)	18 (90)
Black	4 (6)	0
Hispanic	3 (4)	0
Asian	2 (3)	0
Other	0 (0.0)	2 (10)
Two kidneys at enrollment, n (%)	63 (89)	19 (95)
History of upper tract UC, n (%)	34 (48)	10 (50)

^aPercentage was calculated from the overall number of patients in the ITT analysis set. ITT, intention-to-treat; LT, long-term; max, maximum; min, minimum; UC, urothelial carcinoma.

SUMMARY OF DURATION OF RESPONSE: LONG-TERM FOLLOW-UP IN BL007 (N=20)

	BL007 (n=20)
Patients with events, n (%)	5 (25.0)
Recurrence of disease	2 (10.0)
Death	3 (15.0)
Patients censored, n (%)	15 (75.0)
Early discontinuation in long-term follow-up	9 (45.0)
Ongoing CR in long-term follow-up	6 (30.0)
Median follow-up time (months) (95% CI)	53.3 (27.9, 65.3)

CR, complete response

CONCLUSIONS

- Patients with LG-UTUC receiving primary treatment with 6 once-weekly intracavitary doses of **UGN-101** in the OLYMPUS trial who then entered the long-term follow-up study experienced extended disease-free intervals
- The median DoR of all patients achieving CR in OLYMPUS was 47.8 months
- In the subset of patients entering the BL007 long-term follow-up study, the median DoR was not estimable due to the low event rate
- These durability data augment a growing body of literature that supports the use of **UGN-101** as primary treatment for patients with LG-UTUC

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Disclosures: Funded by UroGen Pharma.



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M-US-JEL-00062