



TREATMENT OF LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE INVASIVE BLADDER CANCER WITH UGN-102: LONG-TERM OUTCOMES OF THE OPTIMA II STUDY

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INTRODUCTION

- Low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) is a persistent cancer that frequently recurs despite treatment with the current standard of care, transurethral resection of bladder tumor (TURBT)
- **UGN-102** is a reverse thermal gel containing mitomycin being developed as a non-surgical treatment option for LG-IR-NMIBC
- The OPTIMA II phase 2b study (NCT03558503) treated patients with LG-IR-NMIBC with **UGN-102**
- Primary efficacy and safety results have previously been reported for the 12-month parent study;¹ here we report 4-year follow-up data

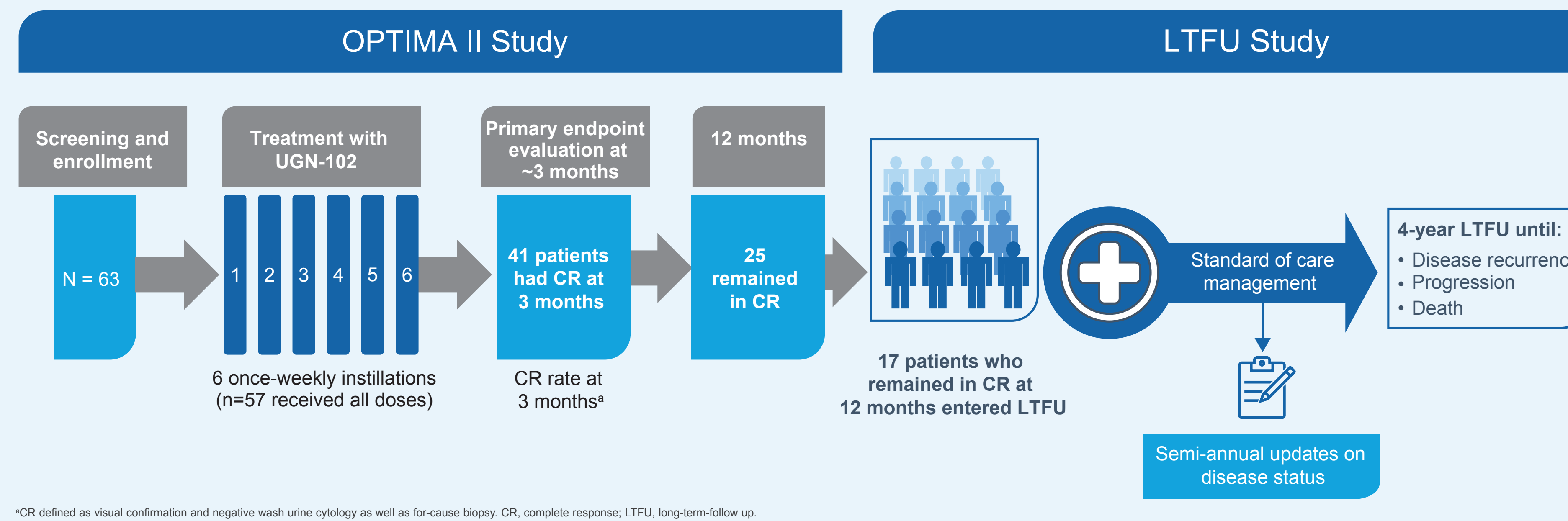
RESULTS

Table 1. Baseline Characteristics and Medical History

Characteristic	OPTIMA II ^a N=63
Age, years, median (range)	68 (33–96)
Sex, n (%)	
Male	38 (60.3)
Female	25 (39.7)
Race, n (%)	
White	55 (87.3)
Black	1 (1.6)
Hispanic	3 (4.8)
Asian	3 (4.8)
Other	1 (1.6)
Recurrent LG-NMIBC, n (%)	49 (77.8)
Mean Number of Prior TURBTs (SD)	4.0 (3.3)
Median Number of Prior TURBTs (range)	3.0 (0–13)

^aBaseline characteristics of the subset of patients entering the LTFU were similar to the entire OPTIMA II population. NMIBC, non-muscle invasive bladder cancer; SD, standard deviation; TURBT, transurethral resection of bladder tumor.

Figure 1. Study Design and Methods



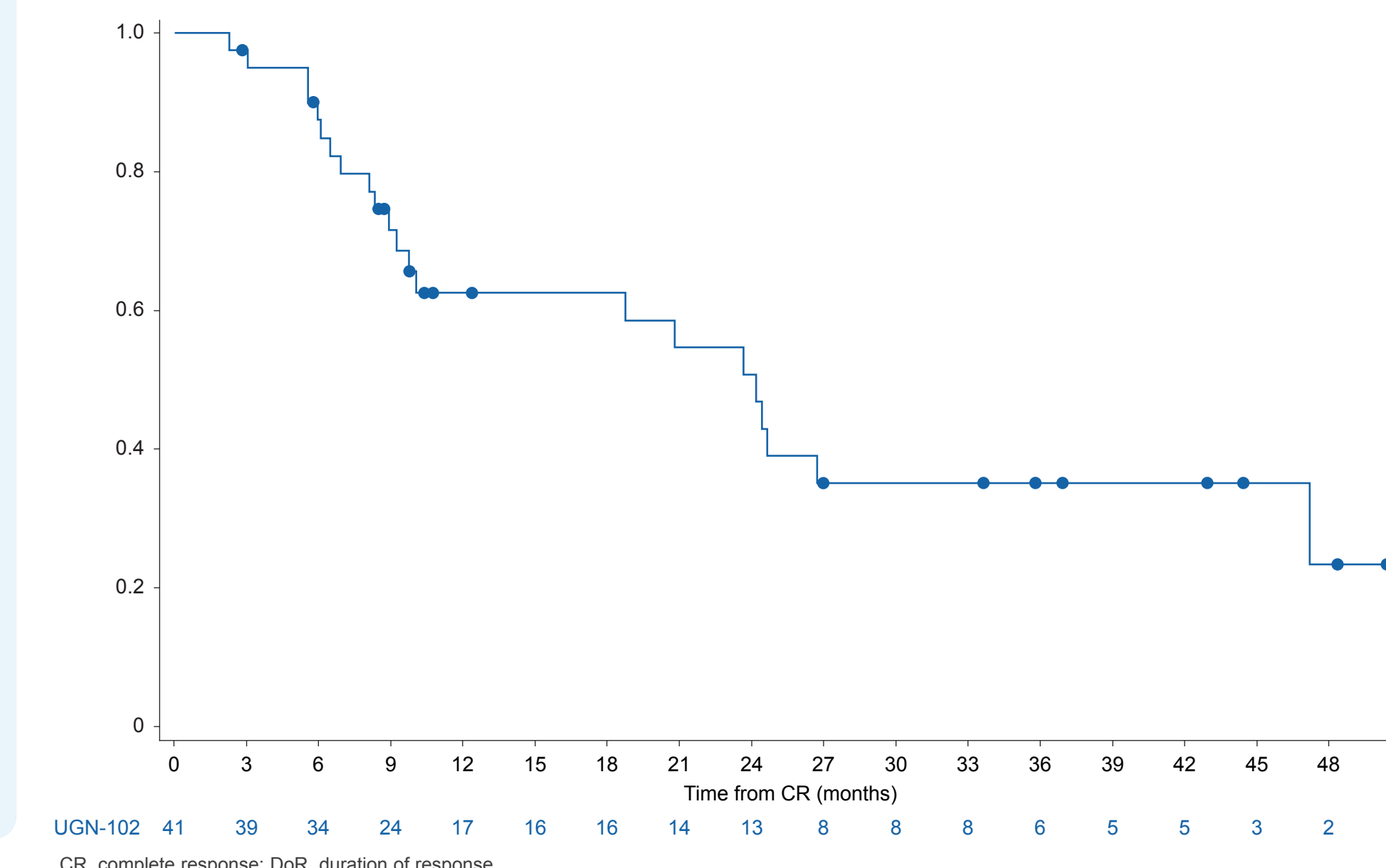
^aCR defined as visual confirmation and negative wash urine cytology as well as for-cause biopsy. CR, complete response; LTFU, long-term follow-up.

Table 2. Summary of Response in OPTIMA II and LTFU

	UGN-102
CR at 3 Months, n (%)	41/63 (65.1)
Patients With Events Between 3 and 12 Months, n (%)	22/41 (53.7)
Recurrence of LG disease	20/41 (48.8)
Progression to HG disease	1/41 (2.4)
Death	1/41 (2.4)
Patients Censored, n (%)	19/41 (46.3)
Early discontinuation in parent study	2/41 (4.9)
CR at end of parent study, did not enter LTFU	8/41 (19.5)
Early discontinuation in rollover study	4/41 (9.8)
Ongoing CR in rollover study	5/41 (12.2)
Continued in LTFU, n (%)	17/41 (41.5)
Early discontinuation in LTFU	4/41 (9.8)
Ongoing CR	5/41 (12.2)
Median follow-up time, months (95% CI)	33.61 (10.78, 42.94)
Kaplan–Meier Estimate of DoR, months (95% CI)	24.2 (9.72, 47.18)

CI, confidence interval; CR, complete response; DoR, duration of response; HG, high grade; LG, low grade; LTFU, long-term follow-up.

Figure 2. Kaplan–Meier Estimate of DoR for All Patients with CR at 3-months in OPTIMA II (N=41)



UGN-102 41 39 34 24 17 16 16 14 13 8 8 8 6 5 5 3 2 0
CR, complete response; DoR, duration of response.

RESULTS (cont.)

- The majority of patients included in OPTIMA II had recurrent disease at parent study baseline (77.8%), with multiple prior TURBT procedures (**Table 1**)
- Among the 41 patients achieving a complete response (CR) at 3 months, 25 remained in CR at 12 months and 17 entered long-term follow-up
 - The median Kaplan–Meier estimate of duration of response (DoR) was 24.2 months (95% confidence interval [CI] 9.72, 47.18), with a median follow-up time of 33.6 months (95% CI 10.78, 42.94) (**Figure 2**)
- 20 patients (48.8%) experienced recurrence of low-grade (LG) disease, 1 patient progressed to high-grade (HG) disease, and 1 patient died due to a cardiac disorder
- 5 patients remained disease-free at the time of the 4-year data analysis (**Table 2**)

CONCLUSIONS

- Patients with LG-IR-NMIBC who achieved CR after receiving treatment with UGN-102 experienced clinically meaningful long-term response, with an estimated DoR of about 2 years
- In addition, recurrence events that occurred were of LG disease
- These results demonstrate that treatment with UGN-102 results in a clinically meaningful DoR in patients with newly diagnosed or recurrent LG-IR-NMIBC
- UGN-102 may represent a durable and safe non-surgical alternative to TURBT, the current standard of care, for treating these patients

Reference:

Chevli KK, et al. J Urol. 2022;207:61-9.

Disclosures:

UGN-102 is an investigational product. The safety and efficacy of UGN-102 has not been established. NDS, AT, DS, YE, JDR, JL, DM, JDR, BF, AS, DSc, WH: investigators/consultants/advisors; UroGen Pharma: BB, AM, SR, ML, MS, employees of UroGen

Acknowledgment:

Editorial support was provided by Jaqui Hodgkinson, DPhil, MBA of Excerpta Medica, funded by UroGen Pharma, in accordance with Good Publication Practice guidelines

Funding:

Funded by UroGen Pharma.

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M-US-ZUS-00030