IMPACT OF TUMOR BURDEN AND FOCALITY IN RECURRENT LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE INVASIVE BLADDER CANCER ON RESPONSE TO TREATMENT WITH UGN-102: A SUBANALYSIS OF THE PHASE 3 ENVISION TRIAL

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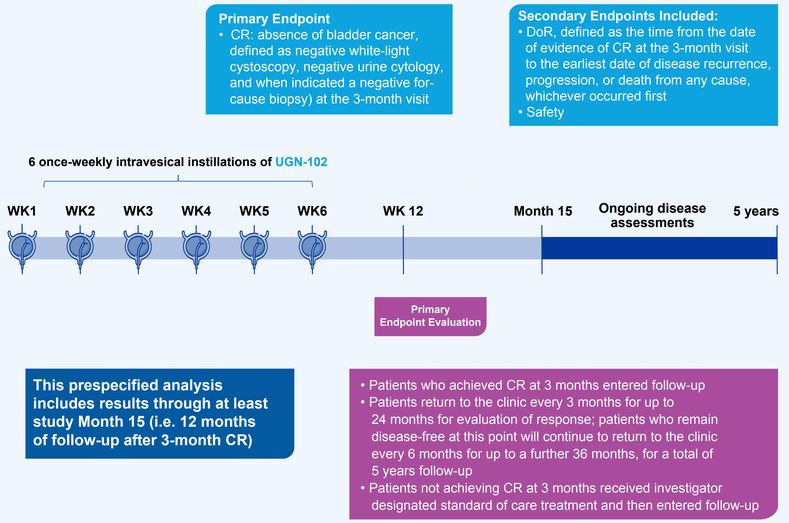
INTRODUCTION

- The ENVISION phase 3 single-arm study (NCT05243550) treated patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) intravesically with **UGN-102**, a reverse thermal hydrogel containing mitomycin
- Primary efficacy and safety results have been previously reported[1]
  - **79.6% (95% CI 73.9, 84.5)** complete response (CR) rate at 3 months (CR: defined as absence of detectable disease)
  - **82.3% (95% CI 75.9, 87.1)** probability of remaining in response 12 months later (by Kaplan–Meier estimate)
- The aim of this prespecified analysis was to evaluate if tumor burden or focality influenced response to treatment with **UGN-102**

METHODS

- 240 patients with LG-IR-NMIBC received at least one intravesical instillation of UGN-102 (75 mg mitomycin) **via urinary catheter in an outpatient setting (Figure 1)**
- 3 months after the first dose, patients were examined for the presence of bladder cancer using cystoscopy, urine cytology, and for-cause biopsy
- In this prespecified analysis, between-group comparisons were performed for CR rate at 3 months and duration of response (DoR) 12 months after achieving CR in patients with
  - **Tumor burden** (sum of the diameters of all visible tumors) **≤3 cm vs >3 cm**
  - **Single vs multiple tumors**
- CR rate comparison (nominal) p values were calculated using Fisher's Exact Test
- Hazard ratios (HRs) of DoR were calculated using a Cox Proportional Hazards model, and (nominal) p values were calculated using a log-rank test

Figure 1. ENVISION Study Design



Abbreviations: CR, complete response; DoR, duration of response; WK, week.

RESULTS

- In patients with multiple vs single tumors, 3-month CR was 79.3% vs 82.9%, respectively, with recurrence rates of 18.5% vs 11.8%, respectively (**Figure 2a**)
- CR rate at 3 months was 82.8% vs 73.2% for patients with tumor burden ≤3 cm and >3 cm, respectively
  - Of the patients with CR at 3 months, 15.4% vs 20% experienced recurrence of low-grade disease, progression (either in stage or grade), or death by 15 months
- DoR HRs and p values were not statistically significant for any comparison made **(Figure 2b)**

Figure 2a. Patients Achieving CR at 3 Months

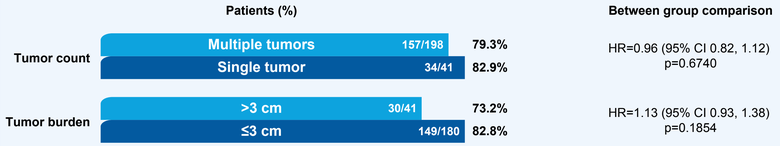
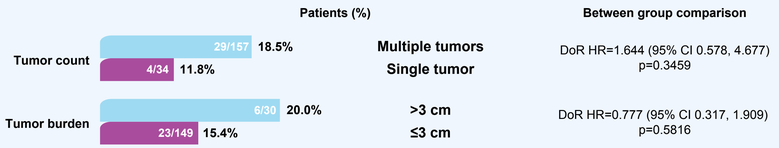


Figure 2b. Recurrence at 15 Months (12 Months After CR)



Abbreviations: CI, confidence interval; CR, complete response; DoR, duration of response; HR, hazard ratio.

CONCLUSIONS

- Treatment with **UGN-102** resulted in a high, clinically meaningful CR rate (CRR) in patients with LG-IR-NMIBC; there was no significant difference in CRR or DoR at 12 months based on tumor burden or focality
- Results should be interpreted with caution given the small sample sizes of the comparator groups
- **UGN-102** may represent a valuable treatment option for many patients with LG-IR-NMIBC

Reference

1. Prasad SM et al. J Urol. 2025. 213:205–216.

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