PATIENT EXPERIENCES WITH UGN-102 FOR RECURRENT LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE INVASIVE BLADDER CANCER (LG-IR-NMIBC): INSIGHTS FOR SHARED DECISION-MAKING

Poster: 81

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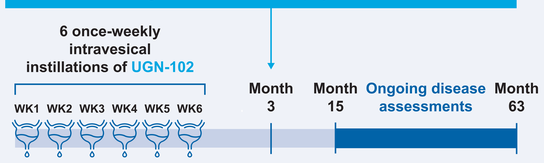
INTRODUCTION

- Recurrent LG-IR-NMIBC management may include transurethral resection of bladder tumor (TURBT) or **UGN-102**, a Food and Drug Administration-approved, reverse thermal hydrogel, containing mitomycin 75 mg for intravesical use
- The Phase 3 ENVISION single-arm study (NCT05243550) treated adults with LG-IR-NMIBC with **UGN-102**[1]
- Given the chronic and recurrent nature of LG-IR-NMIBC, understanding patients' experiences and preferences across available management strategies is essential to support shared decision-making[2]

STUDY DESIGN

FIGURE 1. ENVISION STUDY DESIGN

Primary endpoint at 3 months:
- **CR:** absence of bladder cancer, defined as negative white light cystoscopy, negative urine cytology, and, when indicated, a negative for-cause biopsy



Secondary endpoints included:
- **DoR**, defined as the time from the date of evidence of CR at the 3-month visit to the earliest date of disease recurrence, progression, or death from any cause, whichever occurred first
- **Safety**

- Patients who achieved CR at 3 months entered follow-up and will return to the clinic every 3 months for up to 24 months for evaluation of response; patients who remain disease-free at this point will continue to return to the clinic every 6 months for up to a further 36 months, for a total of 5 years of follow-up
- Patients not achieving CR at 3 months received investigator-designated standard-of-care treatment and then entered follow-up

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

METHODS

- Patients with recurrent LG-IR-NMIBC received 6 intravesical instillations of **UGN-102** (mitomycin 75 mg) **in an outpatient setting** (**Figure 1**)
- Baseline demographics and clinical characteristics are reported in **Table 1**
- Patient-reported outcomes were assessed using the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) NMIBC24[3]
- US-based patients had semi-structured prospective phone interviews that compared experiences of prior TURBT versus **UGN-102** at enrollment and at 3 months, regardless of response status

TABLE 1. BASELINE DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

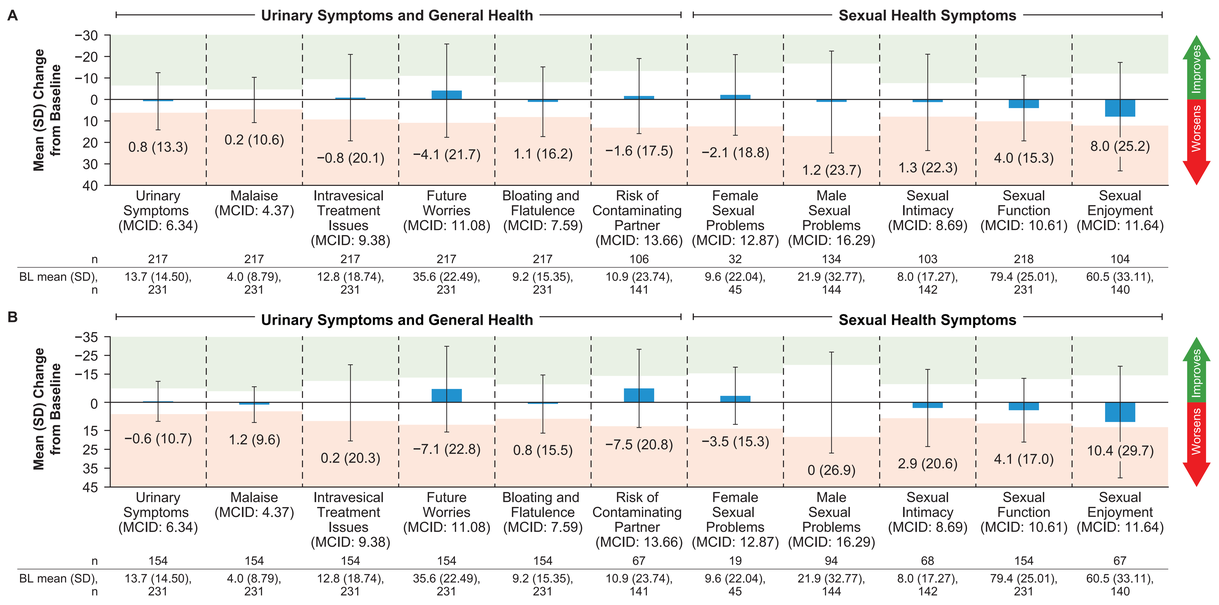
Characteristic	Multinational ENVISION patients N=240, n (%)	US-Based patients, completed both interviews N=29, n (%)
Demographics		
Male	147 (61.3)	18 (62)
Aged 65+ years	162 (67.5)	20 (69)
White	234 (97.5)	24 (83)
Clinical Characteristics		
Tumor Count	n=239	
Single	41 (17.2)	5 (17.2)
Multiple	198 (82.8)	24 (82.8)
Missing	1 (0.4)	–
No. of Previous LG-NMIBC Episodes		
0	11 (4.6)	1 (3.4)
1	145 (60.4)	4 (13.8)
2	37 (15.4)	11 (37.9)
>2	47 (19.6)	13 (44.8)
Tumor Burden[a], cm	n=221	n=24
≤3	180 (81.4)	18 (75.0)
>3	41 (18.6)	6 (25.0)
Missing	19 (7.9)	5 (17.2)

[a]Tumor burden is calculated as the sum of the longest diameters of the measurable lesions.
LG, low grade; NMIBC, non-muscle invasive bladder cancer.

RESULTS

- As of October 2, 2024, 240 patients were enrolled, 232 with previous NMIBC episodes were included; 95.0% received all 6 doses of **UGN-102**
- Mean change from baseline scores at 3 and 12 months post-treatment did not reach minimal clinically important difference thresholds for any EORTC-QLQ-NMIBC24 domains (**Figure 2**)
- Phone interviews found that patients perceived more interference with routines/responsibilities with TURBT versus **UGN-102**, similar urinary symptoms, expressed concern regarding more bleeding with TURBT, and would recommend **UGN-102** as a less invasive, less painful, and less time-consuming procedure than TURBT
- A small number of patients preferred surgery as a 1-day procedure versus 6 weekly intravesical instillations

FIGURE 2. QUALITY OF LIFE CHANGE FROM BASELINE SCORES AT 3 MONTHS (A) AND 12 MONTHS (B) USING THE EORTC-QLQ-NMIBC24



A positive change from BL indicates worsening across all scales/items.
BL, baseline; EORTC, European Organisation for Research and Treatment of Cancer; MCID, minimal clinically important difference; NMIBC, non-muscle invasive bladder cancer; QLQ, Quality of Life Questionnaire; SD, standard deviation.

CONCLUSIONS

- **UGN-102** maintained stable quality-of-life scores across all NMIBC24 domains at 3 and 12 months and was generally preferred by patients instead of surgical resection
- These insights support shared decision-making by helping clinicians and patients weigh procedural convenience against treatment invasiveness in managing recurrent LG-IR-NMIBC

References
1. Prasad SM, et al. *J Urol*. 2025;213:205–16.
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Funding
UroGen Pharma.

Disclosures
A version of this poster was previously presented at the ASCO Genitourinary Cancers Symposium (February 26–28, 2026).
RT: CG Oncology and UroGen Pharma – consultant or advisory role; **RD**, **AN**, **NU**, **VMT**, **MJL**: UroGen Pharma – employees/stockholders; CCP: UroGen Pharma – consultant and advisor.

Acknowledgments
Medical writing support for this ASCO 2026 encore poster (in the form of poster layout and formatting) was provided by Avalere Health Global Limited, funded by UroGen Pharma.

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M-US-ZUS-00060

Presented at the 2026 American Society of Clinical Oncology Annual Meeting (ASCO 2026), May 29 – June 2, 2026, Chicago, IL, USA