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

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INTRODUCTION

- Recurrent LG-IR-NMIBC management may include transurethral resection of bladder tumor (TURBT) or **UGN-102**, an FDA-approved, reverse thermal hydrogel, containing 75mg dose of mitomycin for intravesical use[1]
- The phase 3 ENVISION single-arm study (NCT05243550) treated adults with LG-IR-NMIBC with **UGN-102**
- 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]

METHODS

- Patients with LG-IR-NMIBC received 6 intravesical instillations of UGN-102 (75mg mitomycin) **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 vs UGN-102 at enrollment and at 3 months, regardless of response status

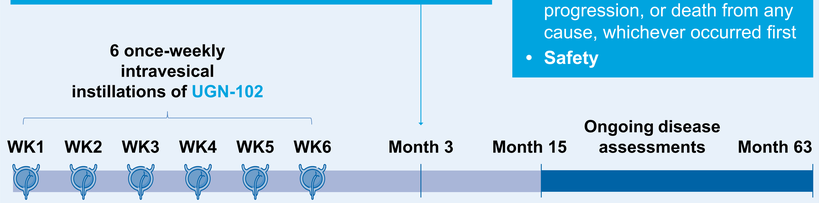
Figure 1. ENVISION Study Design

Primary Endpoint at 3 Months:

- **Complete response:** 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.

Table 1. Baseline Demographic and Clinical Characteristics

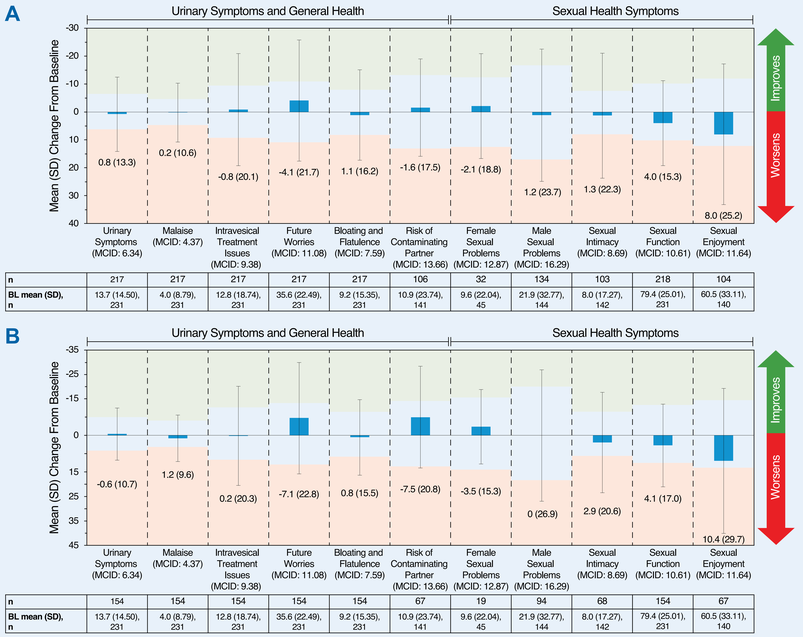
Characteristic	Multinational ENVISION Patients N=240, n (%)	US-Based Patients, Completed Both Interviews N=29, n (%)
Demographics		
Male	147 (61.3)	18 (62)
Aged 65+ years	162 (67.5)	20 (69)
White	234 (97.5)	24 (83)
Clinical Characteristics		
Tumor Count	n=239	
Single	41 (17.2)	5 (17.2)
Multiple	198 (82.8)	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* 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)

*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 2 October 2024, 240 patients were enrolled, 232 with previous NMIBC episodes were included; 95.0% received all 6 doses of UGN-102
- The mean changes from baseline scores of the EORTC-QLQ-NMIBC24 at 3 and 12 months after treatment started did not reach the minimal clinically important difference thresholds of malaise, intravesical treatment issues, risk of contaminating partner, sexual problems, and function (Figure 2)
- Phone interviews found that patients perceived more interference with routines/responsibilities with TURBT vs 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 vs 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 baseline 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

Disclosures
RT: CG Oncology and UroGen Pharma– consultant or advisory role; RD, AN, NU, LVL, VMT, MJL: UroGen Pharma – employees/stockholders; CCP: UroGen Pharma – consultant and advisor.

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