



# PATIENT-REPORTED OUTCOMES FOLLOWING TREATMENT OF LOW-GRADE INTERMEDIATE RISK NON-MUSCLE INVASIVE BLADDER CANCER WITH UGN-102

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## INTRODUCTION

- Transurethral resection of bladder tumor (TURBT) is used to manage low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)
- However, recurrence rates of IR disease after TURBT are high. Also, TURBT can have local and systemic side effects, and typically requires patients to undergo general anesthesia with associated perioperative risks
- UGN-102** (a novel reverse thermal hydrogel containing 75 mg of mitomycin) is being studied as a potential non-surgical, ablative treatment for patients with LG-IR-NMIBC and is administered intravesically by urinary catheter once weekly for 6 weeks in an ambulatory setting
- Notably, 80% of patients treated with **UGN-102** achieved a complete response (CR) at 3 months; the probability of remaining in response 12 months later was 82%<sup>1</sup>
- Here we report on the patient-reported outcomes from the OPTIMA II (NCT03558503),<sup>2</sup> ATLAS (NCT04688931),<sup>3</sup> and ENVISION (NCT05243550) trials<sup>1</sup>

## METHODS

- In the single-arm phase 2b OPTIMA II and pivotal phase 3 ENVISION studies, patients received **UGN-102**; in the phase 3 ATLAS trial, patients were randomized to **UGN-102** or TURBT. Here we include only data from the **UGN-102**-treated patients
- Each study had a treatment period consisting of 6 weeks, an assessment of CR at 3 months, and a follow period between 12 and 63 months
- Patient-reported symptom burden and health status/function were evaluated using the European Organisation for Research and Treatment of Cancer 24-item Quality of Life Questionnaire for NMIBC (EORTC-QLQ-NMIBC24) at baseline, 3 months, and 12 months or end of study (Figure 1)
- Scores for each scale ranged from 1 (not at all) to 4 (very much), transformed to a 0–100 scale, with a high score for a symptom scale/item representing a high level of symptomatology/problems
- Descriptive statistics were used to describe baseline and change from baseline scores; a positive change from baseline indicates worsening in symptom

## RESULTS

- Patients enrolled in the 3 studies (OPTIMA II, ATLAS, ENVISION) had a median age of 68, 68, and 70 years, respectively, and the majority were male (Table 1)

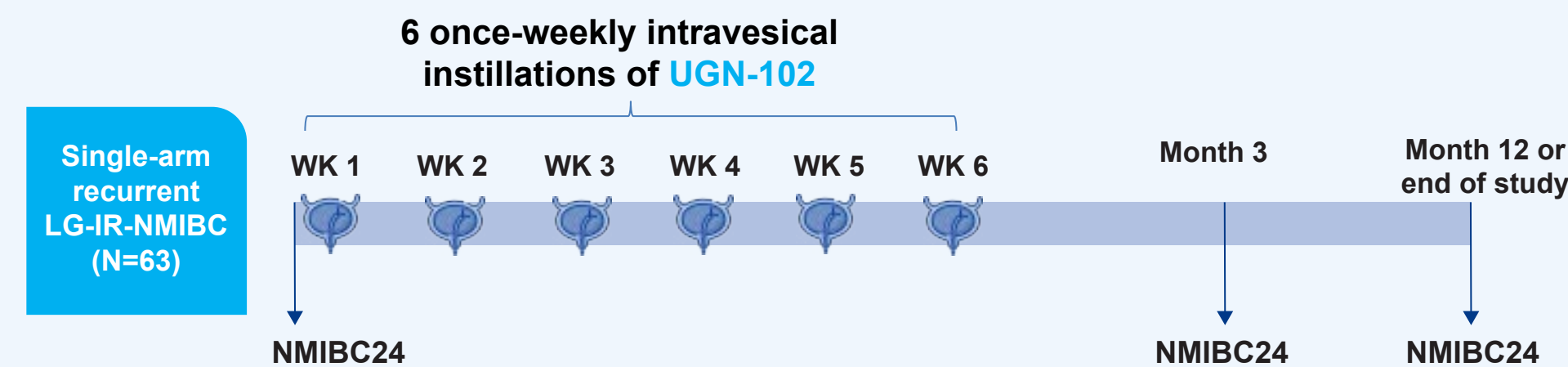
**Table 1. Participant Characteristics at Baseline by Trial**

	OPTIMA II (N=63)	ATLAS (n=142)	ENVISION (N=240)
<b>Age, median (range), years</b>	68.0 (33.0, 96.0)	68.0 (23, 85)	70.0 (30, 92)
<b>Sex, n (%)</b>			
Male	38 (60.3)	105 (73.9)	147 (61.3)
Female	25 (39.7)	37 (26.1)	93 (38.8)
<b>Treatment Course, n (%)</b>			
Full (6 treatments)	57 (90.5)	132 (93.0)	228 (95.0)
Partial (<6 treatments)	6 (9.5)	6 (4.2)	12 (5.0)
No treatment received	–	4 (2.8)	–
<b>NMIBC24 Domain, mean (SD)<sup>a</sup></b>			
Urinary symptoms	23 (21.39)	19.1 (16.85)	13.9 (14.33)
Malaise	3.4 (7.70)	7.5 (12.36)	4.0 (8.74)
Intravesical treatment issues	7.7 (15.99)	12.7 (19.52)	13.2 (18.74)
Future worries	35.8 (27.65)	41.7 (25.32)	35.7 (22.16)
Bloating and flatulence	16.7 (20.34)	12.8 (17.92)	9.1 (15.17)
Risk of contaminating partner	5.9 (17.62)	10.0 (21.03)	16.7 (27.89)
Female sexual problems	16.7 (33.35)	17.6 (20.81)	19.3 (30.05)
Male sexual problems	32.1 (35.88)	17 (26.43)	21.4 (32.58)

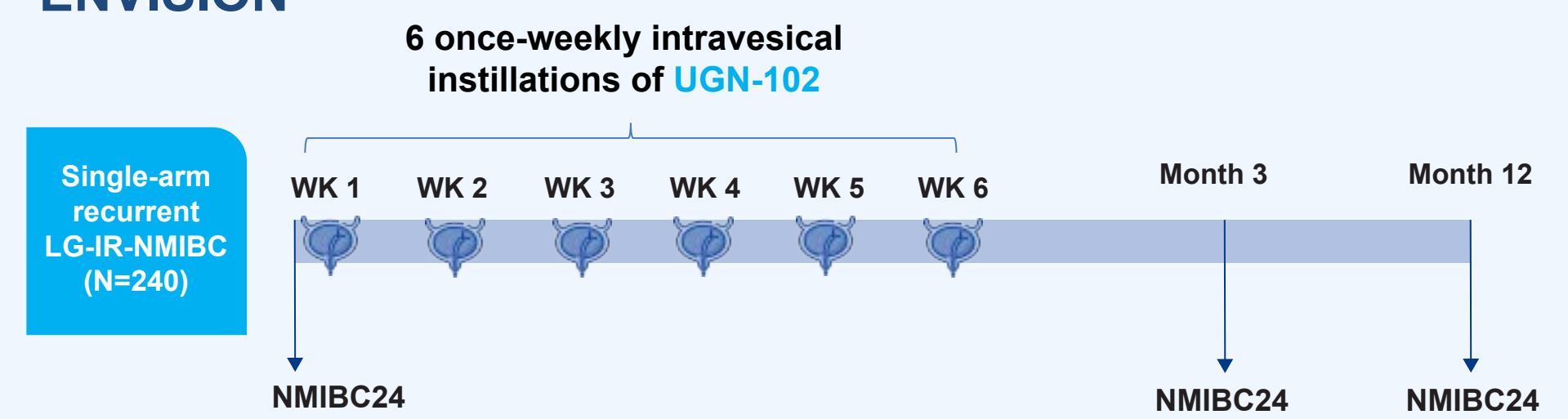
<sup>a</sup>Sample sizes for NMIBC24 domains at baseline for OPTIMA II: n=44 (Intravesical treatment issues, n=43; Risk of contaminating partner, n=17; Female sexual problems, n=4; Male sexual problems, n=26); ATLAS: n=134 (Risk of contaminating partner, n=87; Female sexual problems, n=98); ENVISION: n=239 (Risk of contaminating partner, n=86; Female sexual problems, n=19; Male sexual problems, n=147).  
A high score for a symptom scale/item represents a high level of symptomatology/problems.  
NMIBC24, 24-item non-muscle invasive bladder cancer questionnaire; SD, standard deviation.

**Figure 1. Study Design**

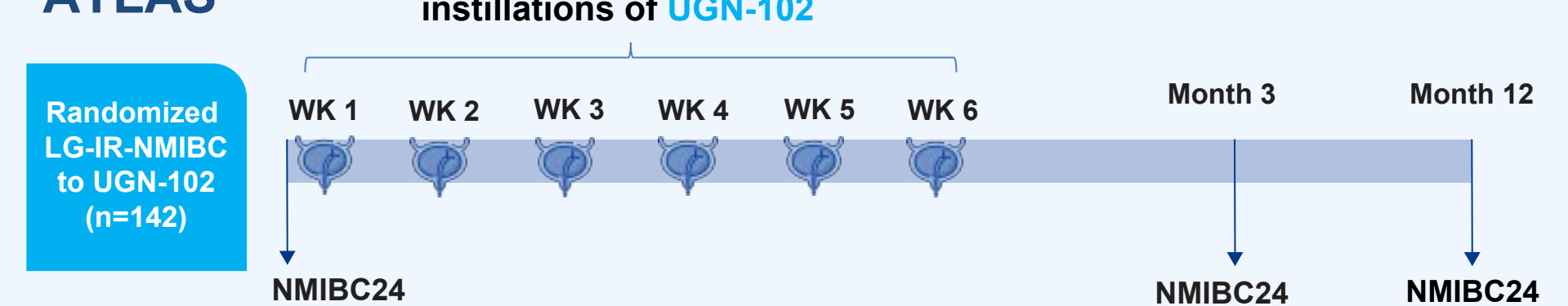
### OPTIMA II



### ENVISION<sup>a</sup>



### ATLAS



<sup>a</sup>The ENVISION study is ongoing and will continue for up to 63 months. The study design figures are simplified and indicate key timepoints for the presented research. CR, complete response; LG-IR-NMIBC, low-grade intermediate-risk non-muscle invasive bladder cancer; NMIBC24, 24-item non-muscle invasive bladder cancer questionnaire; PRO, patient-reported outcomes; TURBT, transurethral resection of bladder tumor; WK, week.

OPTIMA II and ENVISION  
Primary endpoint:  
CR at 3-month visit

ATLAS  
Primary endpoint:  
disease-free survival

All studies  
Secondary/exploratory  
endpoint included:  
PRO (NMIBC24)

## RESULTS (cont.)

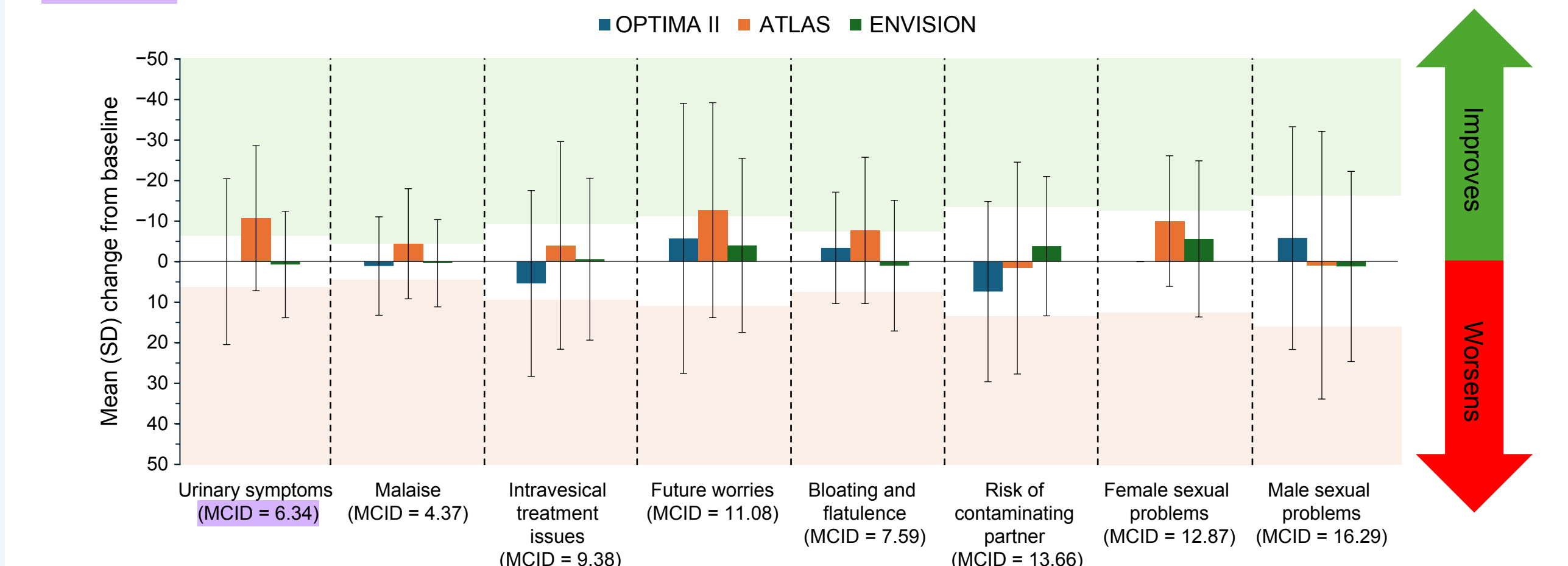
- Mean baseline scores suggest a high level of functioning and low symptom burden prior to the start of the trials (Table 1)
- Treatment with **UGN-102** did not result in sustained decrements to functioning and symptom burden
- Previous work identified minimal clinically important differences (MCIDs), and none of the measured domains reached the worsening MCID threshold at 3 or 12 months (Figures 2 and 3) indicating the treatment period did not negatively affect QoL

## CONCLUSIONS

- In addition to the robust CR and duration of response achieved with **UGN-102** treatment for LG-IR-NMIBC, **UGN-102** did not appear to negatively impact symptom burden, patient function, or QoL, as outcomes did not reach the 'worsening' MCID threshold
- UGN-102** is a potential non-surgical treatment option that does not negatively impact QoL for patients with LG-IR-NMIBC

- Meaningful improvements in urinary symptoms, malaise, future worries, and bloating and flatulence were observed at the 3-month visit in the ATLAS trial (Figure 2)

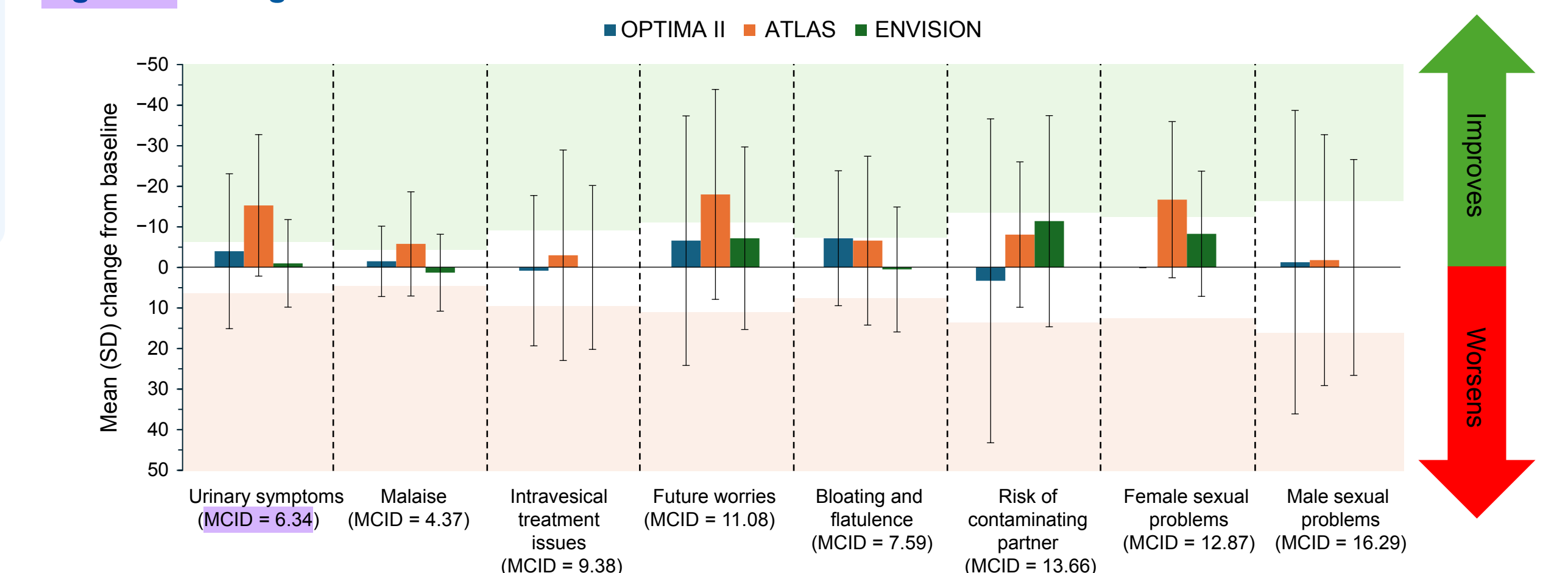
**Figure 2. Change From Baseline at 3 Months in NMIBC24 Domains**



Green and red shaded area indicates MCID threshold for improvement and worsening, respectively, per outcome. OPTIMA II: n=44; 'Intravesical treatment issues', 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=43, 9, 2, and 26, respectively. ATLAS: n=125; 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=61, 10, and 91, respectively. ENVISION: n=224; 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=62, 12, and 137, respectively. MCID, minimal clinically important difference; NMIBC24, 24-item non-muscle invasive bladder cancer questionnaire; QoL, quality of life; SD, standard deviation.

- Meaningful improvements in urinary symptoms, malaise, future worries, and female sexual problems were observed at the 12-month visit in the ATLAS trial (Figure 3)

**Figure 3. Change From Baseline at 12 Months in NMIBC24 Domains**



Green and red shaded area indicates MCID threshold for improvement and worsening, respectively, per outcome. For OPTIMA II, change from baseline was measured at 12 months or end of study. OPTIMA II: n=44; 'Intravesical treatment issues', 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=43, 10, 3, and 26, respectively. ATLAS: n=89; 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=41, 4, and 65, respectively. ENVISION: n=159; 'Risk of contaminating partner', 'Female sexual problems', and 'Male sexual problems', n=38, 8, and 96, respectively. MCID, minimal clinically important difference; NMIBC24, 24-item non-muscle invasive bladder cancer questionnaire; QoL, quality of life; SD, standard deviation.

### References

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### Disclaimer

UGN-102 is an investigational product. The safety and efficacy of UGN-102 has not been established.

### Disclosures

CCP: UroGen Pharma – consultant; UroGen Pharma, Janssen – scientific study; RD, VT, NU, MB, BB, VL, and MJL: UroGen Pharma – employee; TB and MJAA: Prime HCD – employee; ABS: Merck-RTI, Genentech, ARHQ, PCORI, NIH, and UroGen Pharma – grant funding; AMS: UroGen Pharma and Pfizer – research funding via institution; UroGen Pharma – one-time consulting fee (\$2k) to present findings at UroGen Pharma in June 2024.

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