DURATION OF RESPONSE (DOR) FOLLOWING TREATMENT WITH UGN-102 IN PATIENTS WITH RECURRENT, LOW-GRADE, INTERMEDIATE-RISK, NON-MUSCLE INVASIVE, BLADDER CANCER: 18-MONTH DOR DATA FROM THE PHASE 3 ENVISION TRIAL

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INTRODUCTION

- Low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) is persistent and recurrent, and is inadequately controlled by the current standard of care, transurethral resection of bladder tumor (TURBT) under general anesthesia[1,2]
- Recent studies have shown that many patients with LG-IR-NMIBC can be successfully treated with **UGN-102**, a reverse thermal gel containing mitomycin administered via intravesical instillation in the outpatient setting, removing the need for surgery[3,4]
- **ENVISION** (NCT05243550) is an ongoing, prospective, pivotal, phase 3, multinational, single-arm open-label study evaluating the efficacy and safety of **UGN-102** as a treatment for patients with recurrent LG-IR-NMIBC
- Here we report the results of an analysis with cutoff date October 2, 2024, the timepoint when all remaining patients reached at least 18 months of follow-up

KEY INCLUSION CRITERIA

- History of ≥1 prior episode of LG-NMIBC requiring treatment with TURBT
- LG-NMIBC (Ta) confirmed by cystoscopy and cold-cup biopsy of the visualized tumor at screening or within 8 weeks before screening
- Negative voiding cytology for high-grade (HG) disease at screening or within 8 weeks before screening
- IR disease, defined as 1 or 2 of the following: multiple tumors; longest tumor diameter >3 cm; early or frequent recurrence (i.e. ≥1 episode within the previous year)

KEY EXCLUSION CRITERIA

- All three IR features: multiple tumors; longest tumor diameter >3 cm; early or frequent recurrence (i.e. ≥1 episode within the previous year)
- History of muscle invasive or metastatic disease
- History of HG-NMIBC (within the past 2 years)
- Bacillus Calmette–Guérin treatment for urothelial carcinoma (within the past year)
- Treatment with an intravesical chemotherapeutic agent, except for a single dose immediately after any previous TURBT (within the past 2 years)

RESULTS

- All 240 enrolled patients received at least one dose of **UGN-102**; 95% (228) received all 6 weekly doses

EFFICACY OUTCOMES

- **The primary endpoint** of complete response (CR) at 3 months was achieved by 191 patients (79.6%; 95% confidence interval [CI] 73.9, 84.5)
- For patients with CR, the probability, by Kaplan–Meier estimate, of remaining event-free at 18 months following the 3-month visit was 80.6% (95% CI 74.0, 85.7).
- **For the key secondary endpoint** of DoR, the median was not estimable over a median follow-up of 18.7 months due to the paucity of disease recurrence

ENVISION STUDY DESIGN

Primary Endpoint
- CR: absence of bladder cancer, defined as negative white-light cystoscopy, negative urine cytology, and, when indicated, a negative for-cause biopsy at the 3-month visit

Secondary Endpoints include:
- 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

This analysis includes results through at least study Month 21 (i.e. 18 months of follow-up after 3-month CR)

Primary Endpoint evaluation

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

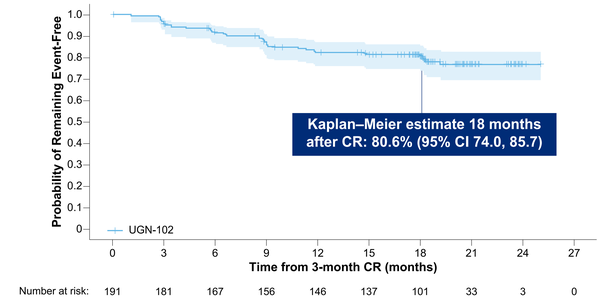
CR, complete response; DoR, duration of response; WK, Week.

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS

Characteristic		UGN-102 (N=240)
Mean age, years (SD)		68.8 (12)
Sex, n (%)		
	Male	147 (61)
	Female	93 (39)
Race, n (%)		
	Asian	2 (0.8)
	Black or African American	3 (1.3)
	White	234 (98)
Mean weight, kg (SD)		79.7 (16)
Tumor longest diameter pre-biopsy (cm)		
	≤3	216 (92)
	>3	19 (8.1)
	Missing	5 (2.1)
Tumor burden pre-biopsy, aggregate (cm)		
	≤3	180 (81)
	>3	41 (19)
	Missing	19 (7.9)
Tumor count		
	Single	41 (17)
	Multiple	198 (83)
	Missing	1 (0.41)

SD, standard deviation. Tumor burden is defined as the sum of diameters of all visible lesions.

DURATION OF RESPONSE IN PATIENTS WITH A CR AT 3 MONTHS (KAPLAN–MEIER PLOT)



CI, confidence interval; CR, complete response.
3-month imputed CR set.

SAFETY OUTCOMES

- The most common adverse events (AEs) (≥5% of patients), were dysuria, hematuria, urinary tract infection, pollakiuria, fatigue, and urinary retention; AEs were generally mild-to-moderate in severity and resolved or resolving
- Serious AEs occurred in 12% of patients (29/240); 2 of these were considered treatment-related (urinary retention and urethral stenosis, both of which resolved)[a]

[a]There were three Grade 4 (life-threatening) adverse events all unrelated to treatment. They consisted of metastatic lung cancer, a cerebrovascular event, and adenocarcinoma of the pancreas. There were three Grade 5 (fatal) adverse events all unrelated to treatment. They consisted of a cardiac event, pneumonia, and unknown.

PRIMARY ENDPOINT: COMPLETE RESPONSE RATE AT 3 MONTHS

	UGN-102 (N=240)	
	n (%)	CRR (95% CI)
Complete response[a]	**191 (80)**	**79.6 (73.9, 84.5)**
Noncomplete response	**49 (20)**	
Residual disease	35 (15)	
Progression	7 (2.9)	
Indeterminate	2 (0.83)	
Missing	5 (2.1)	

[a]Response is imputed as CR for 7 patients who had indeterminate response evaluations at 3 months, but who did not receive active intervention and had CR response evaluation at 6 months. CI, confidence interval; CR, complete response; CRR, complete response rate.

TREATMENT-EMERGENT ADVERSE EVENTS[a]

	UGN-102 (N=240)
Patients with any TEAE(s), n (%)	**137 (57)**
Patients with any serious TEAE(s), n (%)[b]	**29 (12)**
TEAEs occurring in ≥5% of patients, n (%)	
Dysuria	54 (23)
Hematuria	20 (8.3)
Urinary tract infection	17 (7.1)
Pollakiuria	16 (6.7)
Fatigue	13 (5.4)
Urinary retention	12 (5)

[a]The adverse event results are from an analysis with cutoff date April 4, 2024.
[b]COVID-19 (2 patients), atrial fibrillation (2 patients), urinary retention (2 patients), and 1 event each of angina pectoris, second-degree atrioventricular block, cardiac failure, acute cardiac failure, congestive cardiac failure, sinus node dysfunction, Fournier's gangrene, pneumonia, urosepsis, carotid artery disease, carpal tunnel syndrome, cerebrovascular accident, transient ischemic attack, pancreatic adenocarcinoma, lip and/or oral cavity cancer, metastatic lung cancer, urethral stenosis, chronic obstructive pulmonary disease, dyspnea, pulmonary embolism, hemorrhoids, incarcerated inguinal hernia, nausea, gallbladder polyp, cholestatic jaundice, acetabulum fracture, femur fracture, glaucoma, death, blood creatine increased, hyponatremia, intervertebral disc protrusion, hypertensive crisis.
TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Results from **ENVISION** demonstrate that treatment using **UGN-102** results in a high and clinically meaningful CR rate in patients with recurrent LG-IR-NMIBC
- Furthermore, the durability of effect is robust, with trial participants who achieved an initial CR at 3 months having an 80.6% probability of remaining disease-free 18 months later
- These observations provide further evidence that **UGN-102** may represent a well-tolerated and efficacious treatment option for patients with LG-IR-NMIBC
- **UGN-102** would potentially be the first approved medical therapy for this condition

References

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Disclaimer

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