UGN-102 ACHIEVES DURABLE RESPONSES ACROSS EORTC RECURRENCE SCORE GROUPS IN ADULTS WITH RECURRENT LOW-GRADE INTERMEDIATE-RISK NMIBC (ENVISION TRIAL)

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INTRODUCTION

- The phase 3 ENVISION single-arm study (NCT05243550) treated patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) with **UGN-102**, a reverse thermal hydrogel containing 75mg mitomycin
  – Complete response (CR) rate at 3 months was 79.6% (95% confidence interval [CI] 73.9, 84.5); the probability of remaining in response 12 and 24 months after CR, by Kaplan−Meier (KM) estimate, was 82.3% (95% CI 75.9, 87.1)[1] and 72.2% (95% CI 64.1, 78.8)
- The European Organisation for Research and Treatment of Cancer (EORTC) recurrence scores provide estimates of recurrence, after transurethral resection of bladder tumor with or without intravesical treatment, based on baseline prognostic factors[2]
  – Patients with recurrence scores of 1–4, 5–9, or 10–17, had a probability of recurrence at 1 year of 24%, 38%, or 61%, respectively[2]
- We conducted a post hoc analysis of CR and duration of response (DoR) by EORTC recurrence score subgroups

METHODS

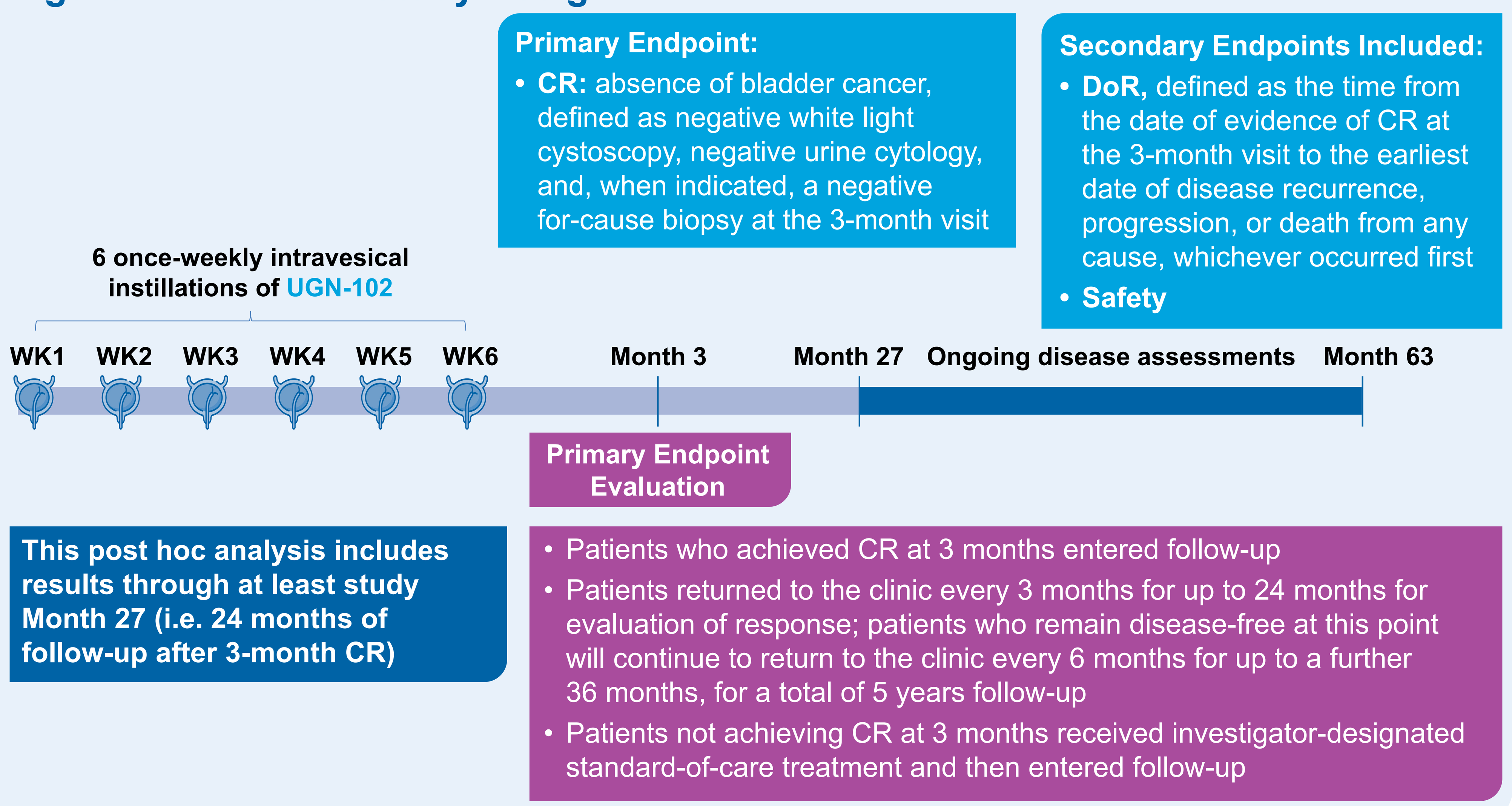
- Patients with LG-IR-NMIBC received 6 once-weekly intravesical instillations of UGN-102 (75mg mitomycin) via urinary catheter in an outpatient setting (Figure 1)
- In this post hoc analysis, CR at 3 months and DoR were calculated in patients grouped by EORTC recurrence scores of 1–4, 5–9, and 10–17 at baseline
  – EORTC recurrence scores[2] were based on 3 factors: number of tumors; tumor size; and prior recurrence rate. The factors T stage, carcinoma in situ, and grade were controlled by trial inclusion/exclusion criteria

Table 1. Baseline Characteristics of ENVISION Patients by EORTC Group

Characteristic	EORTC Recurrence Score Group 1–4 N=31	5–9 N=191	10–17 N=15
Mean Age, years (SD)	71.8 (10.6)	67.8 (11.7)	74.5 (10.1)
Male Sex, n (%)	17 (54.8)	118 (61.8)	10 (66.7)
Treatment Course, n (%)			
<6 installations	3 (9.7)	7 (3.7)	1 (6.7)
6 installations	28 (90.3)	184 (96.3)	14 (93.3)
Tumor Count, n (%)			
Single	24 (77.4)	16 (8.4)	0
Multiple	7 (22.6)	175 (91.6)	15 (100)
Tumor Burden,[a] n (%)	n=30	n=180	n=11
≤3cm	29 (96.7)	150 (83.3)	1 (9.1)
>3cm	1 (3.3)	30 (16.7)	10 (90.9)
Missing[b]	1 (3.2)	11 (5.8)	4 (26.7)

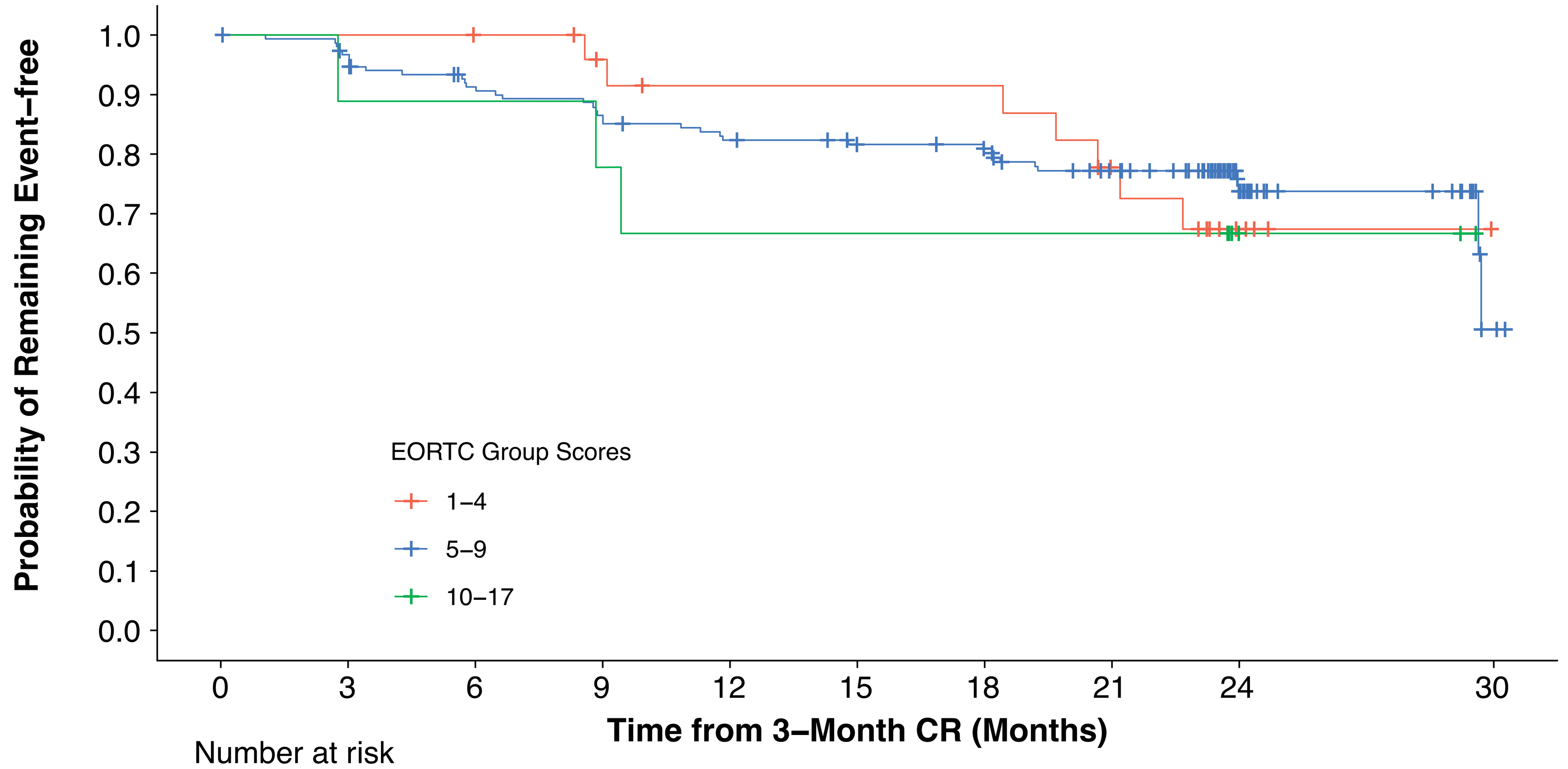
EORTC, European Organisation for Research and Treatment of Cancer; SD, standard deviation.
[a]Calculated as the sum of the longest diameters of the measurable lesions.
[b]For missing data, percentages are computed using N as the denominator. For non-missing data, percentages are computed using the number of non-missing data as the denominator.

Figure 1. ENVISION Study Design



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

Figure 2. Kaplan−Meier Plot of Duration of Response by EORTC Group



Number at risk	0	3	6	9	12	15	18	21	24	30
1–4	26	26	25	22	20	20	20	15	5	0
5–9	155	145	133	126	119	114	111	99	34	2
10–17	9	8	8	7	6	6	6	6	2	0

CR, complete response; EORTC, European Organisation for Research and Treatment of Cancer.

RESULTS

- 240 patients were enrolled in ENVISION and received ≥1 dose of UGN-102
- Of the 240 ENVISION patients, 31, 191, and 15 patients had recurrence scores of 1–4, 5–9, and 10–17, respectively (Table 1); scores were not measurable for 3 patients
- CR rate at 3 months was 83.9%, 81.2%, and 60% for patients with recurrence scores of 1–4, 5–9, and 10–17, respectively (Table 2)
- The probability of remaining event-free at 24 months was 67.4%, 73.7%, and 66.7% for patients with scores 1–4, 5–9, and 10–17, respectively (Figure 2 and Table 2)
- The median duration of follow-up for each group is shown in Table 2; KM estimate of median DoR was not estimable for any group due to the low event rates

Table 2. Response Rate at 3 Months and Duration of Response by EORTC Group

Characteristic	EORTC Recurrence Score Group 1–4 N=31	5–9 N=191	10–17 N=15
CR at 3 Months, n (%)	26/31 (83.9)	155/191 (81.2)	9/15 (60)
CRR (95% CI)	83.9 (66.3, 94.5)	81.2 (74.9, 86.4)	60.0 (32.3, 83.7)
Patients With Events,[a] n (%)	7/26 (26.9)	37/155 (23.9)	3/9 (33.3)
Recurrence of LG disease	5/26 (19.2)	27/155 (17.4)	3/9 (33.3)
Progression	0	7/155 (4.5)	0
Death	2/26 (7.7)	3/155 (1.9)	0
Probability of Remaining Event-Free at 24 Months, % (95% CI)[b]	67.4 (43.2, 83.1)	73.7 (64.6, 80.8)	66.7 (28.2, 87.8)
Median Duration of Follow-up, months (95% CI)[c]	23.3 (23.0, 23.9)	23.7 (23.7, 23.9)	23.9 (23.7, NE)

CI, confidence interval; CR, complete response; CRR, complete response rate; EORTC, European Organisation for Research and Treatment of Cancer; LG, low grade; KM, Kaplan−Meier; NE, not estimable.
[a]24 months after 3-month CR. Percentage is based on the number of subjects with CR at Month 3.
[b]Calculated using the KM method, with Brookmeyer−Crowley CIs.
[c]Estimated using reverse KM method.

CONCLUSIONS

- **UGN-102** showed high complete response rates across all EORTC recurrence score subgroups, including patients with higher baseline recurrence risk
- Most patients remained recurrence-free at 24 months
- Interpretation is limited by the small sample size in the 1–4 and 10–17 subgroups
- Despite the post hoc design and small subgroup size, these findings suggest **UGN-102** provides durable and clinically meaningful disease control in recurrent LG-IR-NMIBC

Disclosures
SMP: UroGen Pharma, Merck, CG Oncology, Ferring – investigator; UroGen Pharma – speaker; WCH: UroGen Pharma, Histosonic, Merck, CG Oncology, Immunity Bio – investigator; UroGen Pharma – speaker; MJL, NU, LVL, AM, BB, MS: UroGen Pharma – employees/stockholders; MK: UroGen Pharma, Relmada, Pfizer, Merck, Aura – consulting or advisory role.

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References
1. Prasad SM, et al. J Urol. 2025;213:205-16.
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