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Treatment With UGN-102 in Patients With Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer: 24-Month Duration of Response Data From the Phase 3 ENVISION Trial

Sandip M. Prasad, Nikola V. Mihaylov, Pencho Genov, Vasyl Terzi, William C. Huang, Michael J. Louie, Brent Burger, Andrew Meads, Mark Schoenberg; on behalf of The ENVISION Study Group

Mark Schoenberg, MD
Professor and Chair; and Chief Medical Officer

The Department of Urology, Montefiore Medical Center: Einstein Campus, Bronx, NY, US
UroGen Pharma, Princeton, NJ, US

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Authors and Disclosures

Sandip M. Prasad[1], Nikola V. Mihaylov[2], Pencho Genov[3], Vasyl Terzi[4], William C. Huang[5], Michael J. Louie[6], Brent Burger[6], Andrew Meads[6], Mark Schoenberg[6,7]

[1]Morristown Medical Center/Atlantic Health System and Garden State Urology, Morristown, NJ, US; [2]University Multiprofile Hospital for Active Treatment, Plovdiv, Bulgaria; [3]University Multiprofile Hospital for Active Treatment Kanev, Ruse, Bulgaria; [4]Multiprofile Hospital for Active Treatment Varna, Military Medical Academy, Bulgaria; [5]NYU Langone Urology Associates, New York, NY, US; [6]UroGen Pharma, Princeton, NJ, US; [7]The Department of Urology, Montefiore Medical Center: Einstein Campus, Bronx, NY, US

Disclosures

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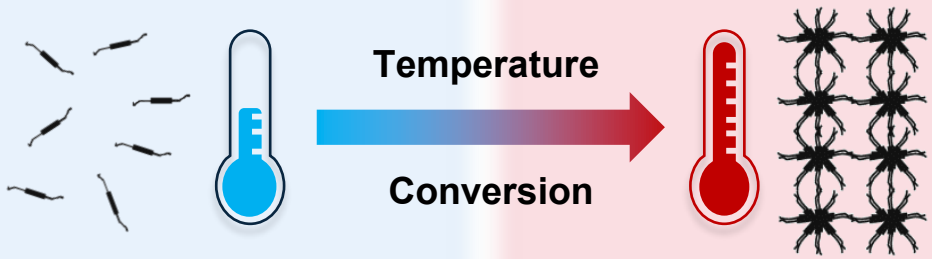
Introduction

- LG-IR-NMIBC is a persistent cancer that frequently recurs despite treatment with TURBT with or without immediate postoperative IVCT
- UGN-102 is a reverse thermal gel containing mitomycin (75mg) developed as a nonsurgical chemoablative treatment and the only FDA-approved medicine for the treatment of adults with recurrent LG-IR-NMIBC
- The ENVISION (NCT05243550) study is a pivotal, prospective, phase 3, multinational, single-arm trial evaluating UGN-102 as treatment for patients with a history of LG-NMIBC requiring TURBT

Median Dwell Time of UGN-102 is 5 hours[a]



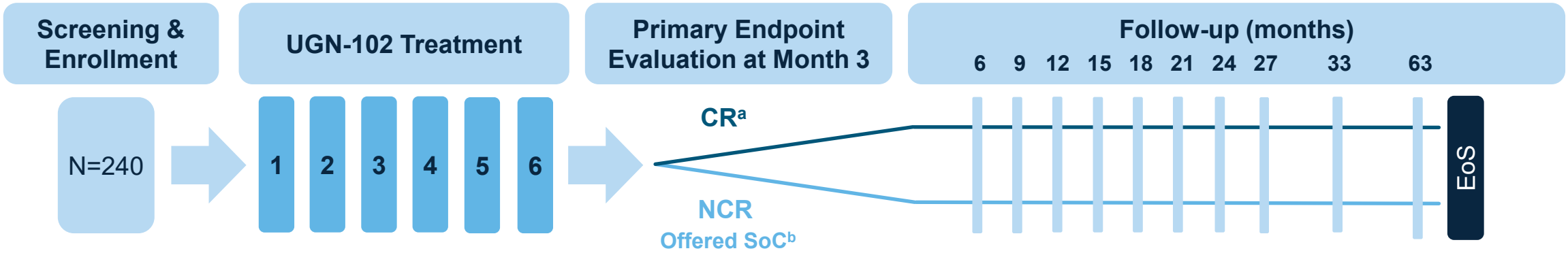
Locally administered liquid polymer under **chilled conditions**

Semisolid gel depot of mitomycin at **body temperature**

IVCT, intravesical chemotherapy; LG-IR-NMIBC, low-grade intermediate-risk non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumor.

[a] Median 5 hours, up to 24 hours, based on patient-reported visibility of gel in urine after instillation.

Study Design



6 once-weekly intravesical instillations
(228 patients received all 6 doses)

No maintenance treatment was administered

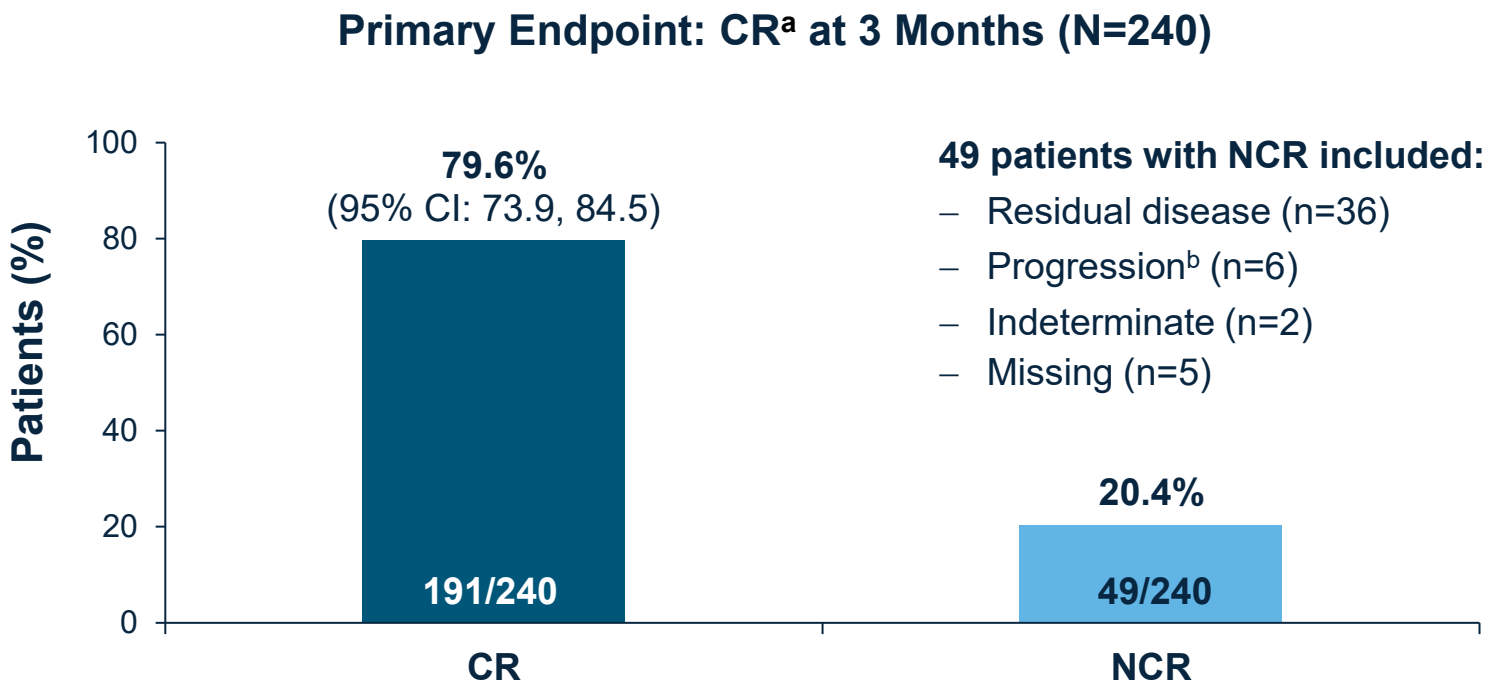
During the follow-up period after the CR assessment at Month 3:

- Patients returned to clinic every 3 months, up to Month 27
- Patients who remain disease-free at Month 27 will return to the clinic every 6 months until Month 63, or until recurrence, progression, or death

CR, complete response; EoS, end of study; NCR, noncomplete response; SoC, standard of care.

[a] CR defined as negative white light cystoscopy, negative urine cytology, and, when indicated, a negative for-cause biopsy.
[b] Patients with an NCR and residual disease undergo investigator designated SoC treatment and then enter the follow-up period. Patients with an NCR and disease progression undergo investigator designated SoC treatment and have a separate EoS visit. During the follow-up period, patients confirmed to have disease recurrence or progression undergo investigator designated SoC treatment and have a separate EoS visit.

Complete Response Rate at 3 Months

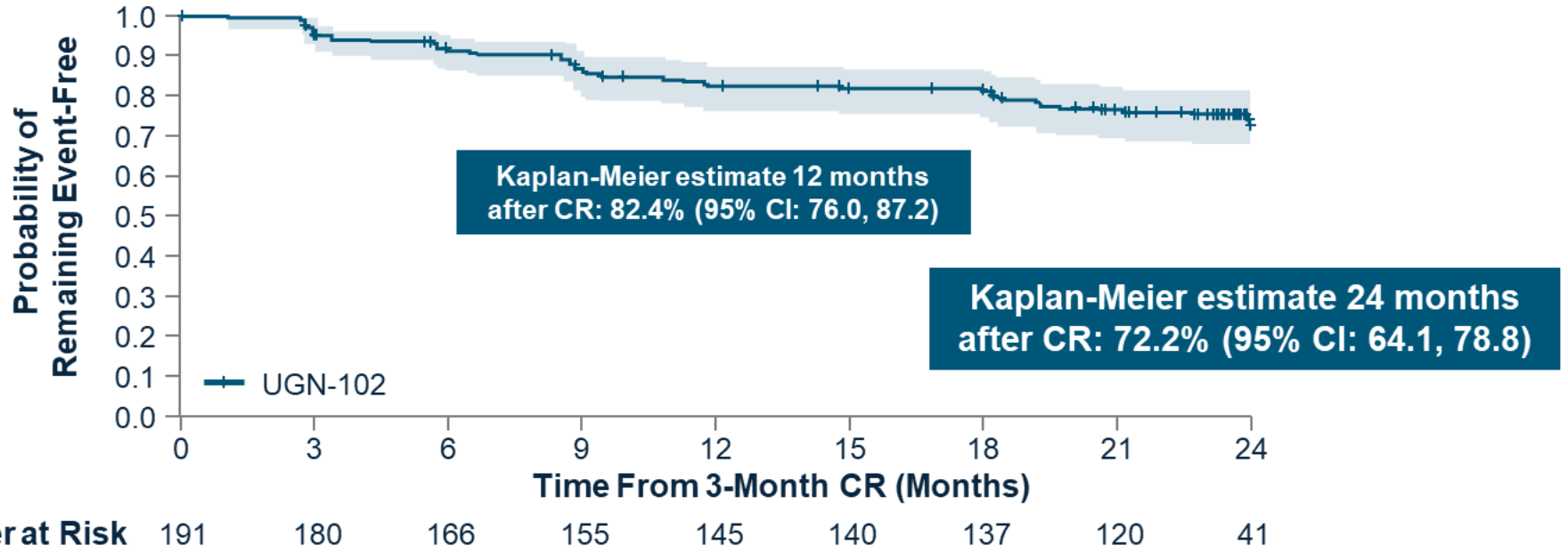


CI, confidence interval; CR, complete response; NCR, noncomplete response.

[a] CR defined as negative white light cystoscopy, negative urine cytology, and, when indicated, a negative for-cause biopsy.

[b] Includes progression to high grade Ta disease, T1, and Cis.

Kaplan-Meier Plot of Duration of Response



CI, confidence interval; CR, complete response; DoR, duration of response.
Figure based on 3-month imputed CR analysis set.
DoR, defined as time from CR at 3 months until the earliest date of recurrence, progression, or death, was calculated using the Kaplan-Meier estimation method.
Limitations of the current study include its single-arm design, which requires caution when interpreting outcomes without a concurrent control.
The following information reports DoR from the 3-month CR population (N=191) which is different from the USPI efficacy population (N=173).
This analysis includes results through at least study Month 27 (i.e. 24 months of follow-up after 3-month CR). DoR range was 0 to 25+ months. Study is ongoing, and further results will follow.

Summary of Adverse Events (Safety Analysis Set, N=240)

	Events	n (%)
Any AEs	664	146 (61)
Any serious AEs	56	39 (16)
Any TEAEs	626	143 (60)
Any grade ≥3 TEAEs	54	43 (18)
Any treatment or procedure related TEAEs	301	99 (41)
Any treatment related TEAEs	248	82 (34)
Any procedure related TEAEs	134	65 (27)
Any TEAEs leading to treatment discontinuation	9	7 (2.9)
Any TEAEs leading to study discontinuation	12	11 (4.6)
Any serious TEAEs	55	38 (16)
Any treatment or procedure related serious TEAEs	5	5 (2.1)
Any treatment related serious TEAEs	2	2 (0.83)
Any procedure related serious TEAEs	4	4 (1.7)
Any TEAEs leading to death	8	7 (2.9)
Any TEAEs of special interest	286	102 (43)

TEAEs by descending incidence rate (≥3%)[a]	n (%)
Dysuria	55 (23)
Hematuria	20 (8.3)
Urinary tract infection	17 (7.1)
Pollakiuria	16 (6.7)
Fatigue	13 (5.4)
Urethral stenosis	13 (5.4)
Urinary retention	11 (4.6)
COVID-19	9 (3.8)
Constipation	9 (3.8)
Nausea	9 (3.8)

AE, adverse event; TEAE, treatment-emergent AE. Date of data cutoff: April 8, 2025.
All AEs, including local and systemic reactions were collected from the signing of the informed consent form until the 6-month visit. After the 6-month visit, all AEs assessed as related to study treatment or study procedures will be collected until the end of study visit.

[a]Patients may have more than 1 AE per preferred term. At each level of patient summarization, a patient was counted once if the patient reported 1 or more AEs.

Safety Outcomes, Incidence by Worst Grade per Patient

Incidence of TEAEs (≥5%)	UGN-102, n (%)[a] (N=240)					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Patients with any TEAE	54 (22.5)	46 (19.2)	33 (13.8)	3 (1.3)[b]	7 (2.9)[c]	143 (59.6)
Dysuria	46 (19.2)	8 (3.3)	1 (0.4)	0	0	55 (22.9)
Hematuria	15 (6.3)	5 (2.1)	0	0	0	20 (8.3)
UTI	6 (2.5)	10 (4.2)	1 (0.4)	0	0	17 (7.1)
Pollakiuria	12 (5.0)	4 (1.7)	0	0	0	16 (6.7)
Fatigue	10 (4.2)	3 (1.3)	0	0	0	13 (5.4)
Urethral stenosis	7 (2.9)	4 (1.7)	2 (0.8)	0	0	13 (5.4)

AE, adverse event; TEAE, treatment-emergent AE; UTI, urinary tract infection. Date of data cutoff: April 8, 2025.

[a] Patients may have more than one AE per preferred term. At each level of patient summarization, a patient was counted once, under the worst severity category.
[b] Grade 4 events included cerebrovascular accident, adenocarcinoma pancreas, and lung cancer metastatic; none of which were related to study treatment.
[c] Deaths that occurred during the study were due to AEs of septic shock, acute myocardial infarction, pneumonia, cardiac failure, sepsis, cardiopulmonary failure, or unknown reason; none of these AEs were related to study treatment.

Conclusions

- Results from ENVISION demonstrate that treatment with **UGN-102** results in a robust and clinically meaningful CR rate (79.6%) in patients with recurrent LG-IR-NMIBC
- Trial participants who achieved an initial CR had a high probability, per Kaplan-Meier estimation method, of remaining event-free 12 and 24 months later: 82.4% and 72.2%, respectively
  - The following information reports DoR from the 3-month CR population (N=191) which is different from the USPI efficacy population (N=173)
- Limitations of the current study include its single-arm design, which requires caution when interpreting outcomes without a concurrent control
- **UGN-102** is a valuable nonsurgical option for the treatment of patients with recurrent LG-IR-NMIBC, with demonstrable durability and tolerability

CR, complete response; DoR, duration of response; LG-IR-NMIBC, low-grade intermediate-risk non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumor.