# UTOPIA: A PHASE 3 TRIAL OF UGN-103, AN INTRAVESICAL MITOMYCIN REVERSE THERMAL HYDROGEL FOR TREATMENT OF RECURRENT LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE INVASIVE BLADDER CANCER

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## INTRODUCTION

- Management of recurrent low-grade, intermediate-risk NMIBC (LG-IR-NMIBC) remains challenging due to frequent recurrence after transurethral resection of bladder tumor (TURBT)[1]
- UGN-102, an intravesical mitomycin reverse thermal hydrogel, is the only Food and Drug Administration-approved treatment for adults with recurrent LG-IR-NMIBC
  - UGN-102 demonstrated an 80% (95% Confidence interval [CI]: 74, 85) complete response (CR) at 3 months after treatment initiation in the ENVISION trial[2–4]
  - There was an 82% (95% CI: 76, 87) and 72% (95% CI: 64, 79) probability of remaining in response at 12 and 24 months from initial CR at 3 months, respectively[2,4]
- UGN-103 is a novel formulation of UGN-102, consisting of mitomycin in a reverse-thermal hydrogel developed to simplify drug preparation and improve manufacturing efficiency

## OBJECTIVES

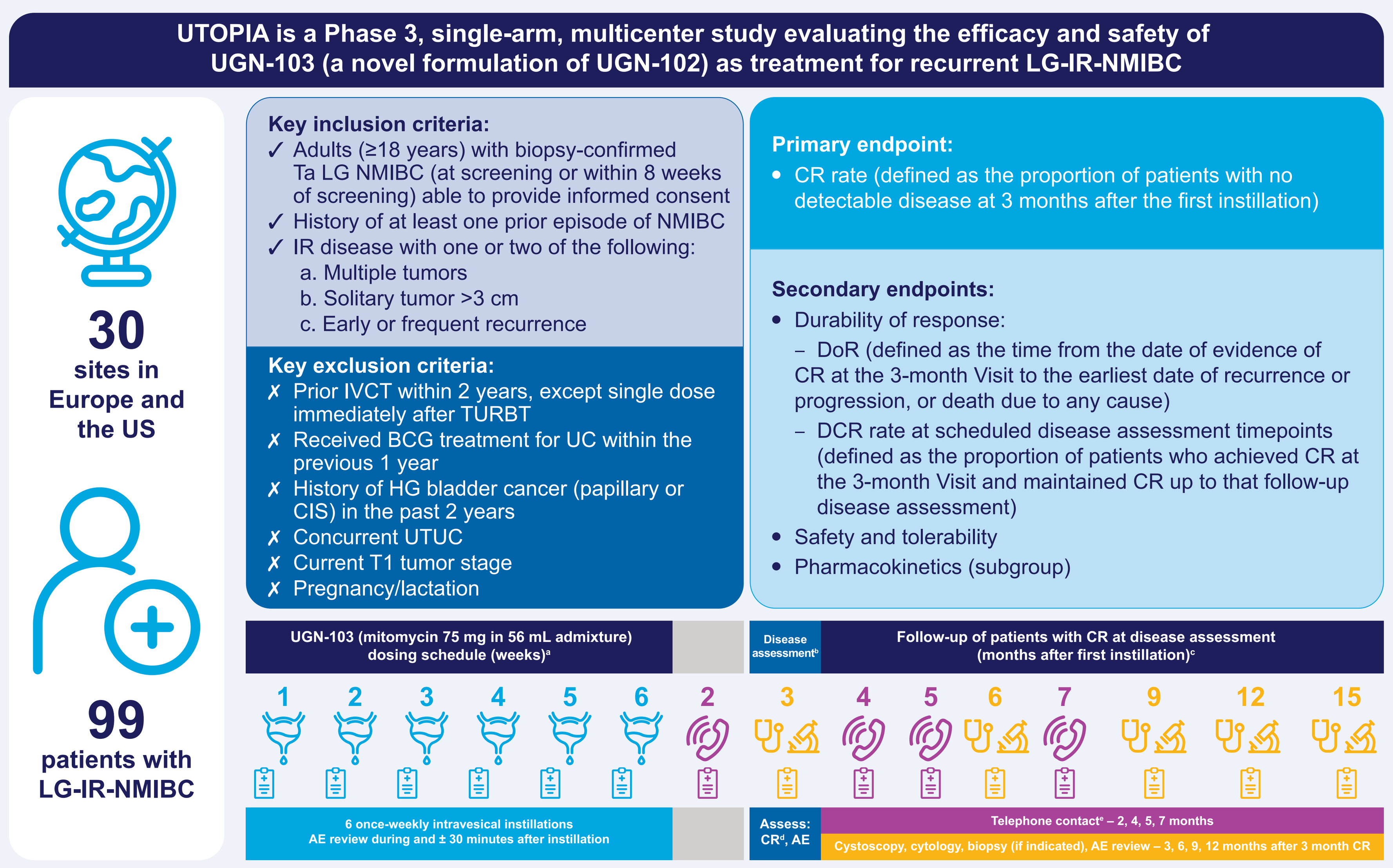
- The primary endpoint was to evaluate the tumor ablative effect of UGN-103, a reformulation of UGN-102, in patients with recurrent LG-IR-NMIBC
- Key secondary endpoints include evaluating durability of response, safety, and tolerability

## METHODS

### STUDY DESIGN

- UTOPIA (NCT06331299) is an ongoing study of adult patients with recurrent LG-IR-NMIBC treated with UGN-103 (**Figure 1**)
- Data cutoff for this analysis: September 3, 2025

### FIGURE 1. STUDY DESIGN




[a]Administered locally into the bladder via urinary catheter. [b]Patients who have a CR at the 3-month Visit will enter follow-up. Patients who have an NCR at the 3-month Visit will undergo investigator designated SoC and have a separate EoS Visit performed. [c]Patients with CR at 3 months will return to the clinic every 3 months for evaluation of response by cystoscopy, for-cause biopsy, and urine cytology. Patients will remain on study until disease recurrence, disease progression, death, or the last patient completes 12 months of follow-up (12 months after 3-month CR), whichever occurs first. [d]CR will be determined by cystoscopy, for-cause biopsy, and urine cytology. [e]AE and pregnancy review.
AE, adverse event; BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; CR, complete response; DCR, durable complete response; DoR, duration of response; EoS, end of study; HG, high grade; IR, intermediate risk; IVCT, intravesical chemotherapy; LG, low grade; NCR, non-complete response; NMIBC, non-muscle invasive bladder cancer; SoC, standard of care; Ta, non-invasive papillary stage; TURBT, transurethral resection of bladder tumor; UC; urothelial carcinoma; US, United States; UTUC, upper tract urothelial carcinoma.

## RESULTS

- A total of 99 patients were enrolled, and received ≥1 instillation of UGN-103; 97% (n=96) received all 6 instillations

### DEMOGRAPHICS

- Baseline and disease characteristics are presented in **Table 1**
  - Patients were predominantly ≥65 years (77.8%), male (71.7%), White (99.0%), and among those with available data (n=97), most had multiple tumors (89.7%) with a longest tumor diameter ≤3 cm (95.9%)

### TABLE 1. BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

| Characteristic, n/N (%) unless otherwise noted | UGN-103 (N=99) |
|---|---|
| Median age (range), years | 71.0 (46, 93) |
| ≥65 years | 77 (77.8) |
| Sex | |
| Male | 71/99 (71.7) |
| Female | 28/99 (28.3) |
| Race | |
| White | 98/99 (99.0) |
| Not reported | 1/99 (1.0) |
| Smoking history | |
| Non-smoker | 49/99 (49.5) |
| Smoker | 50/99 (50.5) |
| Longest tumor diameter[a] (cm) post-biopsy | |
| ≤3 | 94/95 (98.9) |
| >3 | 1/95 (1.1) |
| Tumor burden[b] (cm) post-biopsy | |
| ≤3 | 78/90 (86.7) |
| >3 | 12/90 (13.3) |
| Tumor count post-biopsy | |
| Single | 16/95 (16.8) |
| Multiple | 79/95 (83.2) |
| Number of prior TURBT to treat LG NMIBC | |
| 0 | 4/99 (4.0) |
| 1 | 59/99 (59.6) |
| ≥2 | 36/99 (36.4) |
| Previous LG NMIBC episodes | |
| Yes | 98/99 (99.0) |
| No | 1/99 (1.0) |
| Previous LG NMIBC episodes within 1 year of the current diagnosis | |
| Yes | 57/99 (57.6) |
| No | 42/99 (42.4) |

Percentages are computed using the number of non-missing data as the denominator.
[a]Longest tumor diameter is the longest diameter among all measurable lesions. [b]Tumor burden is calculated as the sum of the longest diameters of the measurable lesions.
LG, low grade; NMIBC, non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumor.

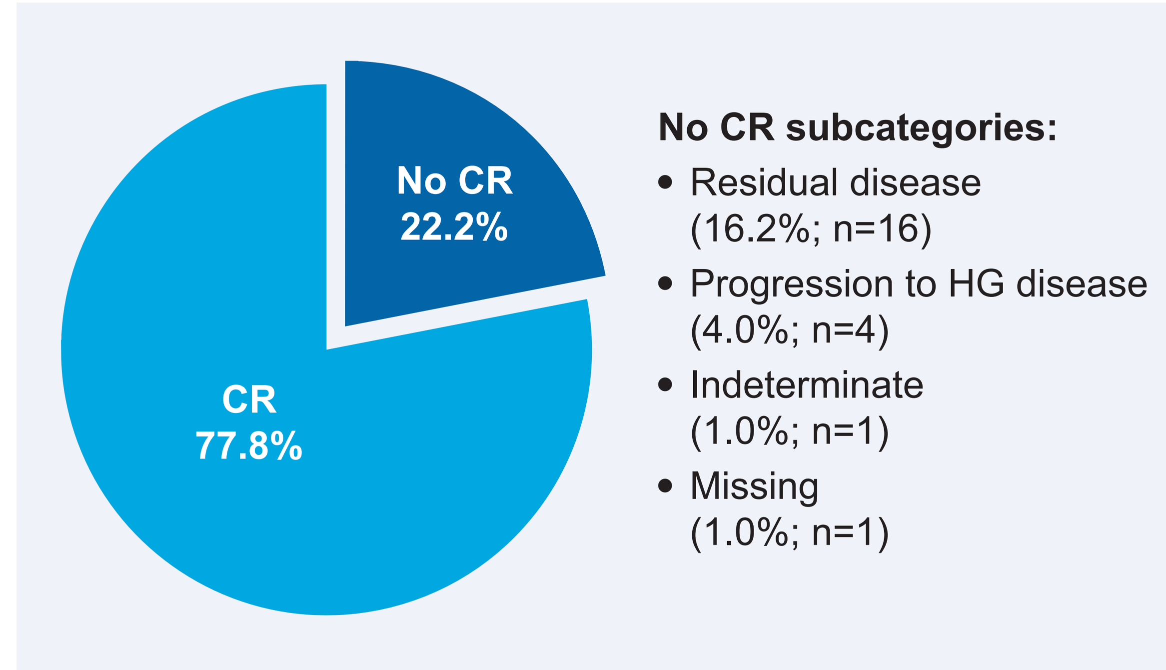
## CONCLUSIONS

- UGN-103 demonstrated efficacy and safety consistent with UGN-102 in patients with recurrent LG-IR-NMIBC
  - A 78% CR rate was achieved at 3 months, similar to UGN-102 (80%)
  - A consistent safety profile was observed, with low serious AE incidence
- These results support further evaluation of UGN-103 as a treatment option for recurrent LG-IR-NMIBC

### EFFICACY

- The CR rate was 77.8% (95% CI: 68.3, 85.5) at 3 months in the intent-to-treat population (ITT) (N=99)
- NCR occurred in 22.2% of patients, and was most commonly due to residual disease (**Figure 2**)
- Median follow-up (interquartile range) in the ITT population, measured from treatment initiation to data cutoff was 6.1 months (3.2, 7.2)
- Median duration of response is not yet estimable (NE [95% CI: 3.25, NE])
  - Median follow-up for DoR was 2.43 months (95% CI: 0.03, 2.83)

### FIGURE 2: SUMMARY OF RESPONSE RATE AT 3-MONTH DISEASE ASSESSMENT (ITT POPULATION)




Any missing or indeterminate responses are considered as NCR in this analysis.
CR, complete response; HG, high grade; ITT, intent-to-treat; NCR, non-CR.

### SAFETY

- Treatment-emergent adverse events (TEAEs) were reported in 59.6% of patients (**Table 2**)
  - Most were mild to moderate in severity and were resolved/resolving
- TEAEs leading to treatment discontinuation occurred in 3.0% of patients (**Table 2**)
  - No TEAEs led to study discontinuation or death

### TABLE 2. SUMMARY OF TEAES

| TEAEs | UGN-103 (N=99) Events | n (%) |
|---|---|---|
| Any TEAEs | 185 | 59 (59.6) |
| Any grade ≥3 TEAEs | 6 | 5 (5.1) |
| Any treatment- or procedure-related TEAEs | 98 | 37 (37.4) |
| Any treatment-related TEAEs | 76 | 31 (31.3) |
| Any procedure-related TEAEs | 54 | 25 (25.3) |
| Any TEAEs leading to treatment discontinuation | 5 | 3 (3.0) |
| Any TEAEs leading to study discontinuation | 0 | 0 |
| Any serious TEAEs | 3 | 2 (2.0) |
| Any treatment- or procedure-related serious TEAEs | 0 | 0 |
| Any TEAEs leading to death | 0 | 0 |

A TEAE is defined as an AE that occurs on or after the day of first instillation of UGN-103, or a pre-treatment AE that worsens during the study.
AE, adverse event; TEAE, treatment-emergent adverse event.

- Serious TEAEs were reported in 2.0% of patients (**Table 3**)
  - Serious TEAEs reported were atrial fibrillation, osteoarthritis, and respiratory failure
  - None were treatment related
- The most frequently reported TEAEs (≥5%) were dysuria (19.2%), fatigue (9.1%), pollakiuria (8.1%), urinary tract infection (7.1%), and hematuria (6.1%) (**Table 3**)

### TABLE 3. TEAES (≥5%) AND SERIOUS TEAES

| Preferred term | UGN-103 (N=99) |
|---|---|
| Patients with any TEAE ≥5% | 59 (59.6) |
| Dysuria | 19 (19.2) |
| Fatigue | 9 (9.1) |
| Pollakiuria | 8 (8.1) |
| Urinary tract infection | 7 (7.1) |
| Hematuria | 6 (6.1) |
| Patients with any serious TEAE | 2 (2.0) |
| Atrial fibrillation | 1 (1.0) |
| Osteoarthritis | 1 (1.0) |
| Respiratory failure | 1 (1.0) |

A TEAE is defined as an AE that occurs on or after the day of first instillation of UGN-103, or a pre-treatment AE that worsens during the study. AEs were coded to preferred term using the Medical Dictionary for Regulatory Activities coding dictionary version 28.0. Patients may have more than one AE per preferred term. At each level of patient summarization, a patient was counted once if the patient reported one or more AEs.
AE, adverse event; TEAE, treatment-emergent adverse event.

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