



# HOME INSTILLATION OF UGN-102 FOR PRIMARY CHEMOABLATION OF LOW-GRADE INTERMEDIATE-RISK NON-MUSCLE INVASIVE BLADDER CANCER: A SINGLE-ARM, OPEN-LABEL, PHASE 3B TRIAL

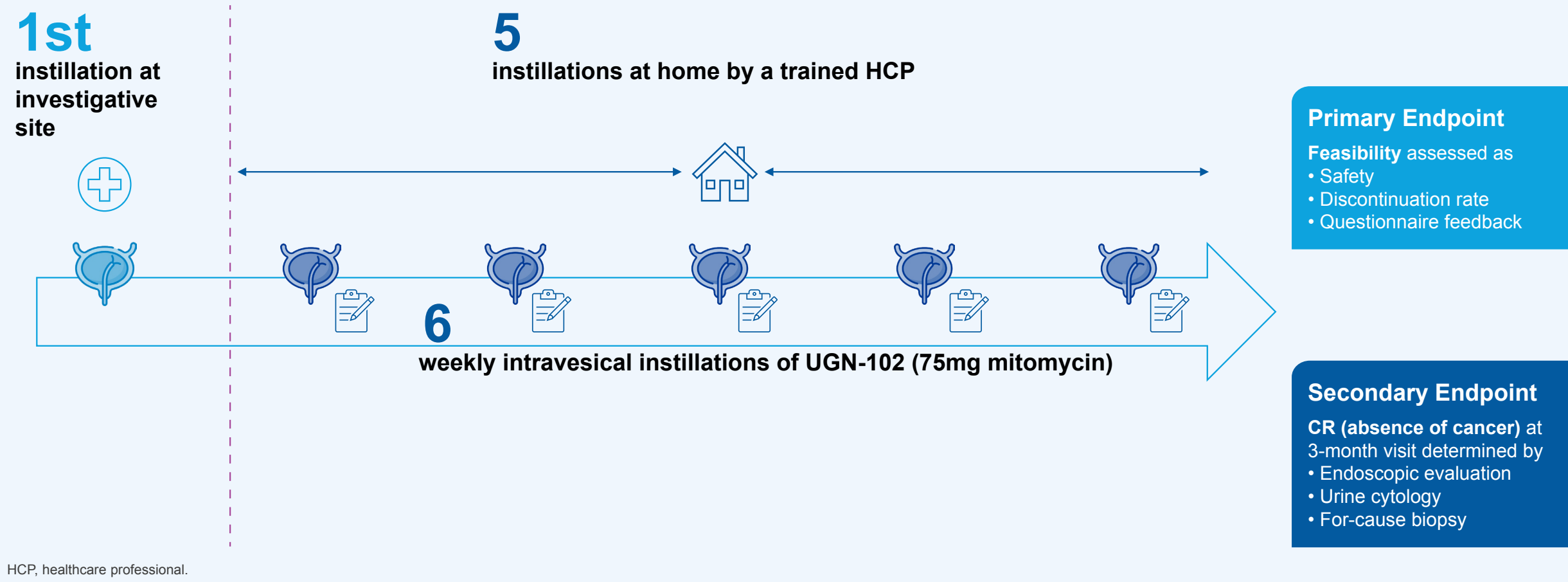
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## INTRODUCTION

- Bladder cancer is the 6th most common cancer in the USA<sup>1</sup>
  - ~83,000 incident cases annually
- At diagnosis, 75% of patients present with non-muscle invasive bladder cancer (NMIBC)<sup>2,3</sup>
- Low-grade, intermediate-risk NMIBC (LG-IR-NMIBC) is a chronically relapsing disease, and the standard of care for treatment is transurethral resection of bladder tumor (TURBT) under general anesthesia<sup>4</sup>
- Recent trials suggest 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, without the need for surgery<sup>5,6</sup>
- We report the experience of administering **UGN-102** to patients with LG-IR-NMIBC in the home by a trained healthcare provider (HCP), to examine feasibility

## STUDY DESIGN



## KEY INCLUSION CRITERIA

- Aged ≥18 years
- Newly diagnosed or historical LG-IR-NMIBC (Ta) histologically confirmed by cold cup biopsy at screening or within 8 weeks before screening
- IR disease was defined as 1 or 2 of the following
  - The presence of multiple tumors
  - A solitary tumor of >3 cm
  - Recurrence (≥1 occurrence of LG-NMIBC within 1 year of the current diagnosis at the initial screening visit)
- Negative voiding cytology for high-grade (HG) disease within 6 weeks before screening

## KEY EXCLUSION CRITERIA

- Bacillus Calmette-Guérin (BCG) treatment for urothelial carcinoma within the previous 1 year
- A history of high-grade bladder cancer (papillary or carcinoma in situ) in the past 2 years
- Known allergy or sensitivity to mitomycin that, in the investigator's opinion, could not be readily managed

## RESULTS

### PRIMARY ENDPOINT

- Patients highly rated their home instillation experience for each domain of the patient questionnaire; the median patient questionnaire scores remained the same throughout the treatment period, indicating that patients had no change in their home instillation experience over time
  - Median **comfort domain score** was 12.0 (range: 10 to 12)
  - Median **safety domain score** was 4.0 (range: 3 to 4)
  - Median **communication domain score** was 8.0 (range: 6 to 8)
  - Median **preference domain score** was 4.0 (range: 2 to 4)
  - Median **overall experience score** was 4.0 (range: 3 to 4)
  - Median **composite score** was 32.0 (range: 26 to 32)
- Home instillation was reported as feasible by visiting HCPs
  - At each instillation visit, the majority of available responses were in favor of home instillation, and most HCPs reported having no difficulty in performing it in the patients home

### SAFETY

- Most patients had mild-to-moderate AEs that resolved or were resolving
- Serious AEs occurred in 3 patients; none were considered treatment-related

### SECONDARY ENDPOINT

- At the 3-month visit, 6 of the 8 participants achieved a complete response (CR), with 2 patients who discontinued treatment counted as non-responders

### PATIENT DEMOGRAPHICS AND MEDICAL HISTORY

Characteristic	UGN-102 N=8
<b>Age, years</b>	
Median (min, max)	75.0 (55, 84)
<b>Sex, n (%)</b>	
Male	5 (62.5)
Female	3 (37.5)
<b>Race, n (%)</b>	
White	8 (100)
<b>BMI (kg/m<sup>2</sup>)</b>	
Median (min, max)	27.29 (20.6, 33.6)
<b>Any known prior UC medical history</b>	8 (100)
Any prior NMIBC episode	8 (100)
Previous LG NMIBC episodes	8 (100)
Previous LG NMIBC episodes within 1 year of the current diagnosis	6 (75.0)
<b>Patients with prior TURBT for treatment of NMIBC, n (%)</b>	8 (100)

BMI, body mass index; LG, low-grade; max, maximum; min, minimum; NMIBC, non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumor; UC, urothelial carcinoma.

### END OF STUDY SURVEY SUMMARY

- 6 patients (75%) completed all 6 instillations
- 2 discontinued due to an AE
- 5 out of 6 patients recommend UGN-102 over TURBT
- 3 out of 4 investigators considered at-home treatment "not different" from in-office treatment

AE, adverse event; TURBT, transurethral resection of bladder tumor.

### SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS

	Overall Incidence n (%)	Treatment-Related n (%)
<b>Patients with any TEAEs</b>	8 (100)	4 (50.0)
<b>Serious TEAEs</b>	3 (37.5)	0
<b>TEAEs occurring in 2 or more patients by preferred term</b>		
Dysuria	2 (25.0)	2 (25.0)
Fatigue	2 (25.0)	2 (25.0)
Hypertonic bladder	2 (25.0)	1 (12.5)
Urinary tract infection	2 (25.0)	1 (12.5)

TEAE, treatment-emergent adverse event.

## CONCLUSIONS

- Results from this small feasibility study demonstrate that home instillation of the chemoablation agent **UGN-102** for the treatment of LG-IR-NMIBC is feasible and convenient, and results in a clinically meaningful high CR rate
- The overall safety profile was consistent with that observed in the rest of the **UGN-102** development program
- With trained home healthcare personnel, home instillation of **UGN-102** may provide patients with a convenient alternative to in-clinic instillation, thus reducing the treatment burden

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