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Poster
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# DURATION OF RESPONSE TO UGN-102 BY AGE AT BASELINE ACROSS 3 CLINICAL TRIALS IN PATIENTS WITH RECURRENT LOW-GRADE INTERMEDIATE-RISK BLADDER CANCER

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## INTRODUCTION

- Young Onset Bladder Cancer (YOBC) is a newly defined entity
- The Bladder Cancer Advocacy Network (BCAN) and International Bladder Cancer Group (IBCG) arrived at a consensus definition of YOBC as a diagnosis aged ≤50 years[1]
- The YOBC population is distinguished by a higher percentage of low-grade (LG) disease than is typically diagnosed in an older population
- Low-grade, intermediate-risk, non-muscle invasive bladder cancer (LG-IR-NMIBC) can be managed with a transurethral resection of bladder tumor (TURBT), a surgical procedure conducted under general anesthesia; however, disease recurrence is common[2]
- UGN-102, a reverse thermal hydrogel formulation of mitomycin (75mg dose), is a US Food and Drug Administration (FDA)-approved non-surgical chemoablative treatment for adults with recurrent LG-IR-NMIBC that can be administered via a urinary catheter in an ambulatory setting
- OBJECTIVE: To assess the efficacy of UGN-102 across different age subgroups of patients with recurrent LG-IR-NMIBC, using pooled data from three prospective clinical trials: OPTIMA II (phase 2b), ENVISION (pivotal phase 3), and ATLAS (phase 3)

## METHODS

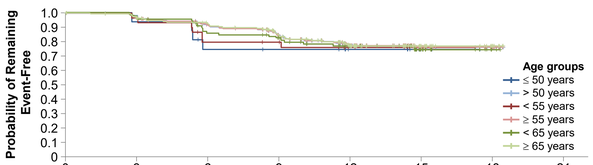
- Data from 3 prospective trials were pooled to assess the 3-month complete response (CR) and long-term duration of response (DoR) of UGN-102-treated patients with recurrent LG-IR-NMIBC: OPTIMA II (NCT03558503),[3] ENVISION (NCT05243550),[4] and ATLAS (NCT04688931)[5]
  - Patients received six once-weekly intravesical instillations of UGN-102 (75 mg)
  - CR: absence of bladder cancer per negative white light cystoscopy, negative urine cytology, and, when indicated, a negative for-cause biopsy
  - Outcomes were analyzed by age group at baseline: ≤50 vs >50 years; <55 vs ≥55 years; and <65 vs ≥65 years
  - DoR was assessed using Kaplan–Meier (KM) methods
  - The pivotal, ongoing ENVISION trial includes up to 5 years of follow-up and was analyzed separately to evaluate longer-term DoR

## RESULTS

- Baseline patient demographics and prognostic factors are shown in **Table 1**
- Pooled baseline characteristics were generally similar:
  - Across the pooled analysis age groups, ≥ 60% of patients were male, ≥ 95% were White, ≥ 67% were not from the US, ≥ 93% received all 6 instillations of UGN-102, ≥ 85% had a tumor longest diameter ≤ 3 cm, and ≥ 81% of patients had multiple tumors

**≥ 70% of patients who achieved the CR rate at month 3 remained event-free for the subsequent 12 months (pooled data) and 24 months (ENVISION) across the age subgroups**

### Figure 1. Duration of Response by Age in Pooled OPTIMA II, ATLAS, and ENVISION Studies




Number at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 16 | 15 | 11 | 10 | 7 | 2 | 0 | 0 |
| 249 | 235 | 213 | 186 | 114 | 45 | 11 | 0 |
| 30 | 29 | 23 | 22 | 14 | 5 | 0 | 0 |
| 235 | 221 | 201 | 174 | 107 | 42 | 11 | 0 |
| 89 | 84 | 71 | 65 | 42 | 17 | 2 | 0 |
| 176 | 166 | 153 | 131 | 79 | 30 | 9 | 0 |

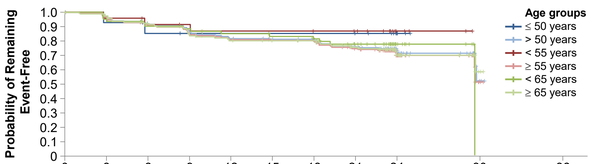
**CR rates at 3 months were consistent across all age subgroups, and baseline age did not impact durability of response to UGN-102**

### Table 1. Baseline Demographics and Prognostic Factors Across Three Clinical Studies: OPTIMA II, ATLAS, and ENVISION

| | Pooled data from OPTIMA II, ATLAS, and ENVISION | | | | | |
|---|---|---|---|---|---|---|
| | ≤ 50 years (N = 20) | > 50 years (N = 318) | < 55 years (N = 37) | ≥ 55 years (N = 301) | < 65 years (N = 117) | ≥ 65 years (N = 221) |
| Median age at screening, years (range) | 44.0 (30, 50) | 70.0 (51, 96) | 50.0 (30, 54) | 71.0 (55, 96) | 59.0 (30, 64) | 75.0 (65, 96) |
| Previous NMIBC episodes,[a] n (%) | | | | | | |
| 1 | 14 (70.0) | 172 (54.1) | 25 (67.6) | 161 (53.5) | 65 (55.6) | 121 (54.8) |
| 2 | 4 (20.0) | 49 (15.4) | 7 (18.9) | 46 (15.3) | 21 (17.9) | 32 (14.5) |
| > 2 | 2 (10.0) | 97 (30.5) | 5 (13.5) | 94 (31.2) | 31 (26.5) | 68 (30.8) |
| Prior TURBT to treat NMIBC,[a] n (%) | | | | | | |
| 0 | 0 | 4 (1.3) | 0 | 4 (1.3) | 2 (1.7) | 2 (0.9) |
| 1 | 15 (75.0) | 178 (56.0) | 27 (73.0) | 166 (55.1) | 66 (56.4) | 127 (57.5) |
| 2 | 3 (15.0) | 51 (16.0) | 5 (13.5) | 49 (16.3) | 21 (17.9) | 33 (14.9) |
| > 2 | 2 (10.0) | 85 (26.7) | 5 (13.5) | 82 (27.2) | 28 (23.9) | 59 (26.7) |
| | ENVISION | | | | | |
| | ≤ 50 years (N = 16) | > 50 years (N = 216) | < 55 years (N = 29) | ≥ 55 years (N = 203) | < 65 years (N = 77) | ≥ 65 years (N = 155) |
| Median age at screening, years (range) | 44.0 (30, 50) | 71.0 (51, 92) | 50.0 (30, 54) | 72.0 (55, 92) | 57.0 (30, 64) | 75.0 (65, 92) |
| Previous NMIBC episodes,[a] n (%) | | | | | | |
| 1 | 12 (75.0) | 128 (59.3) | 21 (72.4) | 123 (60.6) | 50 (64.9) | 94 (60.6) |
| 2 | 3 (18.8) | 35 (16.2) | 5 (17.2) | 30 (14.8) | 12 (15.6) | 23 (14.8) |
| > 2 | 1 (6.3) | 53 (24.5) | 3 (10.3) | 50 (24.6) | 15 (19.5) | 38 (24.5) |
| Prior TURBT to treat NMIBC,[a] n (%) | | | | | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 13 (81.3) | 135 (62.5) | 23 (79.3) | 129 (63.5) | 52 (67.5) | 100 (64.5) |
| 2 | 2 (12.5) | 34 (15.7) | 3 (10.3) | 30 (14.8) | 11 (14.3) | 22 (14.2) |
| > 2 | 1 (6.3) | 47 (21.8) | 3 (10.3) | 44 (21.7) | 14 (18.2) | 33 (21.3) |

**Abbreviations:** eCRF, electronic case report form; NMIBC, non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumor.
[a] Based on data from Urothelial Carcinoma Medical History eCRF page.

### Figure 2. Duration of Response by Age in ENVISION




Number at risk

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 14 | 13 | 11 | 10 | 10 | 10 | 10 | 9 | 2 | 0 | | |
| 173 | 163 | 151 | 142 | 132 | 127 | 124 | 109 | 37 | 2 | | |
| 24 | 23 | 21 | 20 | 19 | 19 | 18 | 17 | 4 | 0 | 0 | |
| 163 | 153 | 141 | 132 | 123 | 118 | 116 | 101 | 35 | 2 | 0 | |
| 63 | 59 | 54 | 52 | 49 | 47 | 45 | 39 | 10 | 0 | 0 | |
| 124 | 117 | 108 | 100 | 93 | 90 | 89 | 79 | 29 | 2 | 0 | |

### Table 2. Summary of Response and Duration of Response Across Three Clinical Studies: OPTIMA II, ATLAS, and ENVISION

| | Pooled data from OPTIMA II, ATLAS, and ENVISION | | | | | |
|---|---|---|---|---|---|---|
| | ≤ 50 years (N = 20) | > 50 years (N = 318) | < 55 years (N = 37) | ≥ 55 years (N = 301) | < 65 years (N = 117) | ≥ 65 years (N = 221) |
| Complete response, n (%) | 15 (75.0) | 242 (76.1) | 29 (78.4) | 228 (75.7) | 86 (73.5) | 171 (77.4) |
| Non-complete response, n (%)[a] | 5 (25.0) | 76 (23.9) | 8 (21.6) | 73 (24.3) | 31 (26.5) | 50 (22.6) |
| Residual disease | 3 (15.0) | 44 (13.8) | 5 (13.5) | 42 (14.0) | 19 (16.2) | 28 (12.7) |
| Progression[b] | 0 | 12 (3.8) | 0 | 12 (4.0) | 3 (2.6) | 9 (4.1) |
| Indeterminate | 1 (5.0) | 15 (4.7) | 1 (2.7) | 15 (5.0) | 6 (5.1) | 10 (4.5) |
| Missing | 1 (5.0) | 5 (1.6) | 2 (5.4) | 4 (1.3) | 3 (2.6) | 3 (1.4) |
| **Complete response rate at 3 m, % (95% CI)[c]** | **75.0 (50.9, 91.3)** | **76.1 (71.0, 80.7)** | **78.4 (61.8, 90.2)** | **75.7 (70.5, 80.5)** | **73.5 (64.5, 81.2)** | **77.4 (71.3, 82.7)** |
| | (n = 16) | (n = 249) | (n = 30) | (n = 235) | (n = 89) | (n = 176) |
| Pts with events at data cut-off 18 m, n (%) | 4 | 52 | 7 | 49 | 20 | 36 |
| Patients with events 12 m after CR, n | 4 (25.0) | 52 (20.9) | 7 (23.3) | 49 (20.9) | 20 (22.5) | 36 (20.5) |
| **KM estimate of DoR 12 m after CR, % (95% CI)[d]** | **74.5 (45.4, 89.6)** | **77.2 (71.1, 82.2)** | **75.9 (56.0, 87.8)** | **77.1 (70.8, 82.3)** | **76.9 (66.1, 84.6)** | **77.0 (69.5, 82.9)** |
| Median follow-up time, m (95% CI)[e] | 14.52 (8.31, 14.98) | 12.19 (12.02, 12.68) | 14.42 (11.76, 14.78) | 12.19 (12.02, 12.52) | 14.06 (11.99, 14.72) | 12.16 (11.99, 12.29) |
| **Median KM estimate of DoR, m (95% CI)[f]** | NE | NE | NE | NE | NE | NE |
| | ENVISION | | | | | |
| | ≤ 50 years (N = 16) | > 50 years (N = 216) | < 55 years (N = 29) | ≥ 55 years (N = 203) | < 65 years (N = 77) | ≥ 65 years (N = 155) |
| Complete response, n (%) | 13 (81.3) | 167 (77.3) | 23 (79.3) | 157 (77.3) | 60 (77.9) | 120 (77.4) |
| Non-complete response, n (%)[a] | 3 (18.8) | 49 (22.7) | 6 (20.7) | 46 (22.7) | 17 (22.1) | 35 (22.6) |
| Residual disease | 2 (12.5) | 31 (14.4) | 4 (13.8) | 29 (14.3) | 11 (14.3) | 22 (14.2) |
| Progression[b] | 0 | 6 (2.8) | 0 | 6 (3.0) | 1 (1.3) | 5 (3.2) |
| Indeterminate | 1 (6.3) | 8 (3.7) | 1 (3.4) | 8 (3.9) | 4 (5.2) | 5 (3.2) |
| Missing | 0 | 4 (1.9) | 1 (3.4) | 3 (1.5) | 1 (1.3) | 3 (1.9) |
| **Complete response rate at 3 m, % (95% CI)[c]** | **81.3 (54.4, 96.0)** | **77.3 (71.1, 82.7)** | **79.3 (60.3, 92.0)** | **77.3 (71.0, 82.9)** | **77.9 (67.0, 86.6)** | **77.4 (70.0, 83.7)** |
| | (n = 14) | (n = 173) | (n = 24) | (n = 163) | (n = 63) | (n = 124) |
| Pts with events at data cut-off 30 m, n (%) | 2 | 45 | 3 | 44 | 14 | 33 |
| Patients with events 24 m after CR, n | 2 (14.3) | 45 (26.0) | 3 (12.5) | 44 (27.0) | 14 (22.2) | 33 (26.6) |
| **KM estimate of DoR 24 m after CR, % (95% CI)[d]** | 85.1 (52.3, 96.1) | 71.3 (62.7, 78.3) | 86.9 (64.6, 95.6) | 70.2 (61.2, 77.5) | 77.9 (64.9, 86.5) | 70.0 (59.6, 78.2) |
| Median follow-up time, m (95% CI)[e] | 23.72 (8.31, 23.98) | 23.72 (23.62, 23.92) | 23.72 (21.88, 23.95) | 23.75 (23.66, 23.92) | 23.56 (23.26, 23.72) | 23.92 (23.72, 23.95) |
| **Median KM estimate of DoR, m (95% CI)[f]** | NE | NE (29.63, NE) | NE | NE (29.63, NE) | 29.63 (NE, NE) | NE (29.70, NE) |

**Abbreviations:** CI, confidence interval; CR, complete response; DoR, duration of response; KM, Kaplan–Meier; m, months; NE, not estimable; Patients, pts.
[a] Missing or indeterminate responses were considered non-complete responses (NCR) in this analysis.
[b] Includes progression to high grade disease, T1 (tumor invades lamina propria), and CIS (carcinoma in situ).
[c] For patients who had missing or indeterminate CR evaluations at 3 months, data were imputed using their 6-month evaluation (responders or non-responders at 6 months). Exact 95% CIs were computed using the Clopper–Pearson method.
[d] Estimated using the Kaplan–Meier method with confidence intervals computed using the Greenwood method with log–log transformation. DoR is defined as time from CR at 3-month assessment until the earliest date of recurrence, progression, or death.
[e] Estimated using the reverse Kaplan–Meier method.
[f] Estimated using the reverse Kaplan–Meier method, with confidence intervals computed using the Brookmeyer–Crowley method.

## RESULTS (continued)

- Younger patients tended to have had numerically fewer prior NMIBC episodes and TURBTs compared with older patients from the pooled analysis **(Table 1)**

## Efficacy

- Patients younger than 50 years of age shared similar CR rates with older patient groups, with no evidence that age negatively impacted response **(Table 2)**
  - No patients with YOBC showed disease progression at 3 months
  - Per **Figures 1** and **2**, most patients remained event-free 12 months after CR (pooled datasets) and 24 months after CR (ENVISION dataset)
  - Given the small cumulative number of events in the YOBC patients **(Table 2)**, these data are hypothesis-generating
  - The KM estimate of DoR was ≥ 74% across all pooled age subgroups at 12 months after CR and ≥ 70% across ENVISION subgroups at 24 months after CR
  - The median DoR was not estimable for any age subgroup from either the pooled or ENVISION-only analyses due to the low event rate (**Table 2**)

## CONCLUSIONS

- **UGN-102 demonstrated consistent efficacy and durability across different age groups**
  - **Most patients achieving the CR rate at month 3 remained event-free for the subsequent 12 months (pooled data) and 24 months (ENVISION) across the age subgroups**
- **Younger patients tended to have had numerically fewer prior NMIBC episodes and prior TURBTs compared with older patients from the pooled analysis**
- **The small YOBC subgroup size and post-hoc design limit definitive conclusions**

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