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Top 30 Abstracts

# Durable 24-Month Outcomes from BOND-003 Cohort C: Phase 3 Study of Intravesical Cretostimogene Grenadenorepvec for High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma In Situ


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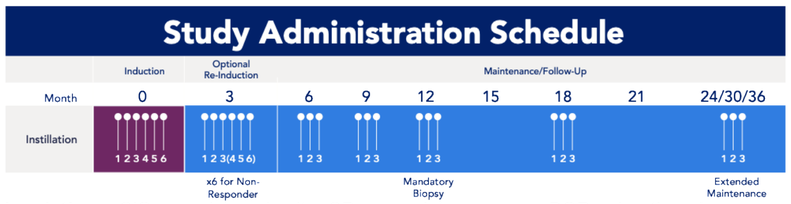
## BACKGROUND

- Considerable unmet need exists for effective, well-tolerated bladder-sparing treatment options for patients with HR BCG-UR NMIBC with CIS[1]
- BCG-UR defined as persistent or recurrent CIS +/- Ta/T1 within 12 months of BCG therapy per FDA guidance[2]
- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with dual mechanisms of action; it selectively replicates in and lyses cancer cells while amplifying the immune response against bladder tumors
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1
- BOND-003 is a pivotal Phase 3 trial designed to evaluate cretostimogene in patients with BCG-UR NMIBC

## METHODS

- Enrolled 112 patients with HR BCG-UR NMIBC with CIS +/- Ta/T1
- All visible disease was resected prior to treatment
- Response assessments include cystoscopy (biopsy as indicated) & cytology every 3 months for first 2 years and every 6 months starting Year 3; all responses are centrally confirmed

### Study Administration Schedule




**Abbreviations:** CIS = carcinoma in situ; CR = complete response; DOR = duration of response; ITT= intention to treat; K-M = Kaplan-Meier; NMIBC = non-muscle invasive bladder cancer; RC= radical cystectomy UR = unresponsive


**References:** **1** NCCN Bladder Cancer Guidelines; 2025, **2** FDA Guidance; 2024



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BOND-003 COHORT C

BCAN 20 Years of Impact

**75.5% CR at Anytime**

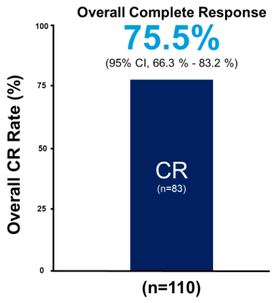
**Median DOR 27.9 Months & Ongoing**

**90% Maintained Response to Year 2**

**0% Grade ≥3 TRAEs**

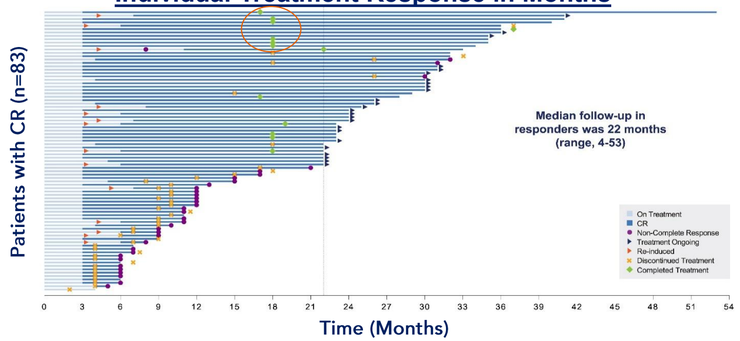
## RESULTS

- Majority of patients are male (74%), white (62%) & >65 years old (83%)
- With a median follow-up time of 25.8 months, CR rate at any time is 75.5% (83/110) (95% CI 66.3-83.2%)
- High landmark CR at 24 mo in ITT population of 41.8% (46/110)
- Median DOR is 27.9 months (95% CI 14.3-NE%) and is on-going
- 96.4% (106/110) were free from progression to ≥T2 disease and 83.6% (92/110) did not undergo RC post recurrence or progression



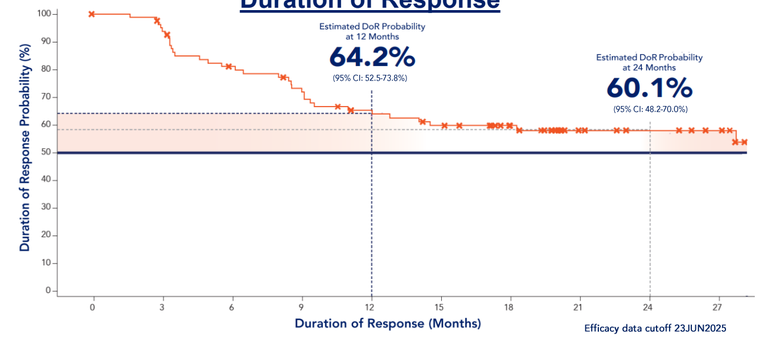

| CR Landmark | CR Rate, % (95% CI) | CR by K-M Est, % (95% CI) |
|---|---|---|
| 12-month | 46.4% (36.9, 56.1) *51 out of 110 patients* | 50.7% (40.9, 59.8) |
| 24-month | 41.8% (32.5, 51.6) *46 out of 110 patients* | 42.4% (32.7, 51.7) |

### Individual Treatment Response in Months




- Responses maintained in patients who completed treatment

### Duration of Response




### Safety Profile

| Preferred Term (MedDRA v.26.1) | Cretostimogene (n=112) | |
|---|---|---|
| | Any Grade (%) | Grade ≥3 |
| Patients with ≥1 TRAE | 71 (63.4%) | 0 (0) |
| **Treatment-Related AE reported in >20% patients** | | |
| Bladder Spasm | 28 (25%) | 0 (0) |
| Pollakiuria | 25 (22.3%) | 0 (0) |
| Urgency | 23 (20.5%) | 0 (0) |

- Most AES were Grade 1-2; 1-day median time to TRAE resolution
- High Tx Compliance- no tx-related discontinuations; few missed (1.8%) or delayed (7.1%) doses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