

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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Disclosures

- CG Oncology- No Conflicts of Interest

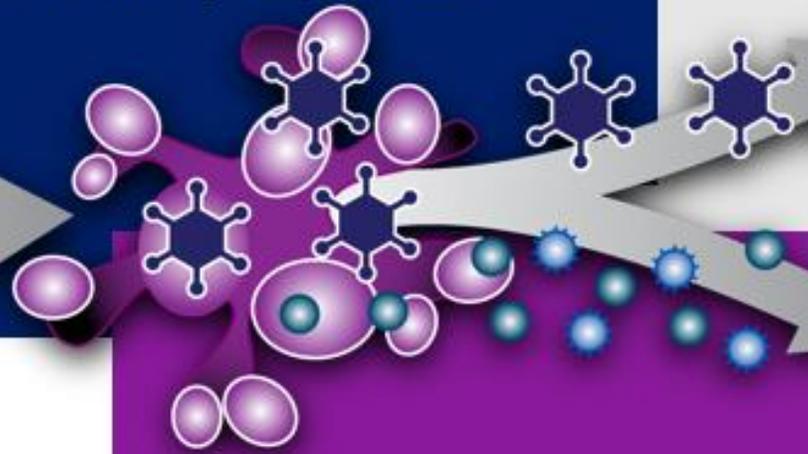
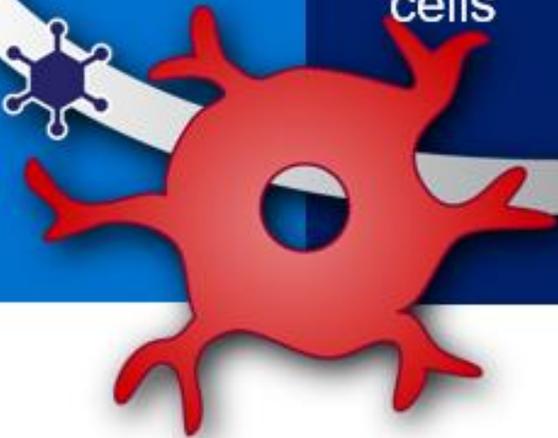


Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action

- 1 Selectively Replicates in and Lyses Bladder Cancer Cells

Enters target cell

Replicates in and lyses cancer cells

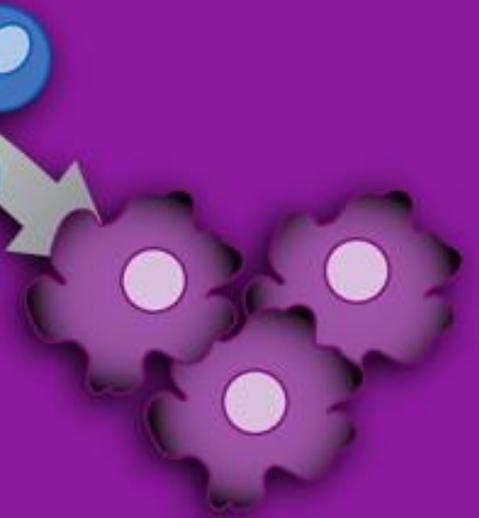


Chain Reaction of Cancer Cell Death:
Viral progeny spread to additional
tumor cells



- 2 Simultaneously Amplifies Anti-tumor Immune Response

Innate to Adaptive Immune Switch:
Cytokine and antigen release
activates T & B-cells, inducing
immunologic memory



Phase 3 Cretostimogene Monotherapy for High-Risk BCG-Unresponsive NMIBC with CIS

BOND-003
COHORT C



HR BCG-Unresponsive NMIBC

Cretostimogene Grenadenorepvec
Single-Arm, Open-Label, IVE Administration

Primary Endpoint:
CR at Any Time

Population

- Enrollment complete (n=112)
- Pathologically confirmed High-Risk BCG-Unresponsive NMIBC with CIS +/- Ta/T1
- All Ta/T1 disease resected prior to treatment
- Mandatory biopsies at 12-month assessment¹

Study Design / Regimen

Induction Course:
Weekly x 6

Second Induction¹:
Weekly x 6 for non-responders

Maintenance Course:
Weekly x 3 Q3M for Year 1
Weekly x 3 Q6M for Year 2-3

Additional Endpoints

- CR at 12-months
- DoR
- RFS
- PFS
- Cystectomy-Free Survival
- Safety

[NCT04452591](#)

CIS = Carcinoma in situ. RFS = recurrence free survival. PFS = progression free survival.

Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years, as well as mandatory bladder mapping at month 12.

¹ All patients required to undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR.

² Second induction course of weekly x 6 for non-responders at month 3.



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Patient Demographics & Baseline Characteristics

| Subjects in Safety Dataset | N=112 | % |
|--|--------------|------|
| Gender | | |
| Male | 83 | 74.1 |
| Female | 29 | 25.9 |
| Age (Years) | | |
| Mean (SD) | 72.9 (9.19) | |
| Median (Range) | 74.0 (43-90) | |
| Age (Categories) | | |
| < 65 | 19 | 17.0 |
| ≥ 65 and < 75 | 43 | 38.4 |
| ≥75 | 50 | 44.6 |
| BCG History: No. of Prior Instillations | | |
| Median (Range) | 12 (7 – 66) | |
| HR NMIBC T-Stage at Study Entry | | |
| CIS with HG Ta/T1 | 22 | 19.6 |
| CIS alone | 90 | 80.4 |
| Prior Therapy Other Than BCG, n (%) | | |
| ≥ 1 Prior Therapy | 53 | 47.3 |
| Adjuvant Chemotherapy | 34 | 30.4 |
| Immunotherapy | 7 | 6.3 |

- Majority of patients are:
 - Male (74%)
 - White (62%)
 - > 65 years (83%)
- 63.4% of patients in US
- **Highly pre-treated population**
 - Prior chemotherapy (41%)
 - Immunotherapy, including systemic IO (6%)

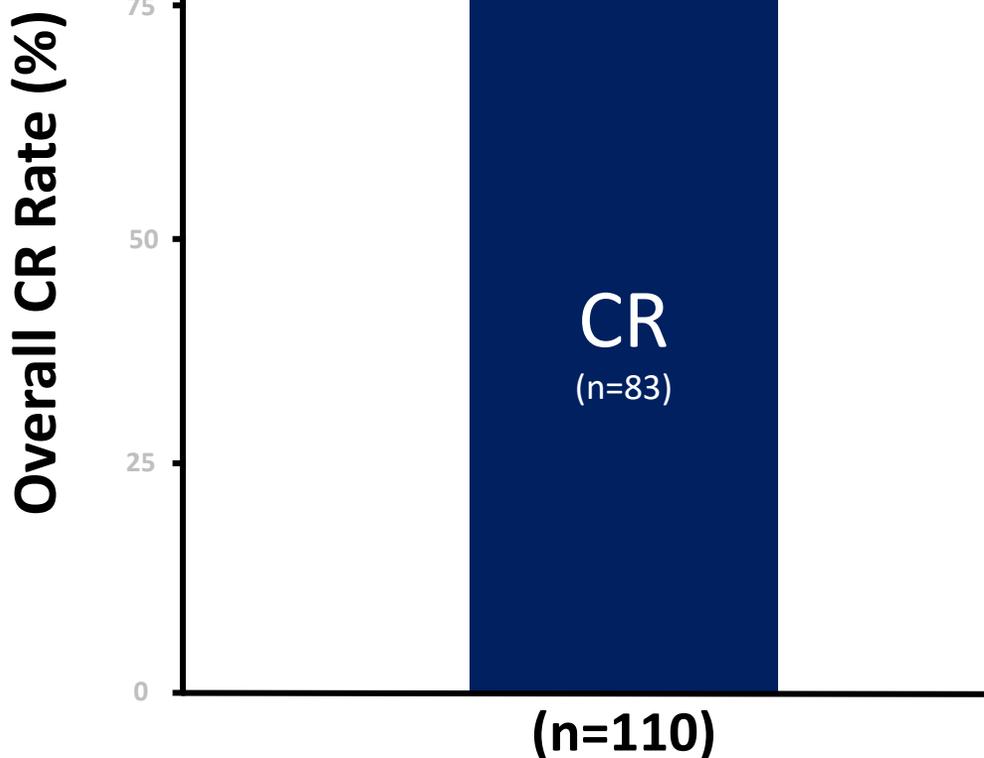


Consistent and Compelling CR & Durability Data

Overall Complete Response

75.5%

(95% CI, 66.3 % - 83.2 %)



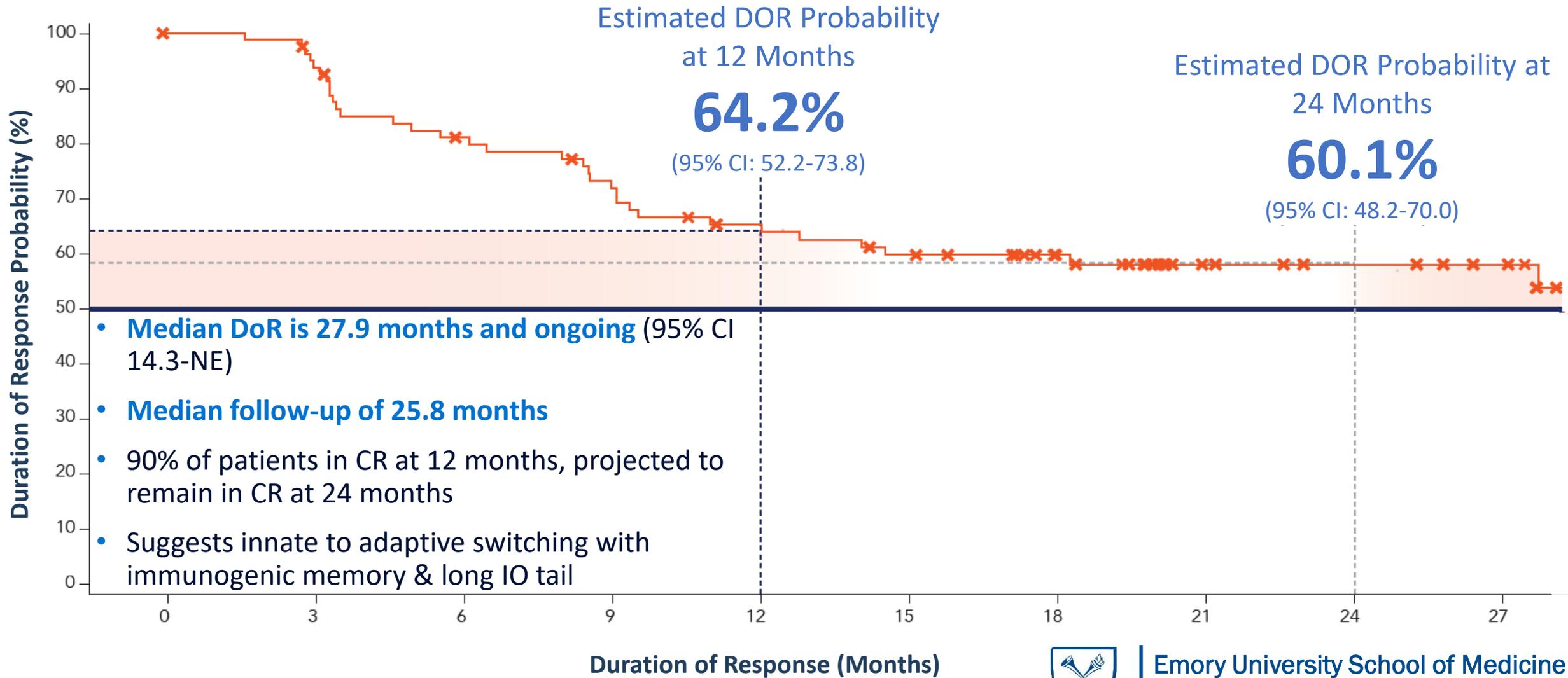
| CR Landmark | CR Rate, % (95% CI) | CR by K-M Est, % (95% CI) |
|-------------|--|------------------------------|
| 12-month | 46.4% (36.8, 56.1) <i>51 out of 110 patients</i> | 50.7% (40.9, 59.8) |
| 24-month | 41.8% (32.5, 51.6) <i>46 out of 110 patients</i> | 42.4% (32.7, 51.7) |

- 96.4% (106/110) were free from progression to \geq T2 disease
- 83.6% (92/110) did not undergo RC post recurrence or progression
 - Among RCs, 83.3% (15/18) were T0 or NMIBC
- All Complete Responses are centrally confirmed*
 - Local:Central concordance: 97.1% of assessments

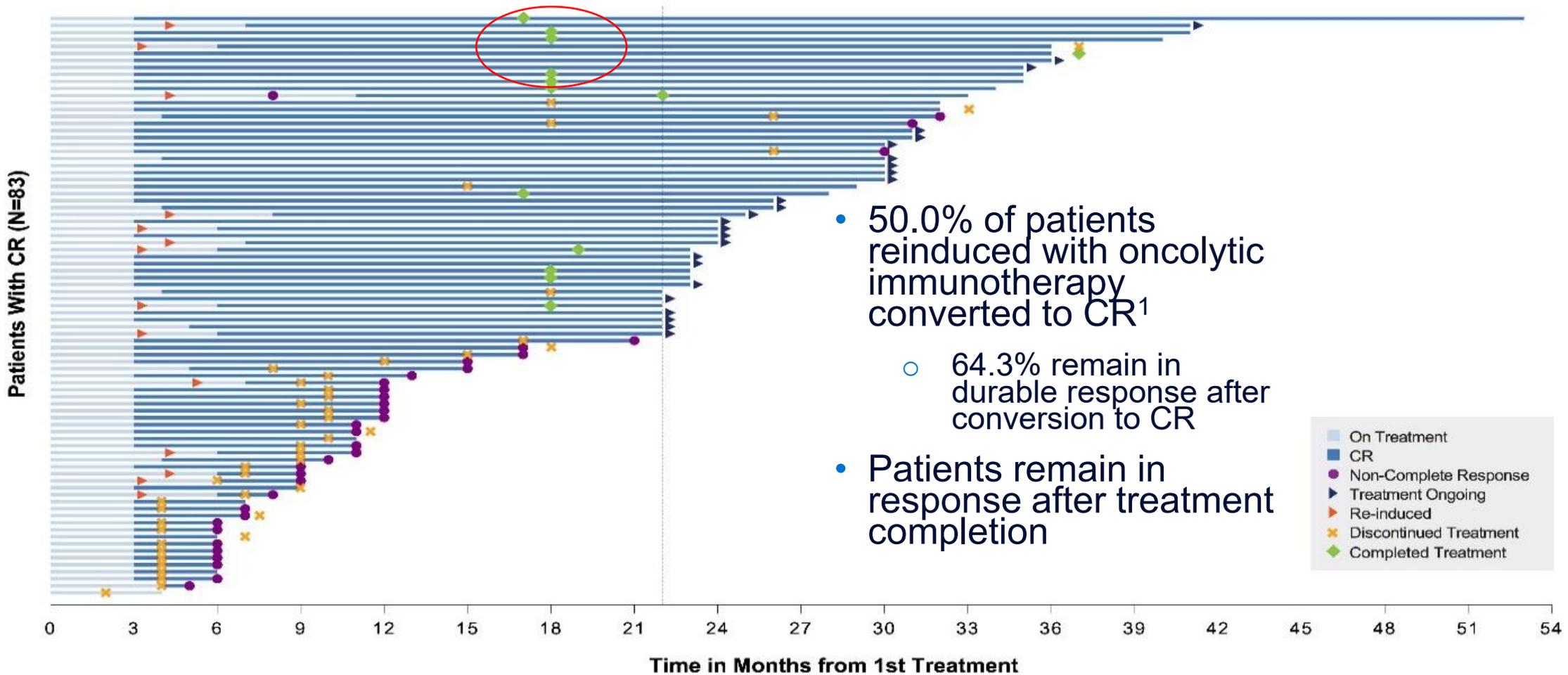
Efficacy data cutoff as of 23JUN2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance.
 *CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy. In addition, all patients at 12-month timepoint undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR and detect potential occult disease in the bladder.
 Analysis based on both landmark CR rate assessed in clinical trial and CR by Kaplan-Meier estimate.



Cretostimogene Demonstrates Durable Responses in HR BCG-UR NMIBC



Sustained Responses Observed over 45 Months

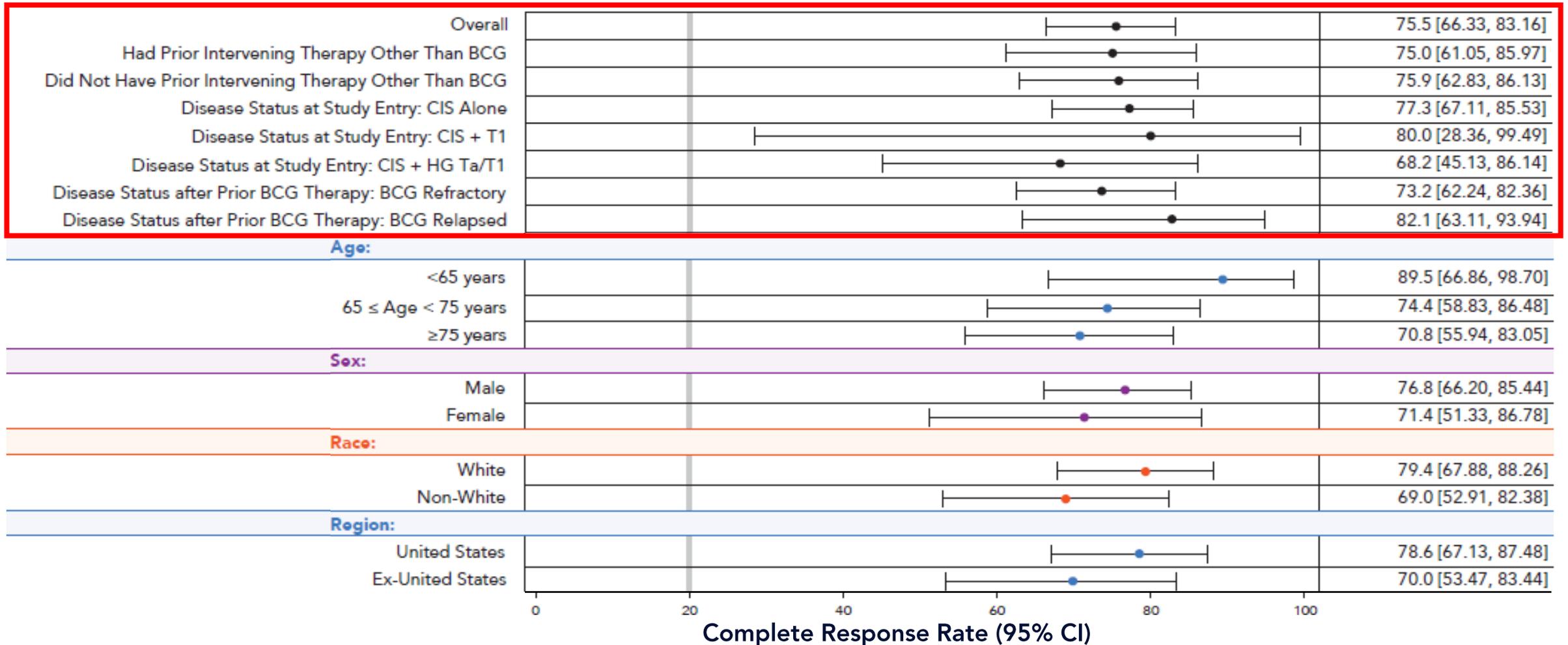


Efficacy data cutoff as of 23JUN2025.

¹ Per 2018 FDA Guidance Document on BCG-Unresponsive NMIBC (page 6), sponsors should consider and discuss with the Agency a patient's disease history, type of disease present at 3 months, and the mechanism of action of the investigational drug regarding patients with CIS who do not achieve a CR at their 3-month assessments.



High CR Rate Consistent Across Patient Subgroups, Including Patients Treated with Prior Chemotherapy



Favorable & Well-Tolerated 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 > 10% patients | | |
| Bladder Spasm | 28 (25.0%) | 0 (0) |
| Pollakiuria | 25 (22.3%) | 0 (0) |
| Urgency | 23 (20.5%) | 0 (0) |
| Dysuria | 21 (18.8%) | 0 (0) |
| Hematuria | 15 (13.4%) | 0 (0) |

¹Treatment-related SAEs were noninfective cystitis (Grade 2) and clot retention (Grade 2).
Unrelated AE leading to treatment discontinuation was Hematuria (Grade 2).

- Most AEs were Grade 1-2
- **0% Grade ≥ 3 TRAEs or deaths**
- **Median time to TRAE resolution: 1 day**
- **No treatment related discontinuations**
- 1.8% (n=2) had serious treatment-related AEs (Grade 2)¹
- 97.3% received all protocol defined treatments



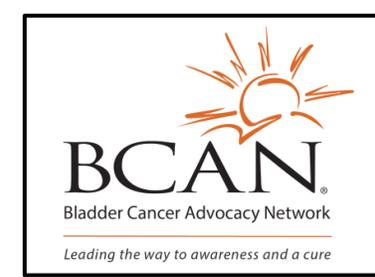
Key Takeaways

- Cretostimogene grenadenorepvec provides **compelling CR rate (75.5%)**
- **Durable responses**
 - Median DoR not reached but exceeds 27 months
 - 90% of 12-month responders sustained durable outcomes at Year 2
- **Very well-tolerated regimen**
 - No grade 3+ TRAE or discontinuations
 - 97.3% completed all protocol defined treatments
- Easily fits and scalable within existing clinic workflow; administered by MAs & RNs
- Future and ongoing clinical trials evaluating cretostimogene monotherapy, and rational combinations, as backbone therapy



Thank You

All Bladder Cancer Patients and Their Families Key Investigators, Study Coordinators, Nurses



| | |
|---------------------------------|---|
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