

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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Dana-Farber
Cancer Institute



Mass General Brigham

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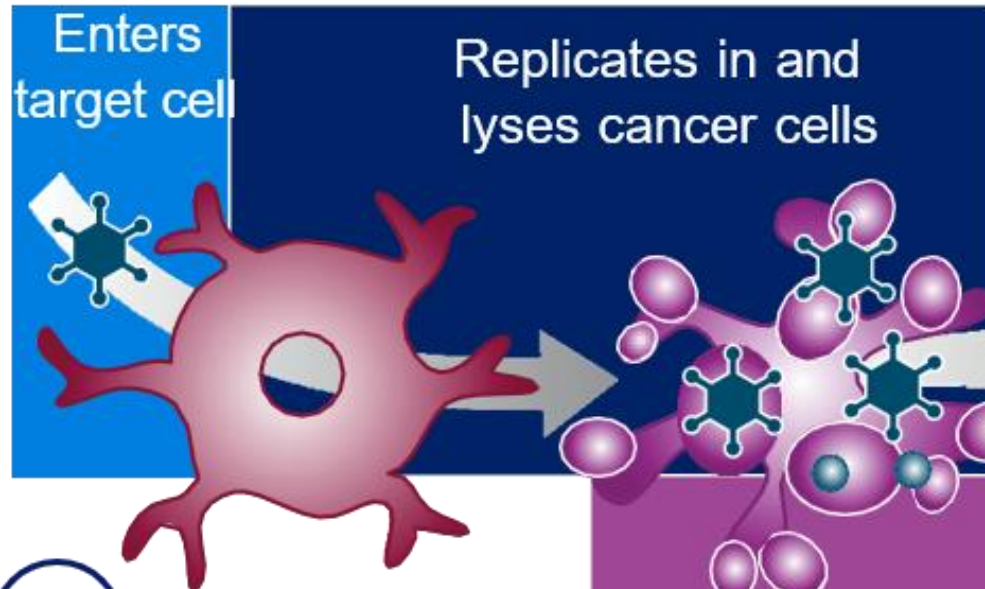


Disclosures

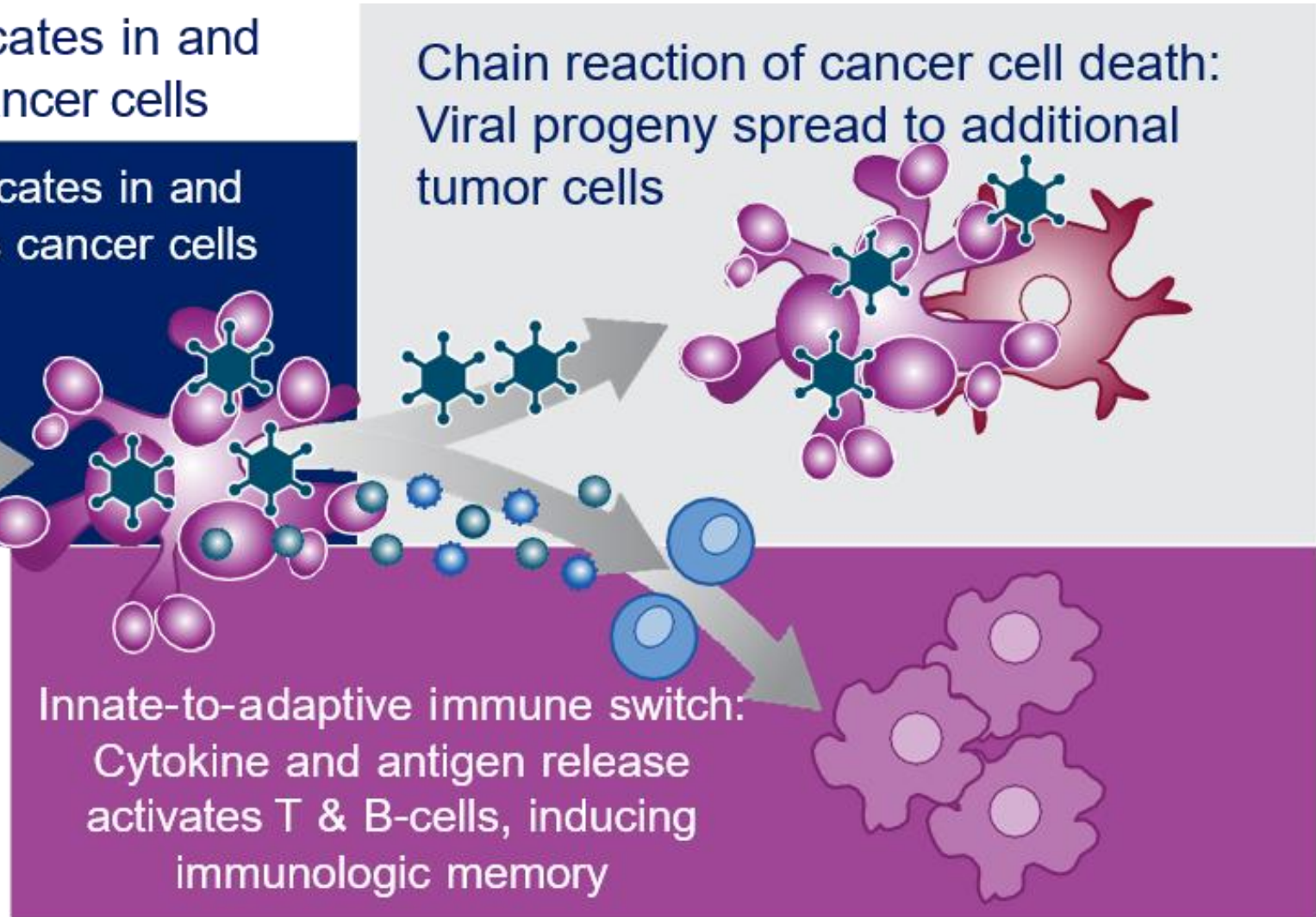
- Clinical trial investigator: CG Oncology, Inc.

Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action

- 1 Selectively replicates in and lyses bladder cancer cells



- 2 Simultaneously amplifies anti-tumor immune response





BOND-003 COHORT C: Phase 3 Cretostimogene Monotherapy for High-Risk BCG-Unresponsive NMIBC with CIS

THE LANCET Oncology

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 INDUCTION ²
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
- CFS
- Safety

BCG: Bacillus Calmette-Guérin; CFS: cystectomy-free survival; CIS: carcinoma in situ; CR: complete response; DoR: duration of response; HR: high risk; IVE: intravesical; NMIBC: non-muscle invasive bladder cancer; PFS: progression-free survival; RFS: recurrence-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.

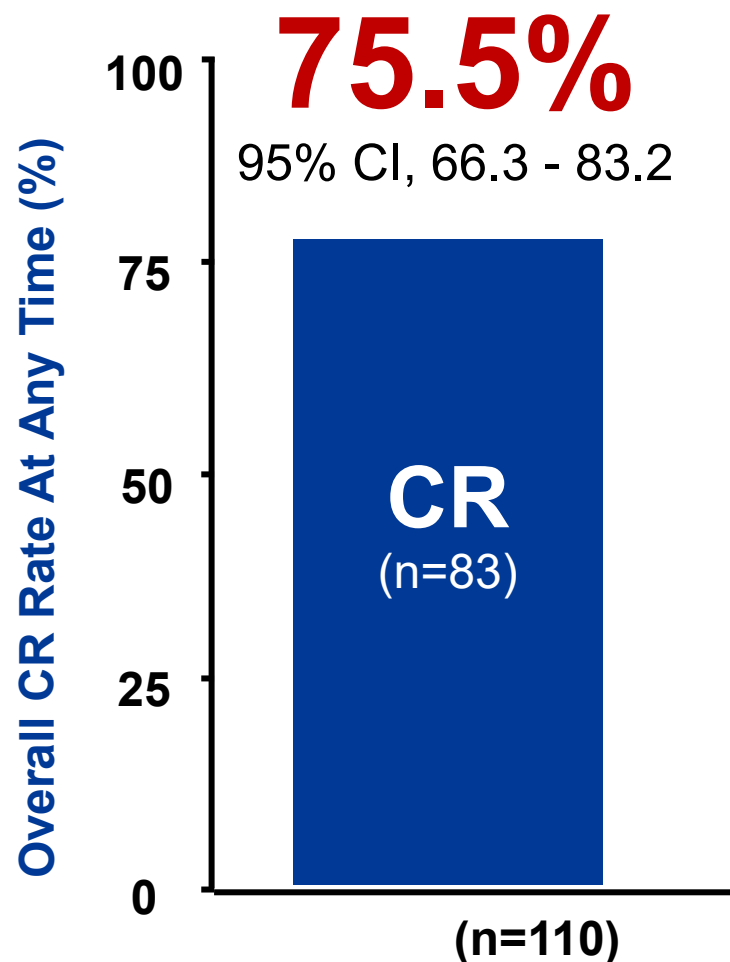


Patient Demographics & Baseline Characteristics

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, incl. systemic IO (6%)

Consistent, Compelling Efficacy & Safety



CR Landmark	CR Rate, % (95% CI)	CR by K-M Est (95% CI)
12-month	46.4% (36.8, 56.1) <i>51/110 patients</i>	50.7% (40.9, 59.8)
24-month ¹	41.8% (32.5, 51.6) <i>46/110 patients</i>	42.4% (32.7, 51.7)

- Median DOR: 27.9 mos (95% CI 14.3-NE), ongoing
- 96.4% (106/110) free from progression to $\geq$ T2 disease
- 90% of patients in CR at 12 mos projected to remain in CR at 24 mos

Efficacy data cutoff as of 23JUN2025.

BCG: Bacillus Calmette-Guérin; CI: confidence interval; CR: complete response; DoR: duration of response;; IVE: intravesical;

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.

Consistent, Favorable and Well-Tolerated Safety Profile

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade $\geq$ 3
Patients with $\geq$ 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)

- Most AEs were Grade 1-2
- **0% Grade $\geq$ 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

Safety data cutoff as of 23JUN2025

AE: adverse event; SAE: serious adverse event; TRAE: treatment-related adverse event

¹Treatment-related SAEs were noninfective cystitis (Grade 2) and clot retention (Grade 2).

Unrelated AE leading to treatment discontinuation was Hematuria (Grade 2).

Key Takeaways



- Cretostimogene grenadenorepvec provides compelling CR rate (75.5%)
- **Durable responses**
 - Median DoR not reached but exceeds 28 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
- Future and ongoing clinical trials evaluating cretostimogene monotherapy, and rational combinations, as backbone therapy



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THANK YOU

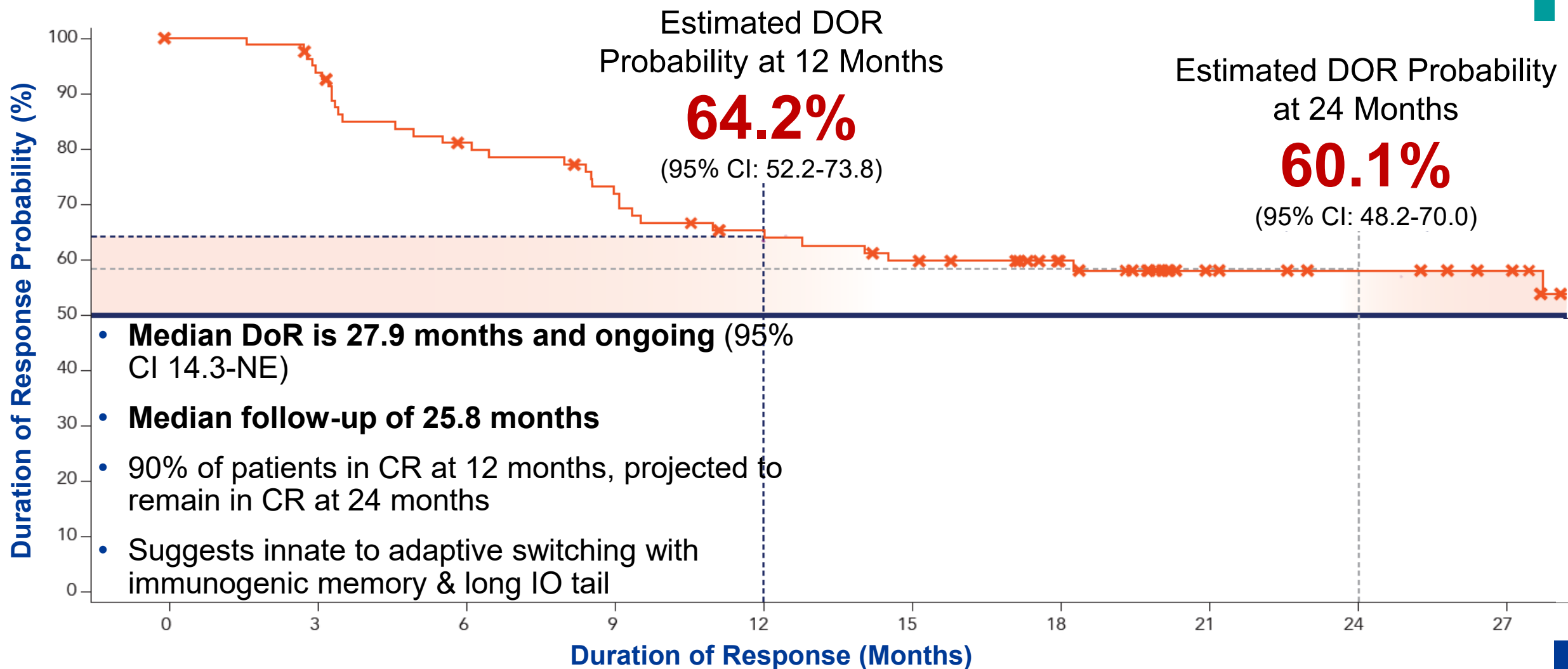
All Bladder Cancer Patients and Their Families Key Investigators, Study Coordinators, Nurses

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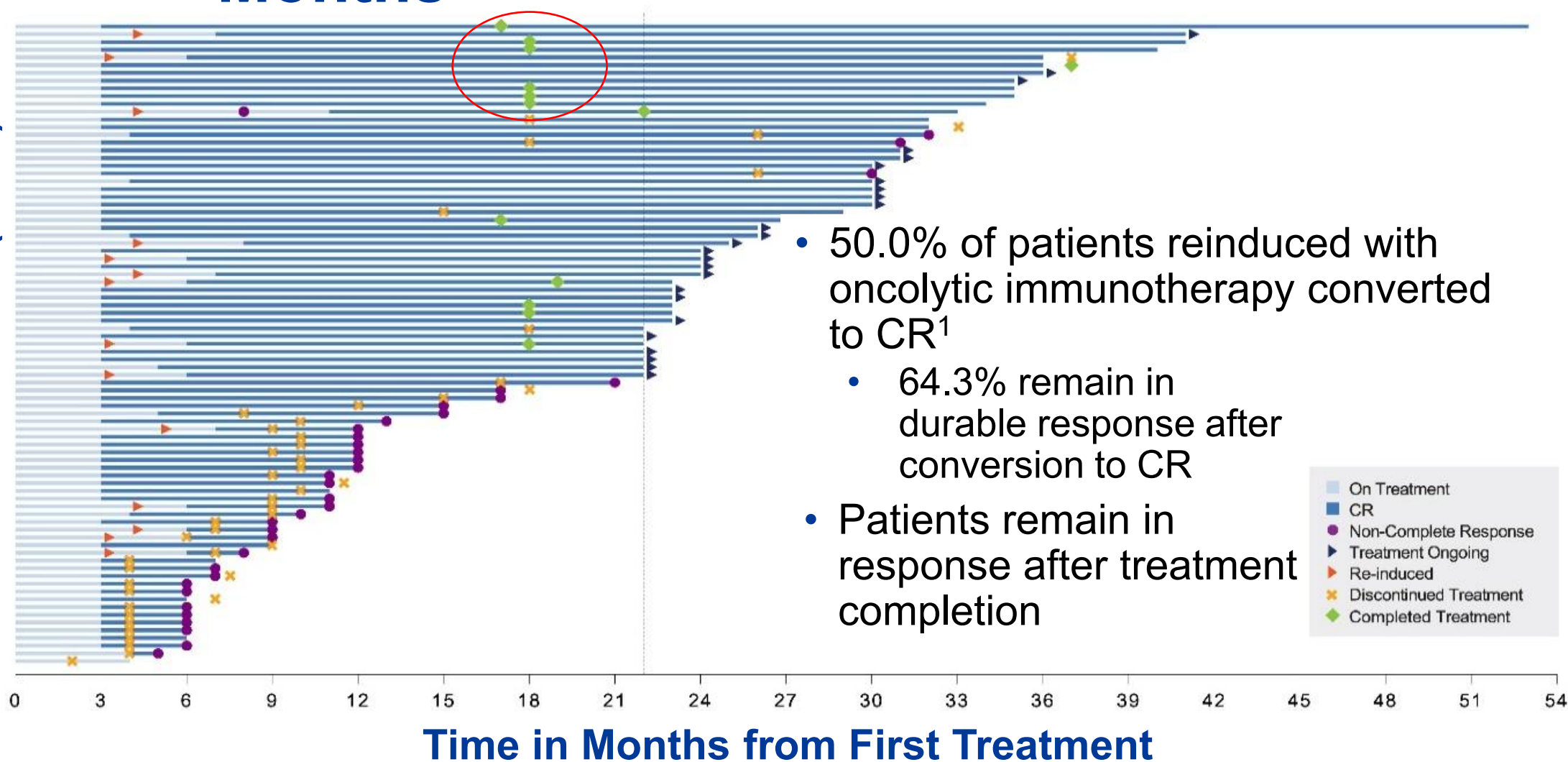


Cretostimogene Demonstrates Durable Responses in HR BCG-UR NMIBC



Sustained Responses Observed over 45 Months

Patients with CR (N=83)



- 50.0% of patients reinduced with oncolytic immunotherapy converted to CR¹
 - 64.3% remain in durable response after conversion to CR
- Patients remain in response after treatment completion

BCG: Bacillus Calmette-Guérin; CIS: carcinoma in situ; CR: complete response; FDA: US Food and Drug Administration; NMIBC: non muscle invasive bladder cancer

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

