

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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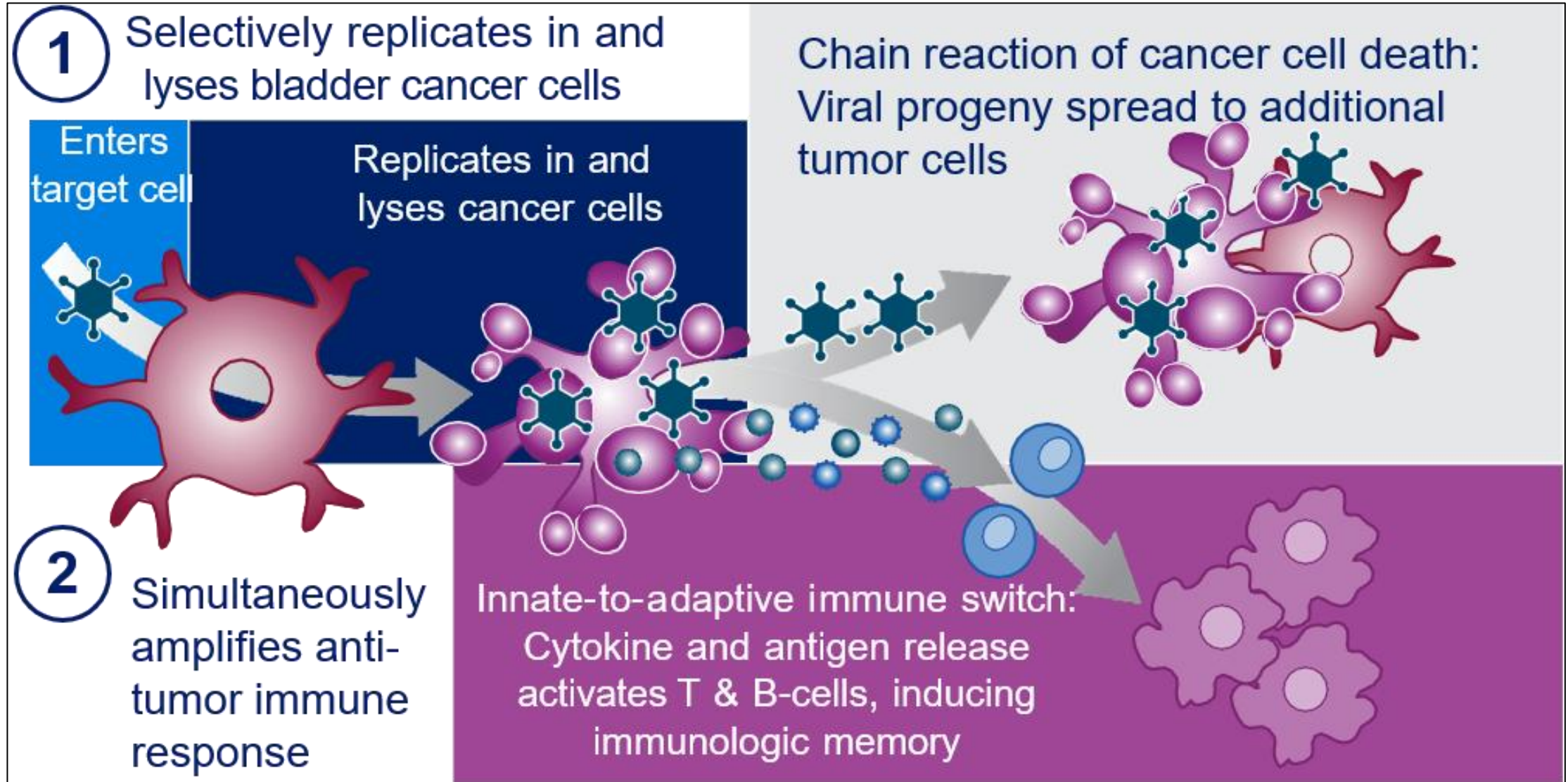


Disclosures

- None related to CG Oncology
- Intuitive surgical



Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action



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Intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer with carcinoma in situ (BOND-003 Cohort C): a single-arm, phase 3 trial

Mark D Tyson II, Jong-Kil Nam, Shreyas S Joshi, Edward M Uchio, Seung Il Jung, Trinity J Bivalacqua, Gary D Steinberg, Neal D Shore, James M Burke, Hiroshi Kitamura, Ben Tran, Roger Li

Tyson, M.D., Nam, J.K., Joshi, S.S., Uchio, E.M., Jung, S.I., Bivalacqua, T.J., Steinberg, G.D., Shore, N.D., Burke, J.M., Kitamura, H. and Tran, B., and Li, R. (2026). Intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer with carcinoma in situ (BOND-003 Cohort C): a single-arm, phase 3 trial. The Lancet Oncology, 27(8), 983-993. [https://doi.org/10.1016/S1470-2045\(26\)00194-4](https://doi.org/10.1016/S1470-2045(26)00194-4)





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

**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](https://clinicaltrials.gov/ct2/show/study/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.

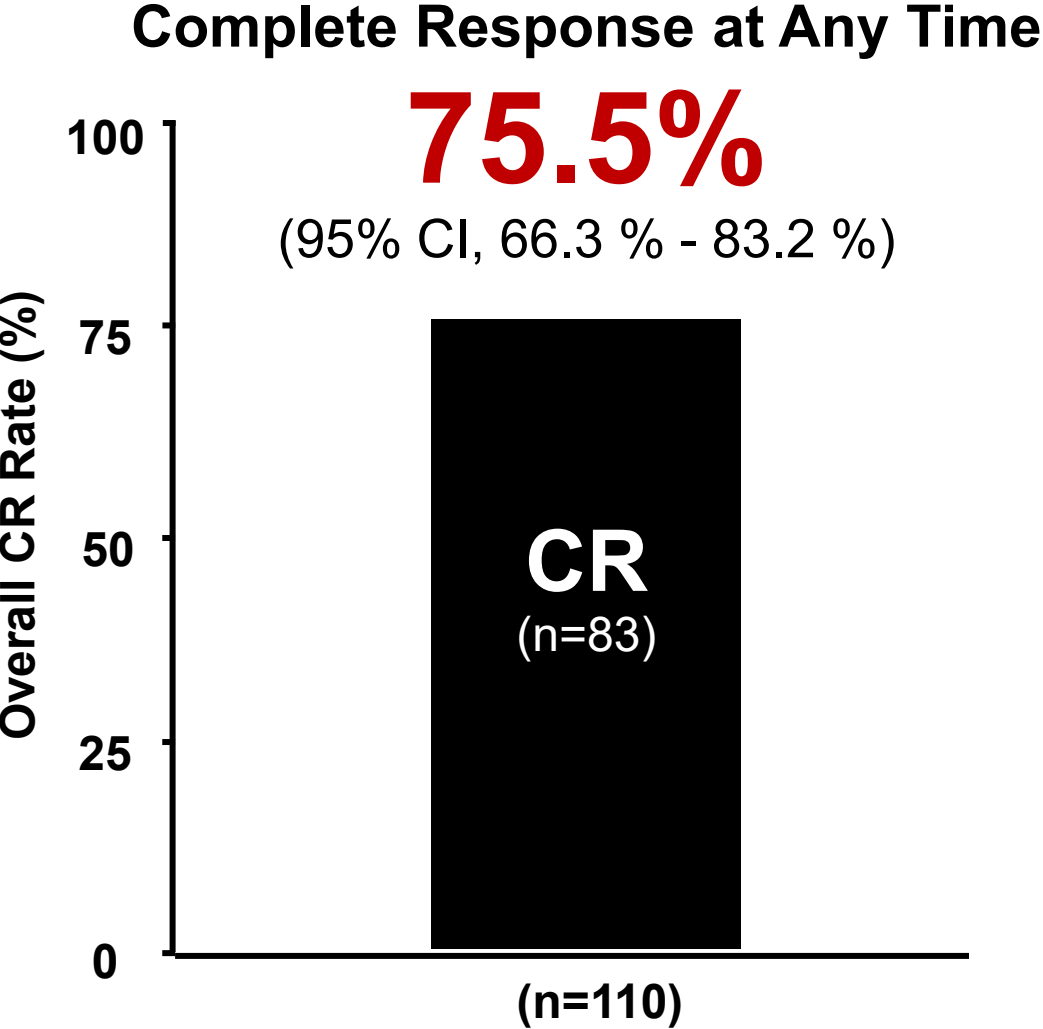
² Second induction course of weekly x 6 for non-responders at month 3.

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 & 24-Month Durability Data

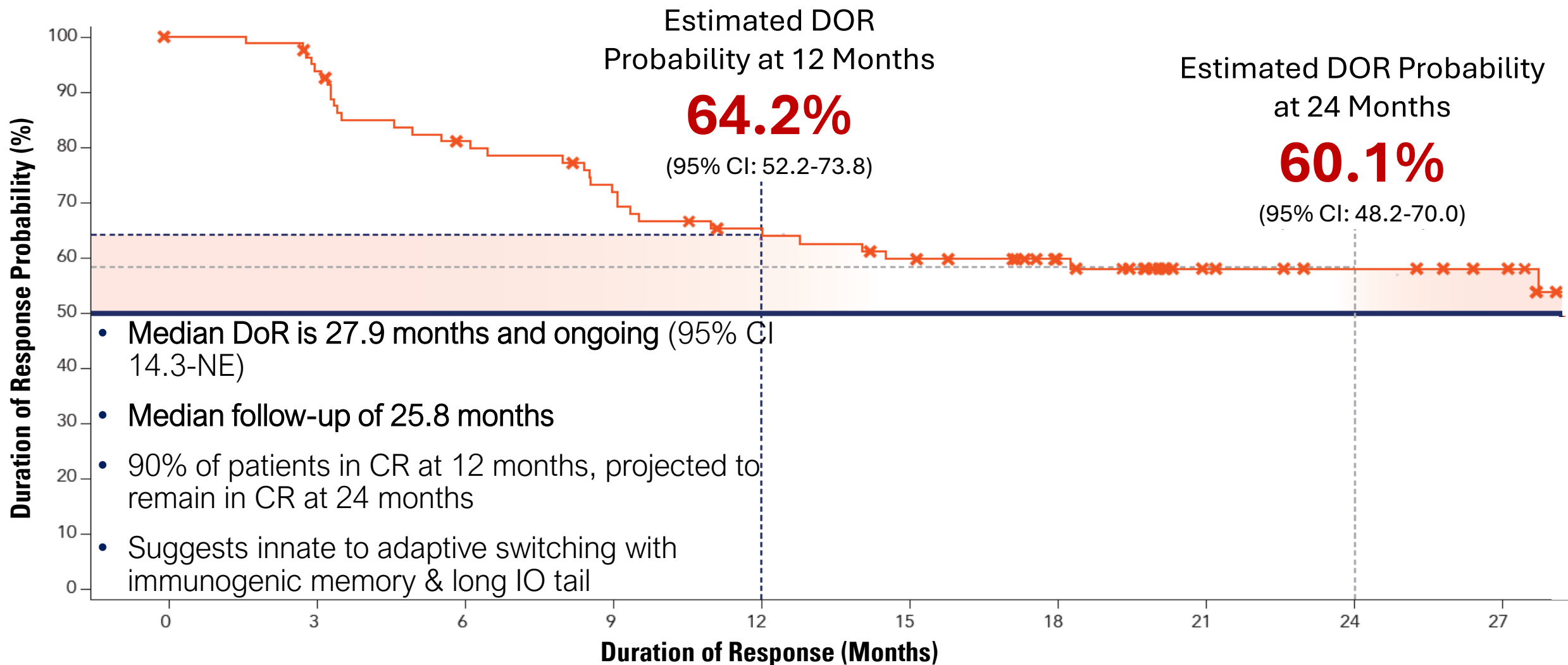


CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	46.4% (36.8, 56.1) <i>51 out of 110 patients</i>	50.7% (40.9, 59.8)
24-month ¹	41.8% (32.5, 51.6) <i>46 out of 110 patients</i>	42.4% (32.7, 51.7)

- Median DOR: 27.9 months (95% CI 14.3-NE%) and ongoing
- 96.4% (106/110) free from progression to $\geq$ T2 disease
- All CRs centrally confirmed*
 - Local : Central concordance: 97.1% of assessments

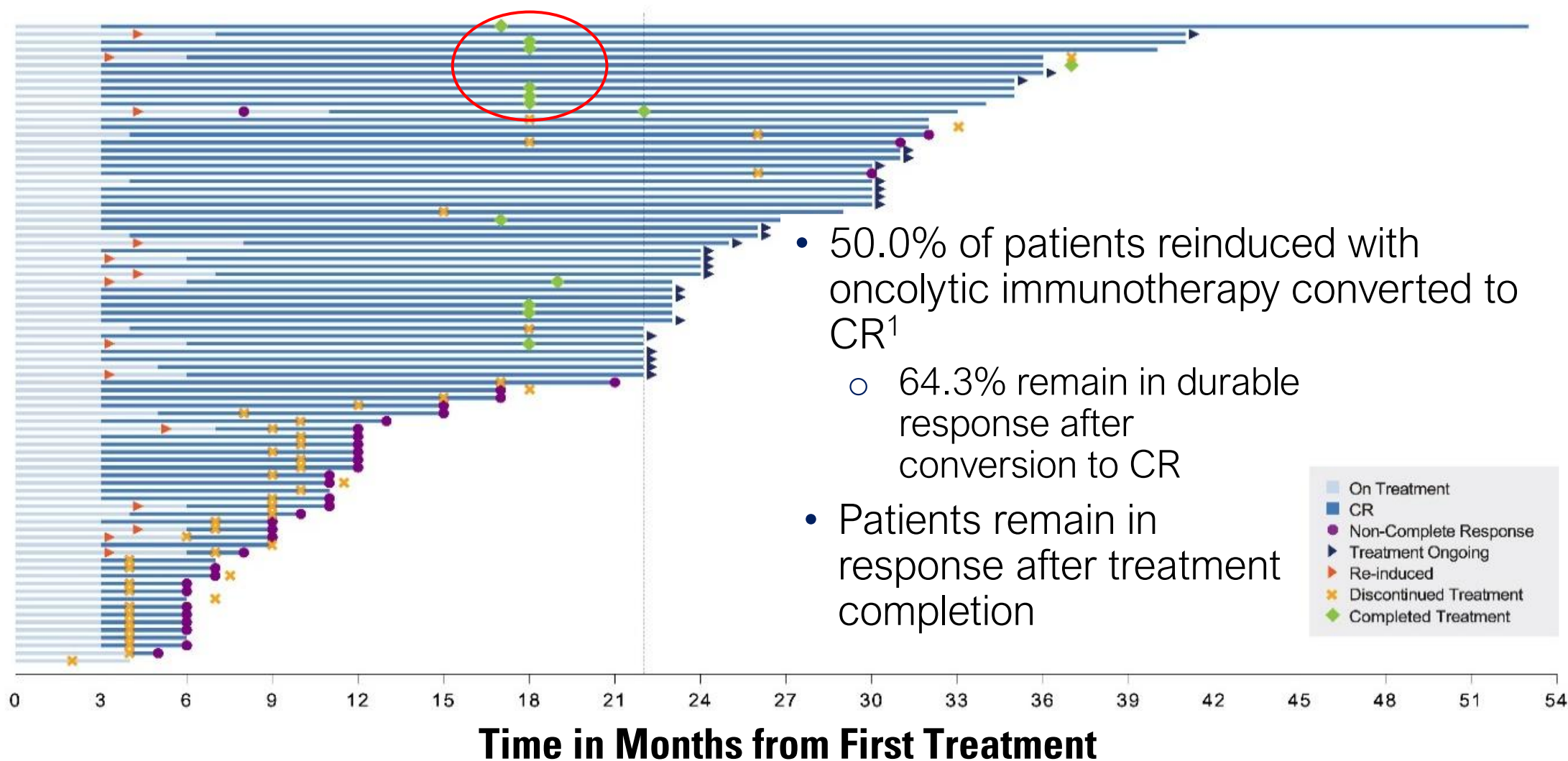
Efficacy data cutoff as of 23JUN2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance.
*CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy. In addition, all 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



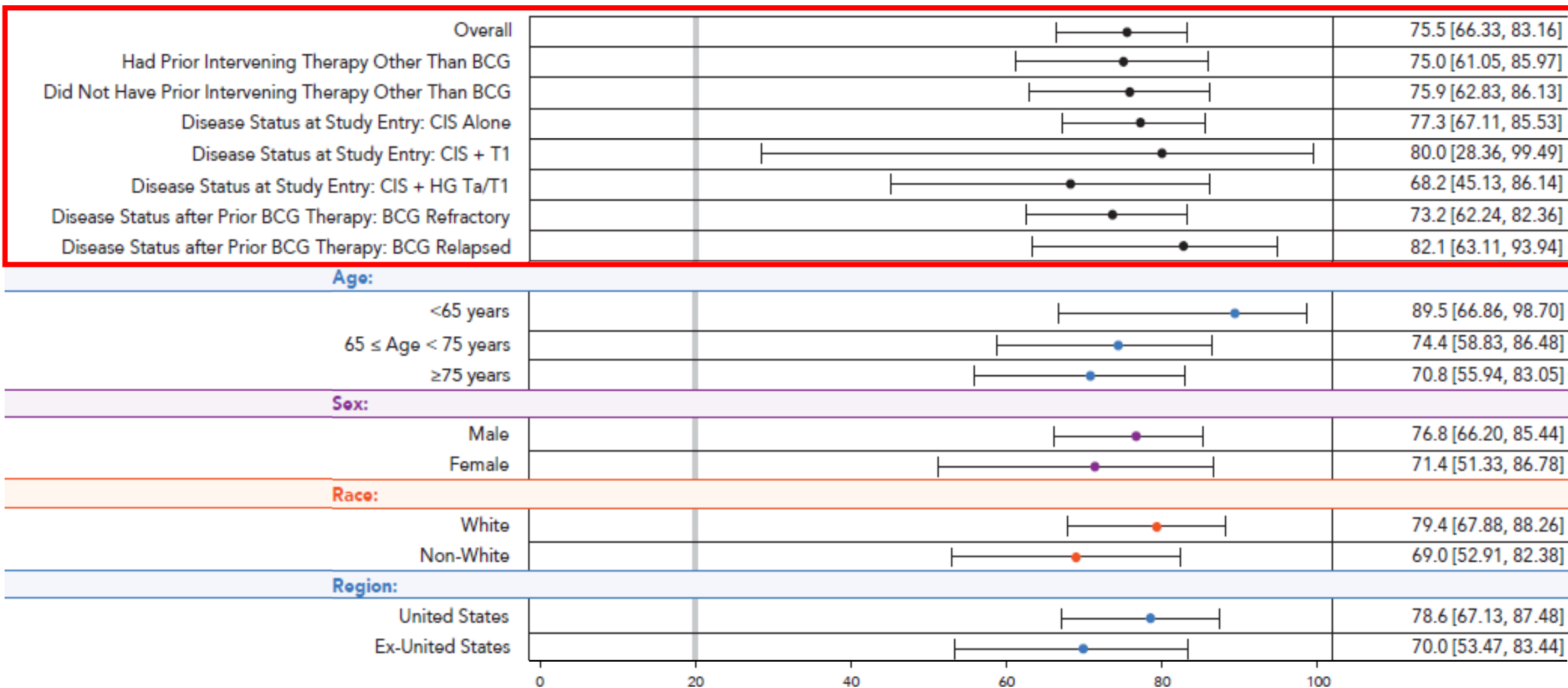
Sustained Responses Observed over 45 Months

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

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



Consistent, Favorable and 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)

- 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
- Feasible and scalable within existing clinic workflow; administered by MAs & RNs
- Future and ongoing clinical trials evaluating cretostimogene monotherapy, and rational combinations, as backbone therapy





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THANK YOU

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