Encore Results: BOND-003 Cohort C- A Phase 3, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for BCG-Unresponsive High-Risk Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ

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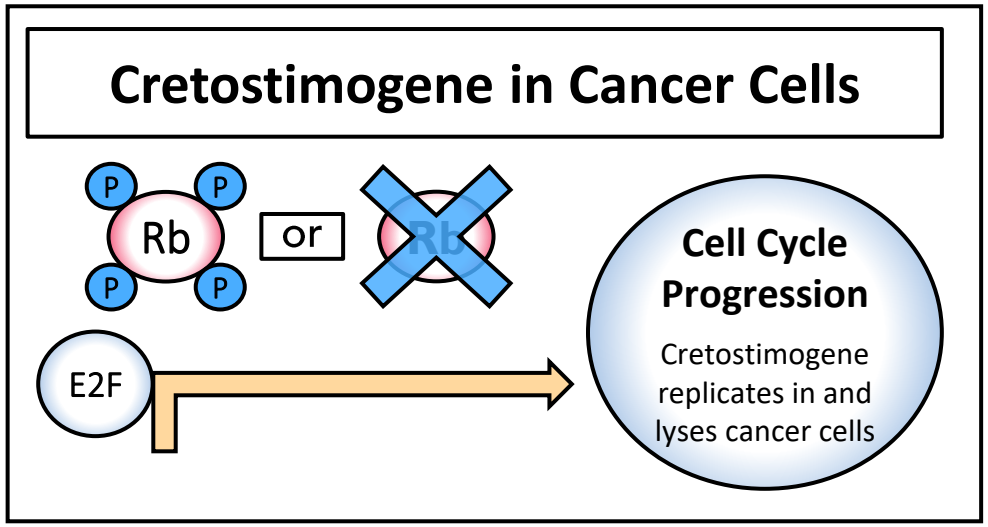
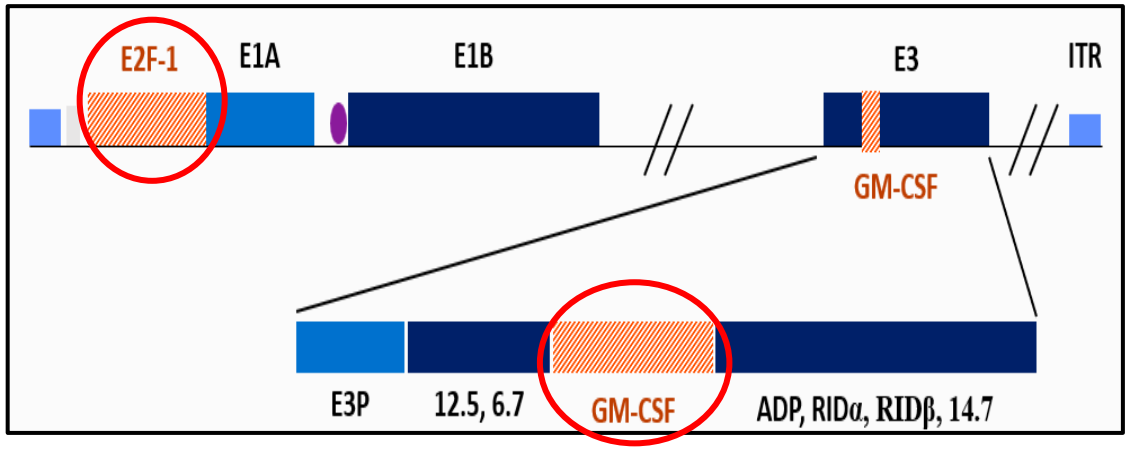
Disclosures

- CG Oncology- No Conflicts of Interest

What is Cretostimogene Grenadenorepvec

- Conditionally replicating adenovirus
  - Highly immunogenic
  - Insertion of human E2F-1 promoter
    - Selective for RB-E2F pathway alterations
  - Encodes GM-CSF transgene
- Binds to Coxsackie Adenovirus Receptor (CAR)
  - Expression in all stages of bladder cancer
- Oncolytic immunotherapy
  - Viral replication results in tumor lysis
  - Stimulation of immune response





CG Oncology proprietary illustration. Sachs, et al. *Urology* 2002
Burke, et al *J Urol* 2012

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

BOND-003 COHORT C

FDA Fast Track Designation

FDA Breakthrough Therapy Designation

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 assessment

Study Design / Regimen

Induction Course:
Weekly x 6

Second Induction[1]:
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] Second induction course of weekly x 6 for non-responders at month 3. [2] All patients required to undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR

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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: Number of Prior Instillations		
Median (Range)	12 (7 – 66)	
High-Risk NMIBC T-Stage at Study Entry		
CIS with HG Ta/T1	22	19.6
CIS alone	90	80.4

- Majority of patients are:
  - Male (74%)
  - White (61%)
  - > 65 years (83%)
- 63.4% of patients in US
- Highly pre-treated population
  - Prior intravesical chemotherapy
  - Systemic immunotherapy

Efficacy data cutoff as of 30SEPT2024

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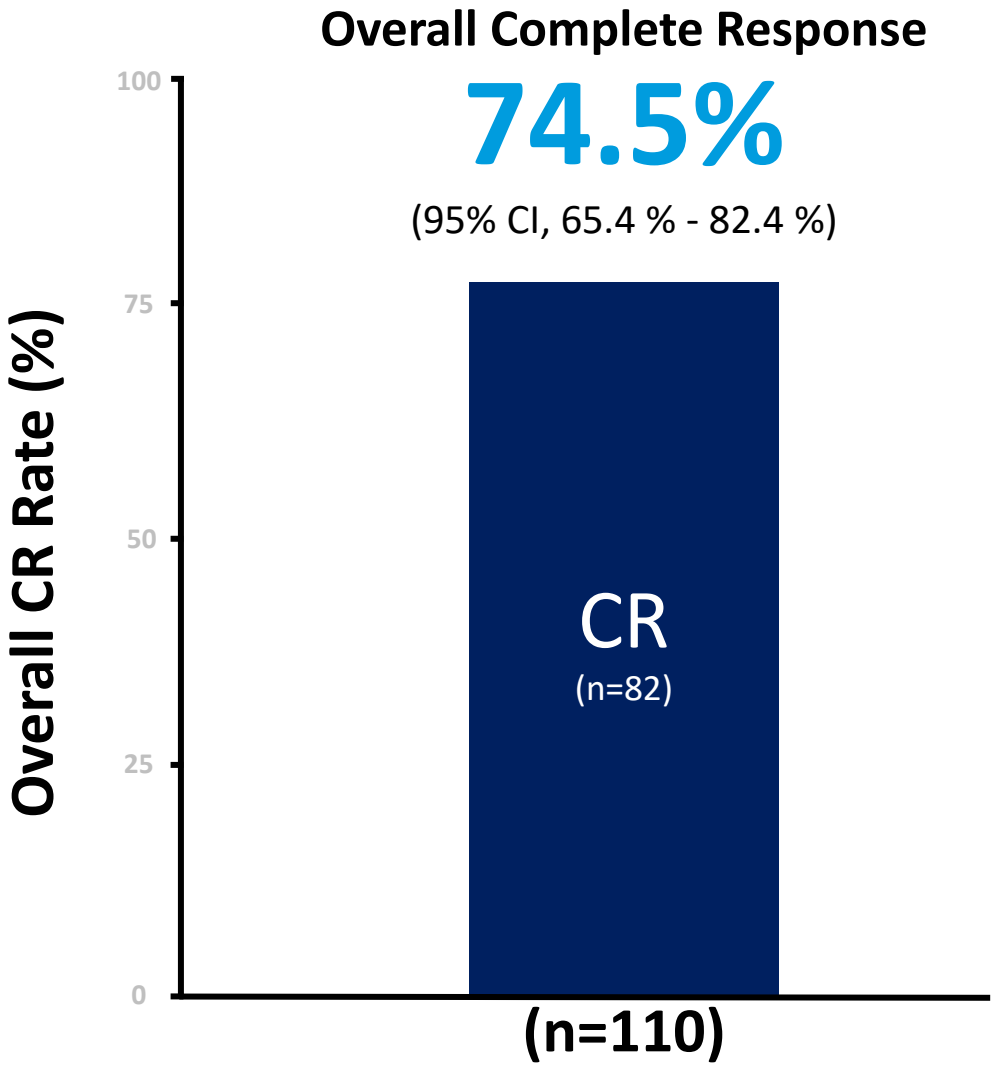
Compelling Efficacy & Durability Data



CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46%** (36.9, 56.1)[1] *51 out of 110 patients*	**50%** (39.6, 58.9)
24-month	*There are 25 confirmed CRs that have reached 24-month timepoint and beyond*[2]	**41%** (30.4, 50.8)

Analysis based on both landmark CR rate assessed in clinical trial and CR by Kaplan-Meier estimate.

- 97.3% free from progression to MIBC at 12 months
- 90.0% Cystectomy-Free Survival at 12 months
- CR rate consistent across patient subgroups
- All complete responses are centrally confirmed[3]

Efficacy data cutoff as of 30SEP2024. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance.
[1] Based on centrally confirmed assessments as of 30SEPT2024 efficacy cutoff including two additional responders centrally confirmed past the data cutoff.
[2] Based on centrally confirmed responders who have reached 24-month evaluation timepoint
[3] A 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.

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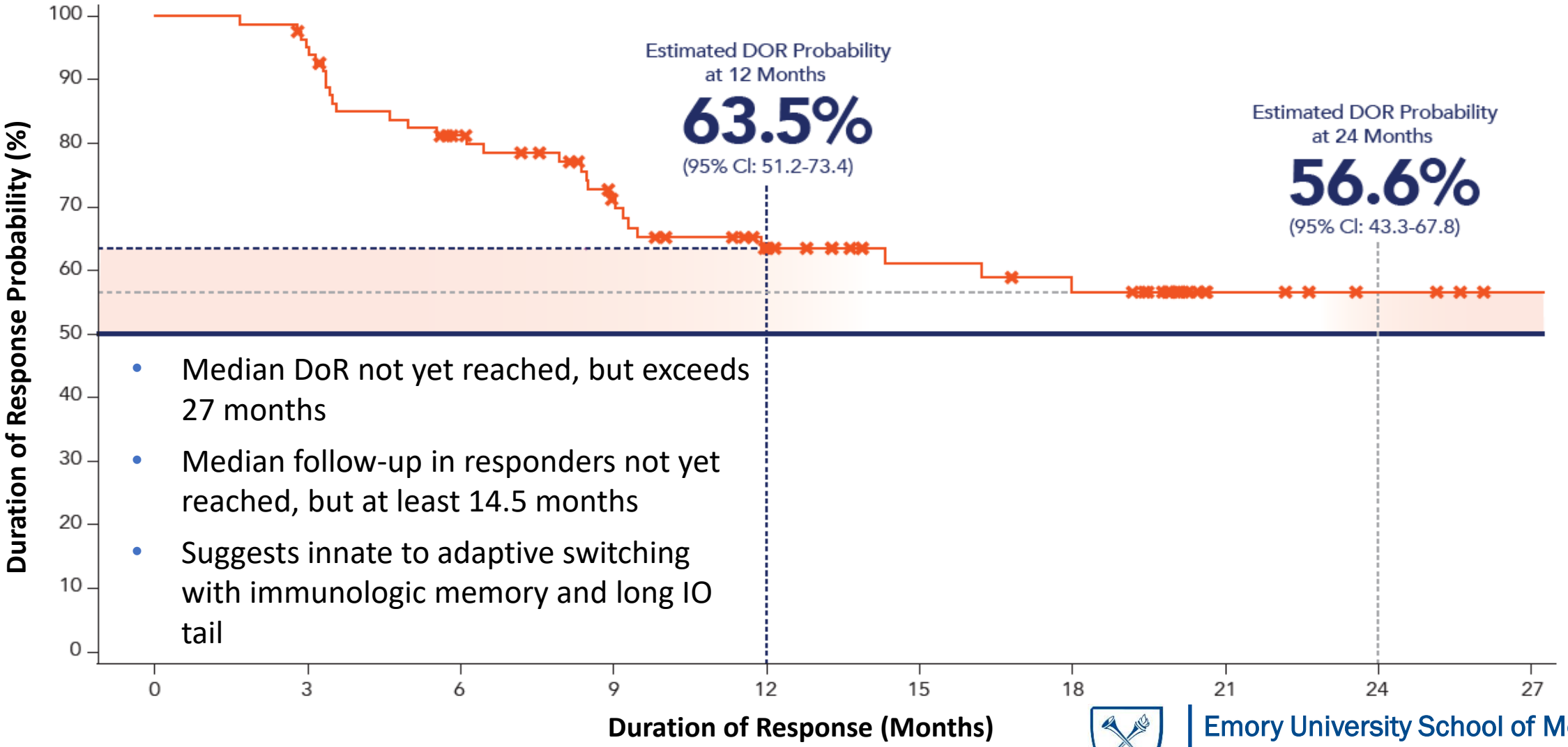
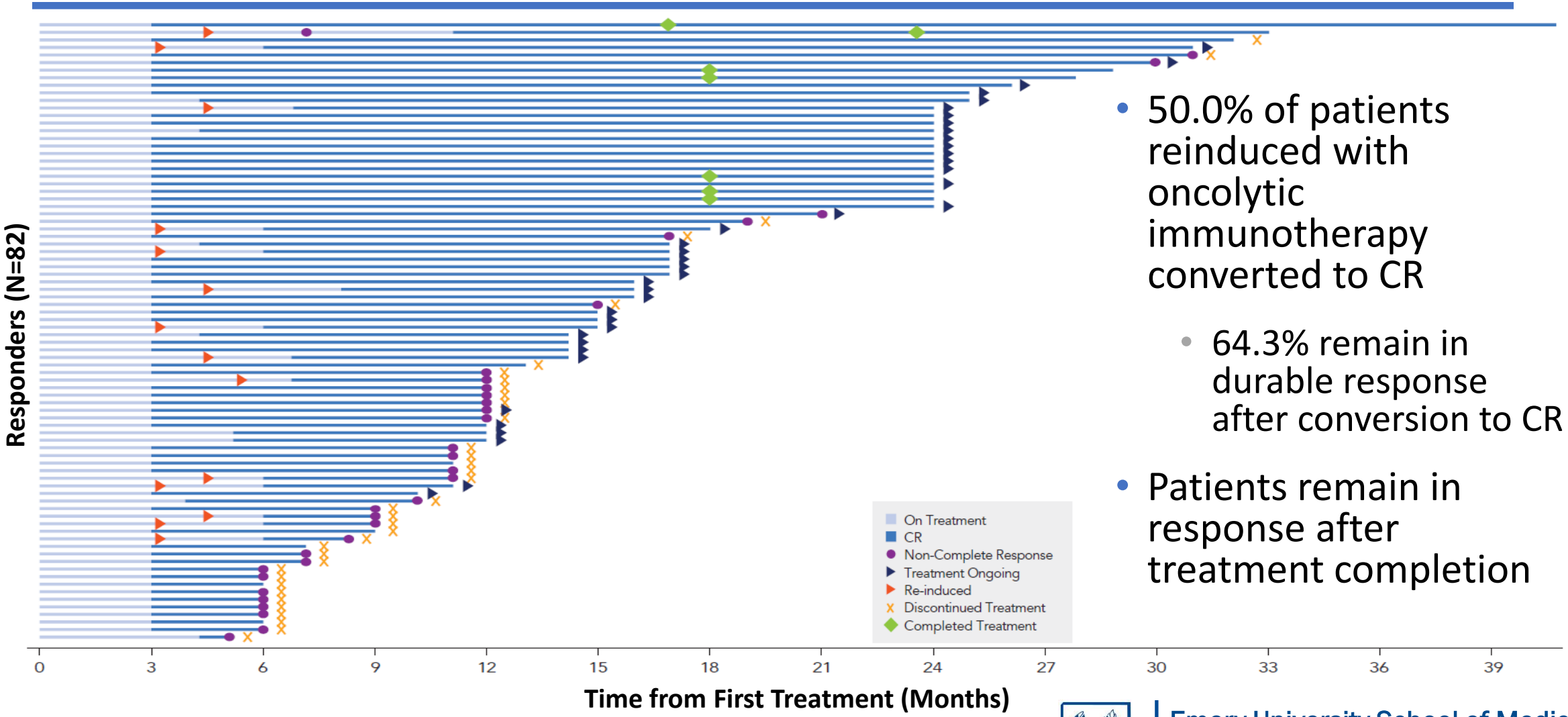
Cretostimogene Demonstrates Sustained Duration of Response in HR BCG-UR NMIBC



- Median DoR not yet reached, but exceeds 27 months
- Median follow-up in responders not yet reached, but at least 14.5 months
- Suggests innate to adaptive switching with immunologic memory and long IO tail

Efficacy data cutoff as of 30SEPT2024

Sustained Responses Observed over 30 Months



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

Efficacy data cutoff as of September 30, 2024.

[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.

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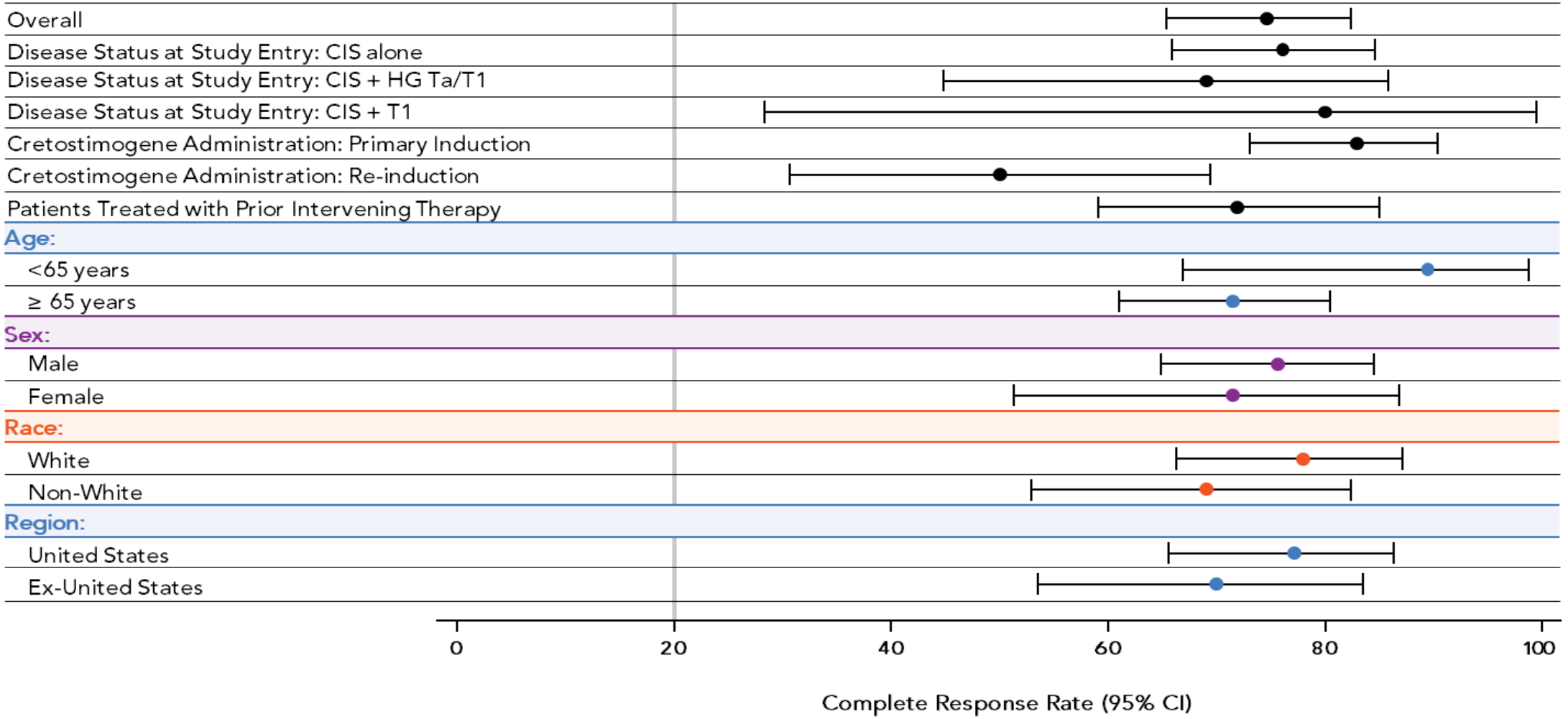
CR Rate Consistent Among Patient Subgroups



Favorable & Well-Tolerated Safety Profile

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade ≥ 3
Patients with ≥ 1 TRAE	72 (64.3%)	0 (0)
Treatment-Related AE reported in > 10% patients		
Bladder Spasm	28 (25.0%)	0 (0)
Pollakiuria	23 (20.5%)	0 (0)
Urgency	22 (19.6%)	0 (0)
Dysuria	17 (15.2%)	0 (0)
Hematuria	15 (13.4%)	0 (0)

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

- 0% Grade ≥ 3 treatment-related AEs or deaths reported
- Most AEs were Grade 1-2
- No treatment related discontinuations
- 97.3% completed all protocol defined treatments
- 1.8% (n=2) had serious treatment-related AEs (Grade 2)[1]

Safety data cutoff as of 30SEPT2024

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Key Takeaways

- Cretostimogene grenadenorepvec provides **compelling CR rate** (**74.5%**)
- **Durable responses**
  - Median DoR not reached but exceeds 27 months
  - 63.5% (95% CI 51.2%- 73.4%) remain in response at 12 months
- **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

BCAN
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Attacking Bladder Cancer for a Better Tomorrow™

Thank You

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

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