MAYO CLINIC

BOND-003 Cohort P: A Multi-national, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High-Risk, Papillary-Only, BCG-Unresponsive NMIBC

Mark Tyson, M.D., MPH

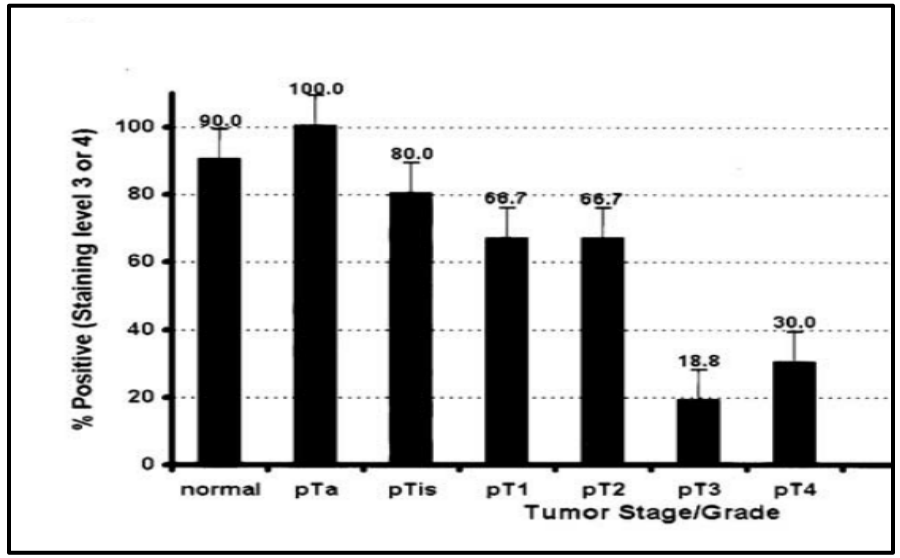
Presented at AUA Annual Meeting; April 28, 2025; Las Vegas, NV

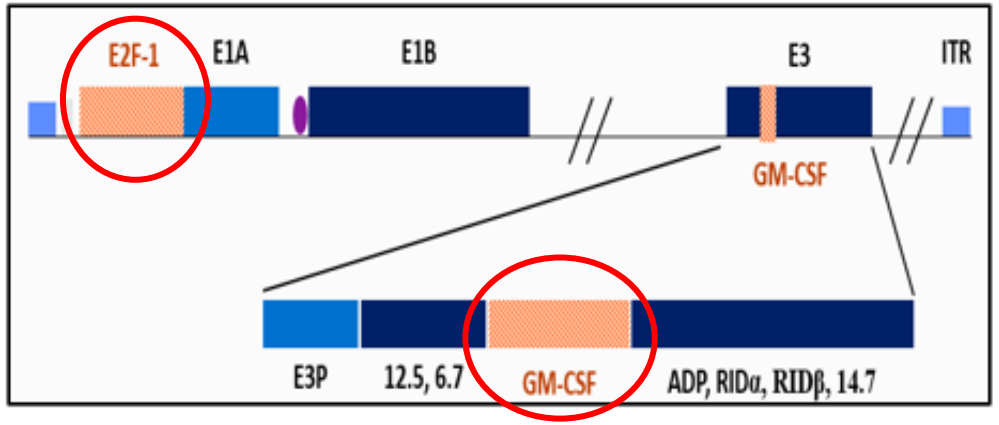
Disclosures

- CG Oncology- No Conflicts of Interest

What is Cretostimogene Grenadenorepvec?

- **Oncolytic immunotherapy with dual MOA**
- Binds to Coxsackie Adenovirus Receptor (CAR) & integrin αvβ5
  - Robust expression in all stages of bladder cancer
- Conditionally replicating, highly immunogenic adenovirus
  - Under regulation of the **human E2F-1 promoter**
    - Selective for RB-E2F pathway alterations
  - Encodes **GM-CSF transgene**



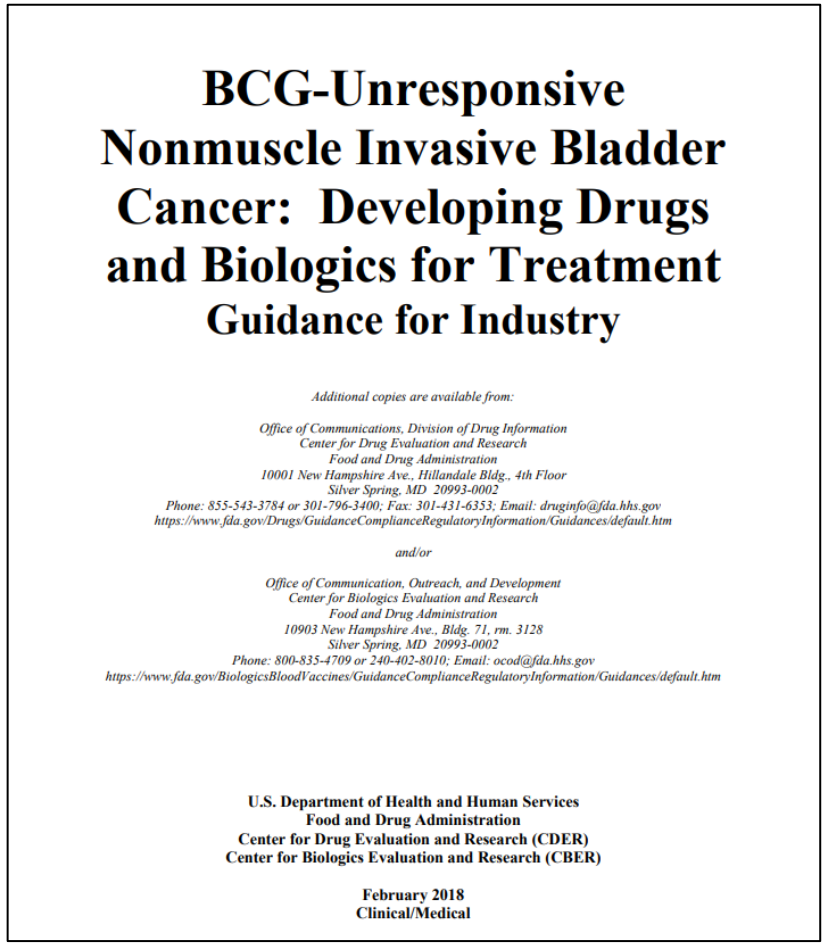


CG Oncology proprietary illustration. Sachs, et al. Urology 2002
Burke, et al J Urol 2012

BCG-UR NMIBC Study Design Considerations

Recommendations from 2018/2024 FDA Guidance

- Single-arm trials appropriate for BCG-UR NMIBC studies
- Primary efficacy endpoints:
  - CR in patients with CIS
  - Time-to-event endpoint for patients with completely resected Ta/T1 disease



BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

and/or

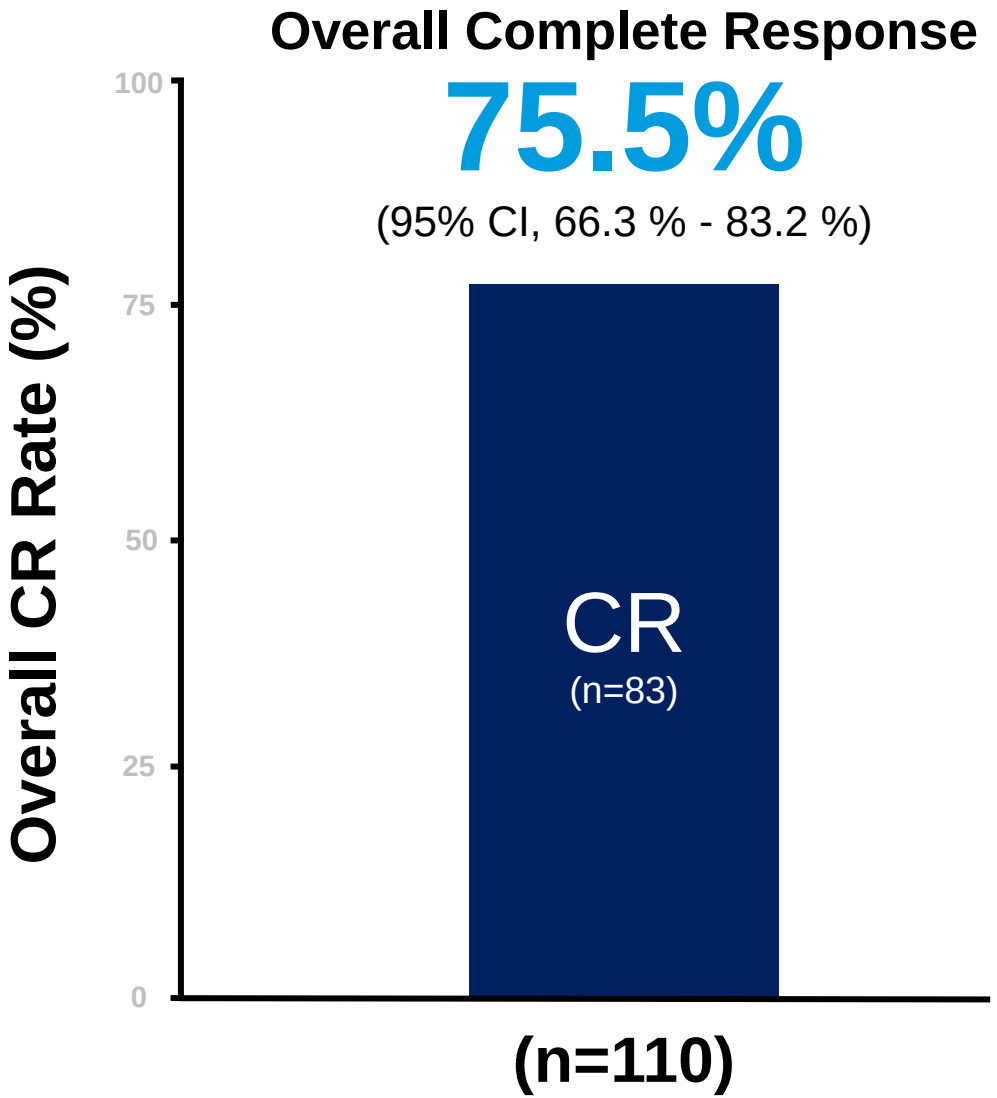
Office of Communication, Outreach, and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, rm. 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010; Email: ocod@fda.hhs.gov
https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2018
Clinical/Medical

CIS +/- Ta/T1- Carcinoma in situ, with or without Ta/T1; CR- Complete Response; NMIBC- Non-Muscle Invasive Bladder Cancer

Consistent and Compelling CR & Durability Data

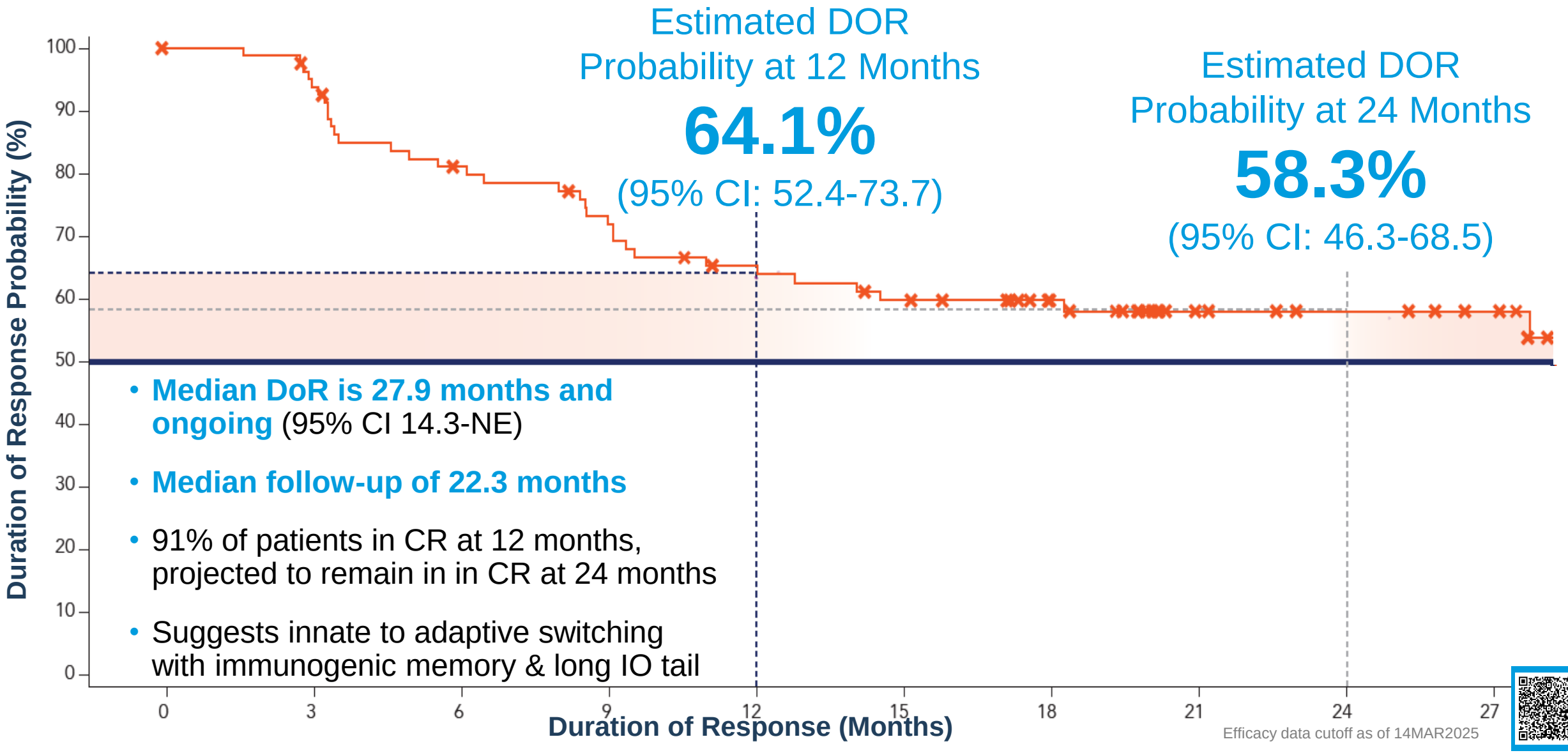


CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46.4%** (36.9, 56.1) *51 out of 110 patients*	**50.7%** (40.9, 59.8)
24-month	**33.7%** (24.8, 43.8) *34 out of 101 evaluable patients, pending 9 ongoing CRs that have yet to reach 24-month assessment*[1]	**42.3%** (32.7, 51.6)

- 97.3% free from progression to MIBC at Month 24
- 84.5% avoided radical cystectomy by Month 24
  - Among RCs, 82.4% (14/17) were T0 or NMIBC
- All Complete Responses are centrally confirmed[2]
  - Local:Central concordance: 96.3% of assessments

Efficacy data cutoff as of 14MAR2025. 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 responders who have reached 24-month evaluation timepoint, data is still accruing.
[2] 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.
Analysis based on both landmark CR rate assessed in clinical trial and CR by Kaplan-Meier estimate.

Cretostimogene Demonstrates Best in Class Duration of Response in HR BCG-UR NMIBC



- **Median DoR is 27.9 months and ongoing** (95% CI 14.3-NE)
- **Median follow-up of 22.3 months**
- 91% of patients in CR at 12 months, projected to remain in in CR at 24 months
- Suggests innate to adaptive switching with immunogenic memory & long IO tail

Efficacy data cutoff as of 14MAR2025

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	24 (21.4%)	0 (0)
Urgency	23 (20.5%)	0 (0)
Dysuria	18 (16.1%)	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).

- 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

Safety data cutoff as of 14MAR2025.

Significant Unmet Need for BCG-UR Papillary NMIBC

- Current FDA approved agents for patients with HR BCG-UR NMIBC **with CIS +/- Ta/T1**[1]
- There is a growing incidence of patients with papillary (Ta/T1) NMIBC[2-3]
- **Current treatments offer modest improvement over FDA benchmark**[4]

DFS/HG-RFS	Pembrolizumab [5]	Nadofaragene [6,7]	N-803+BCG [8]
3 months, % (95% CI)	87.7 (80.7-92.3)	72.9 (58.2-84.7)	Not Reported
6 months, % (95% CI)	53.1 (44.1-61.2)	62.5 (47.4-76.0)	Not Reported
12 months, % (95% CI)	43.5 (34.9-51.9)	43.8 (29.5-58.8)	55.4 (42.0-66.8)
24 months, % (95% CI)	34.9 (26.4-43.4)	33.3 (20.4-48.4)	48.3 (34.5-60.7)

There remains a significant unmet need for clinically effective and well-tolerated bladder-sparing treatment options for the BCG-UR papillary-only NMIBC population

BCG- Bacillus Calmette Guerin; BST- Bladder Sparing Therapy; CIS +/- Ta/T1- Carcinoma in situ, with or without Ta/T1; NMIBC- Non-Muscle Invasive Bladder Cancer

1 Holzbeierlein J et al., AUA/SUO guideline: 2024 amendment.. 2. Nielsen et al 2014. Cancer. 2014 3. Taylor J. Long Term Outcomes of Bladder Sparing Therapy Compared to Upfront Radical Cystectomy in BCG Unresponsive NMIBC in an International Cohort . Presented at: SUO 2023. 4.Rose KM, et al. SIUJ. 2022;3(5):333-339 5. Necchi A, et al. Lancet Oncology. 2024; 25(6):720-730. 6. Boorjian S, et al. Lancet Oncology. 2021; 22(1):107-117. 7. Narayan VM, et al. J Urol. 2024;212(1):74-86. 8. Chamie K, et al. NEJM Evid. 2023; 2(1):EVIDoa2200167.

Phase 3 Cretostimogene Monotherapy for High-Risk, BCG-Unresponsive NMIBC, Papillary Only

BCG-Unresponsive NMIBC

Cretostimogene
Single-Arm, Open-Label, IVE Administration

Primary Endpoint:
HG Event Free Survival

Population

- Enrollment open
- Pathologically confirmed BCG-unresponsive High-Risk NMIBC with HG Ta/T1 **(no CIS)**
- All Ta/T1 disease resected prior to treatment
- **Mandatory biopsies at 12-month assessment**

Study Design / Regimen

Induction Course:
Weekly x 6

Second Induction:
Weekly x 6 for non-responders

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

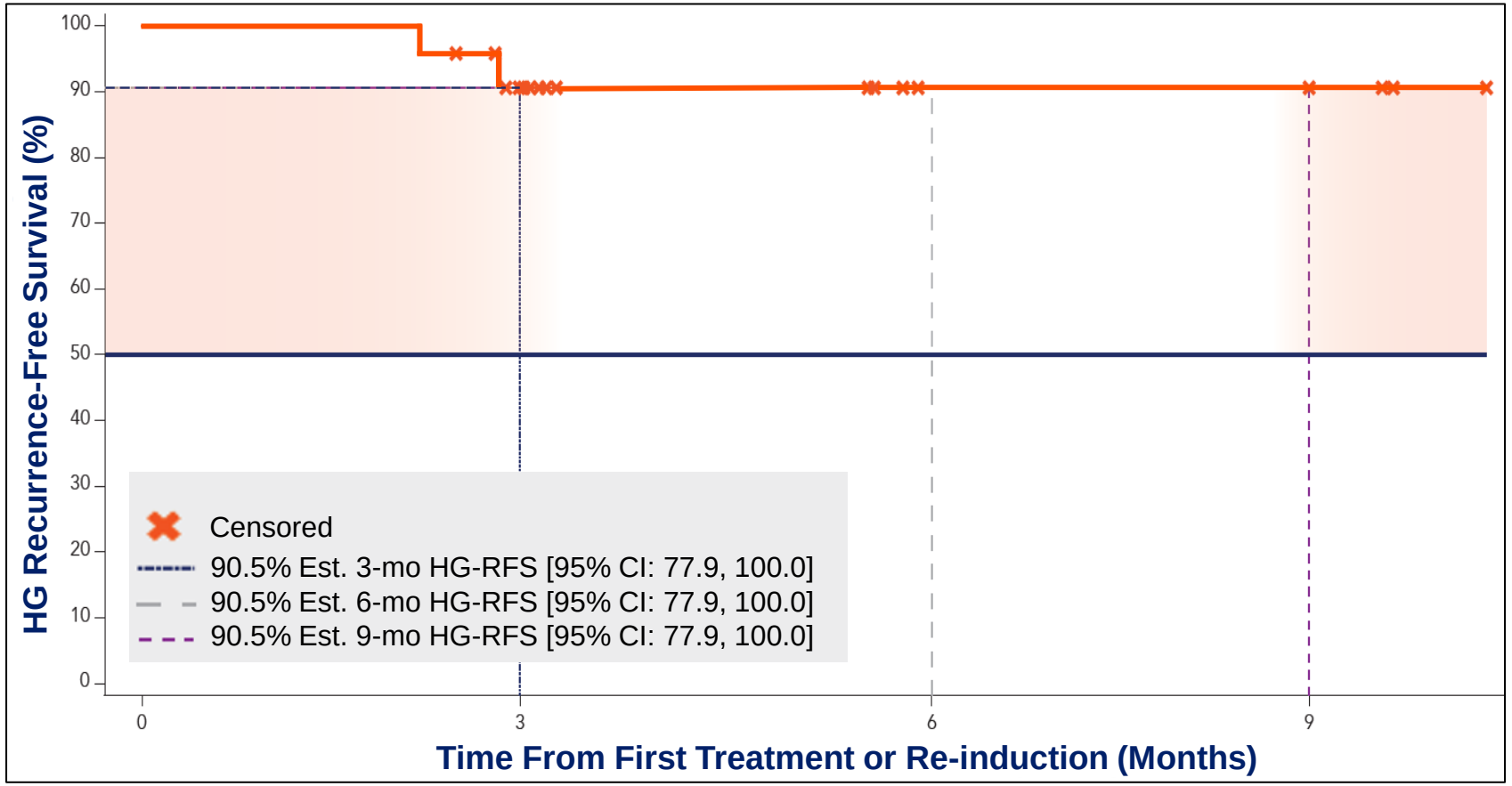
Additional Endpoints

- HG RFS, LG RFS
- PFS
- Cystectomy free survival
- Safety
- Bladder cancer-specific survival
- All-cause EFS

First Results: BOND-003 Cohort P HR NMIBC BCG-Unresponsive HG Ta/T1

- Data from first 24 treated patients
- Strong early responses with **90.5% HG-RFS** (95% CI: 77.9-100%) at 3 and 9 Months
- Very **well-tolerated** regimen
- **Consistent** safety profile
- **No SAEs** related to cretostimogene
- No discontinuations related to cretostimogene

Kaplan-Meier Estimate for High Grade Recurrence-Free Survival



Censored patients include those pending efficacy assessments.

BOND-003 Cohort P: Trial In Progress

- First sites opened and patients enrolled March 2024
- 35+ sites selected across North America and Japan
- Strong, ongoing recruitment

Acknowledgements

All Bladder Cancer Patients and Their Families

The Study Coordinators and Nurses

Key Collaborators

Woodson W. Smelser, Washington Uni, MO

Rian J. Dickstein, Chesapeake Urology, MD

Daniel E. Zainfeld, Urology San Antonio, TX

Roger Li, Moffitt Cancer Center, FL

Siamak Daneshmand, USC, CA

CG Oncology

Andy Darilek

Jee-Hyun Kim

Kara Sabourin

Kristen Scholz

Pat Keegan

Shelja Patel

Vijay Kasturi

BOND-003 COHORT P

BCAN 20 Years of Impact

This research is funded by CG Oncology, Inc..

MAYO CLINIC

Thank You & Questions

For individual reference only. The information accessed through this QR code is intended solely for individual reference and should not be altered, modified, or reproduced in any way.

