MAYO CLINIC

Topline Results From BOND-003 Cohort P-A Multi-national, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk, Papillary Only (HG Ta/T1), BCG-Unresponsive NMIBC

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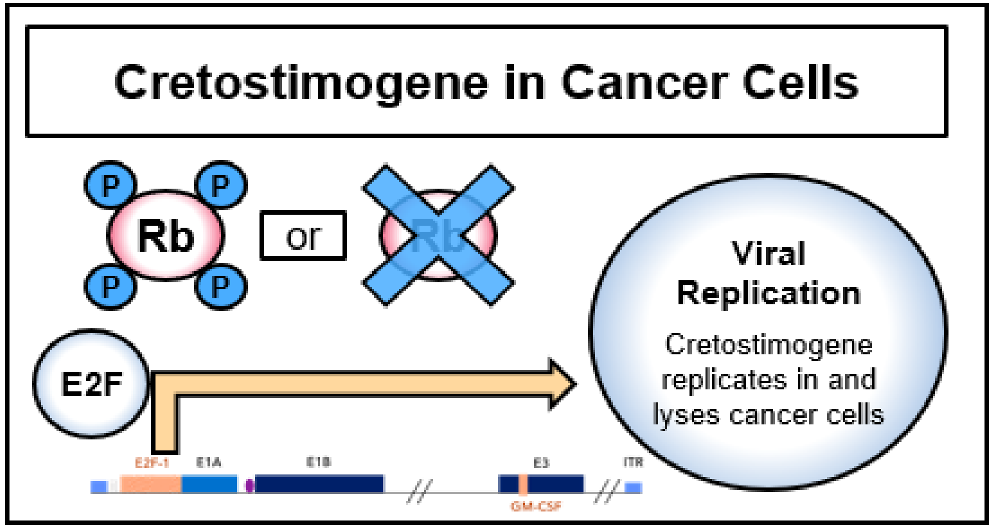
Disclosures

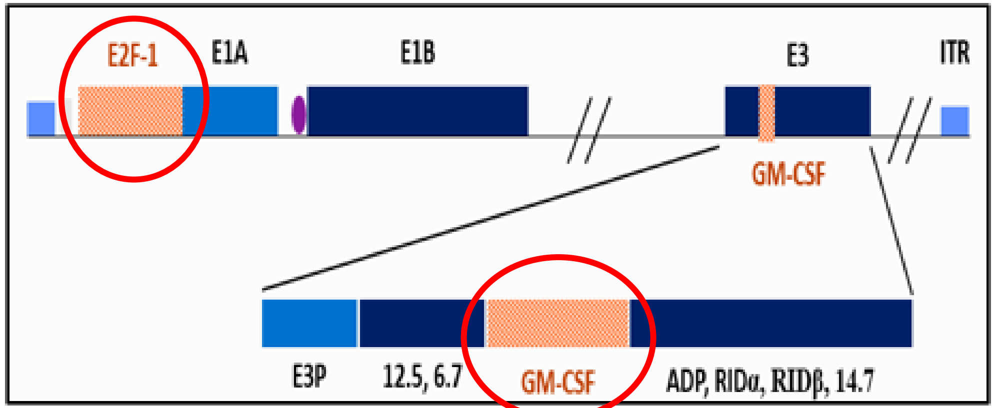
- CG Oncology- No Conflicts of Interest

Cretostimogene Grenadenorepvec Selectively Targets Rb-E2F Pathway Altered Cancers

- Conditionally replicating, highly immunogenic adenovirus
  - Under regulation of the **human E2F-1 promoter**
    - Selective for RB-E2F pathway alterations
  - Encodes **GM-CSF transgene**

- **Oncolytic immunotherapy with <u>dual</u> MOA**
  - 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

Significant Unmet Need for BCG-UR Papillary (HG Ta/T1) NMIBC

- Current FDA approved agents for patients with HR BCG-UR NMIBC **with CIS +/- Ta/T1**[1]
- Patients commonly present with HG Ta/T1 NMIBC[2-3]
- **Benchmarks reported from recent meta-analysis for BCG-UR HG Ta/T1 NMIBC**[4]
  - 73% at 3 mo
  - 58% at 6 mo
  - 48% at 12 mo

DFS/HG-RFS	Pembrolizumab [5]	Nadofaragene [6,7]	N-803+BCG [8]	TAR-200 [9]
3 months, % (95% CI)	87.7 (80.7-92.3)	72.9 (58.2-84.7)	Not Reported	Not Reported
6 months, % (95% CI)	53.1 (44.1-61.2)	62.5 (47.4-76.0)	Not Reported	85.3 (71.6-92.7)
9 months, % (95% CI)	Not Reported	58.3 (43.2–72.4)	Not Reported	81.1 (66.7- 89.7)
12 months, % (95% CI)	43.5 (34.9-51.9)	43.8 (29.5-58.8)	55.4 (42.0-66.8)	70.2 (51.6-82.8)
24 months, % (95% CI)	34.9 (26.4-43.4)	33.3 (20.4-48.4)	48.3 (34.5-60.7)	Not Reported

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; 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. 9. Daneshmand S, et al. *JCO*. 2025. doi: 10.1200/JCO-25-01651.

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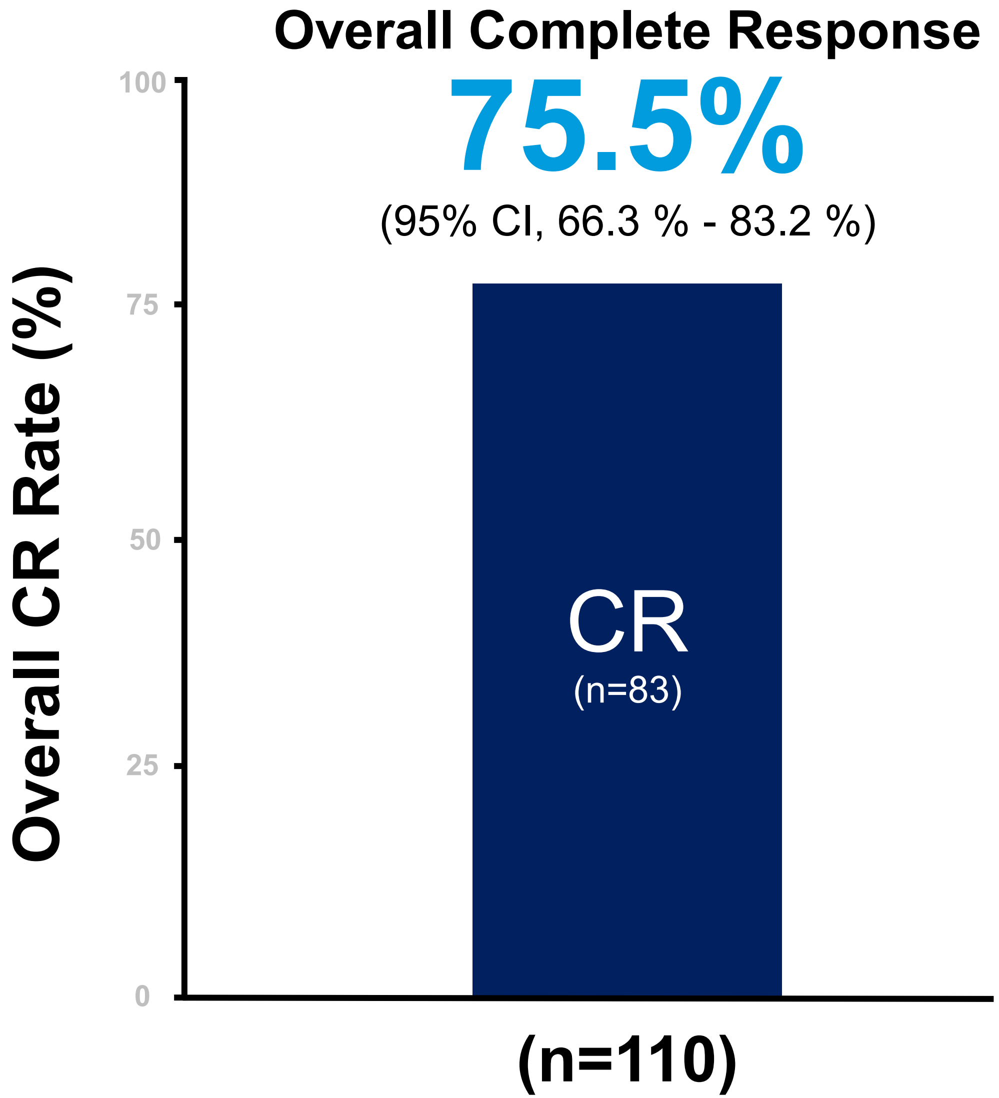
Consistent and Compelling CR & Durability Data



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	**41.8%** (32.5, 51.6)[1] *46 out of 110 patients*	**42.4%** (32.7, 51.7)

- 96.4% were free from progression to MIBC
- 83.6% of patients did not undergo radical cystectomy post recurrence or progression
- Among those patients who underwent RCs post recurrence or progression, 83.3% (15/18) were T0 or NMIBC
- All complete responses have been centrally confirmed[2]
- 0% Grade ≥ 3 TRAEs or deaths; No Tx-related discontinuations

Efficacy data cutoff as of 23JUN2025. Efficacy analysis are 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. All 9 ongoing CRs remained in response at the 24-month assessment, as well as 3 additional patients confirmed to be in CR at Month 24 after further follow-up and central pathologic adjudication.
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.

BOND-003 Cohort P- Papillary Only (HG Ta/T1), BCG-UR, HR-NMIBC

Cohort C (N=112):

- Age ≥ 18 yo
- ECOG PS 0-2
- Pathologically confirmed BCG-UR HR-NMIBC with CIS +/- papillary disease

Primary Endpoint:

- CR at any time

Secondary Endpoints:

- Duration of Response
- CFS, RFS, PFS

Cohort P (N=56):

- Age ≥ 18 yo
- Pathologically confirmed HR BCG-UR NMIBC HG Ta/T1 (Without CIS)
- Completely resected prior to treatment

Primary Endpoint:

- HG-EFS

Secondary Endpoints:

- RFS, PFS, CFS, CSS

	Induction	Optional Re-Induction	Maintenance / Follow-Up						
Month	0	3	6	9	12	15	18	21	24/30/36
Instillation	1 2 3 4 5 6	1 2 3 (4 5 6)	1 2 3	1 2 3	1 2 3		1 2 3		1 2 3
		x6 for Non-responders			Mandatory Biopsy				Extended Maintenance

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Patient Demographics & Baseline Characteristics

Patients in Safety Dataset	N=56	%
Gender		
Male	44	78.6
Female	12	21.4
Age (Years)		
Mean (SD)	71.6 (9.3)	
Median (Range)	74.0 (45-87)	
Age (Categories)		
< 65	13	23.2
≥ 65 and < 75	18	32.1
≥75	25	44.6
ECOG PS		
ECOG PS 0	48	85.7
ECOG PS 1	8	14.3
HR NMIBC T-Stage at Study Entry		
HG Ta	33	58.9
HG T1	23	41.1
BCG History: No. of Prior Instillations		
Median (Range)	9.0 (5 – 21)	

- Majority of patients are:
  - Male (78.6%)
  - White (87.5%)
  - > 65 years (75%)
- 96.4% of patients in US
- **High-Risk population enrolled, with 41.1% HG T1 at baseline**

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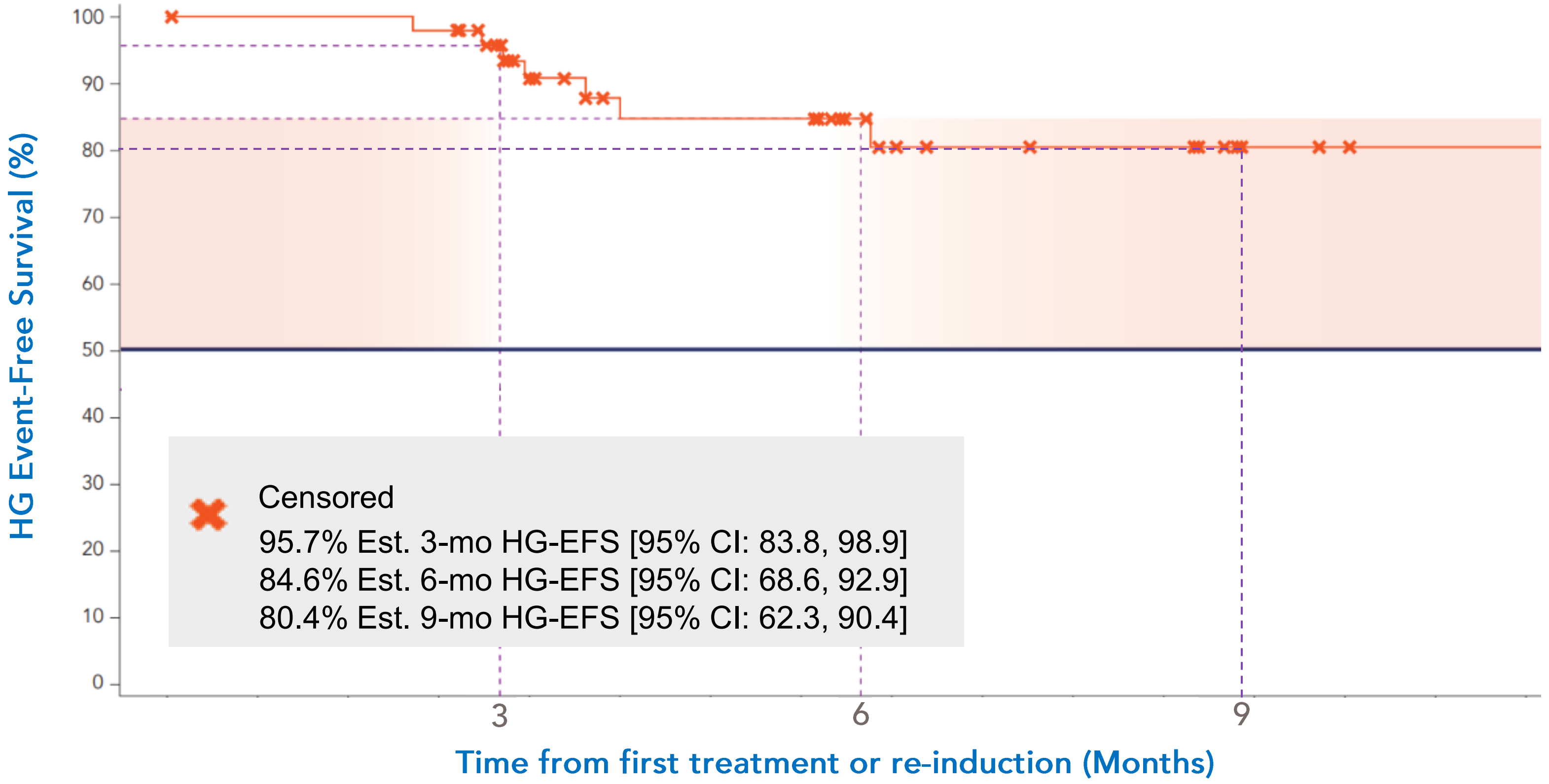
Topline Results: BOND-003 Cohort P HR, Papillary-Only (HG Ta/T1) BCG-Unresponsive NMIBC

- Median follow-up was 6.0 months
- 8 patients were re-induced
- Consistent and high HG-EFS
  - HG-Ta:
    - 92.8% (3 mo)
    - 75.9% (6 mo)
    - 75.9% (9 mo)
  - HG-T1:
    - 100% (3 mo)
    - 100% (6 mo)
    - 87.5% (9 mo)
- No patients underwent RC
- No progression to MIBC*

Kaplan-Meier Estimate for High Grade Event-Free Survival



HR= High-Risk; HG-RFS= High-Grade Recurrence-Free Survival; NMIBC= Non-Muscle Invasive Bladder Cancer; RC= Radical Cystectomy
01SEP2025 data cut off. Censored patients include 5 patients pending efficacy assessments.
HG-EFS time from first study treatment (first re-induction dose) to high-grade recurrence, progression, death, or censoring.
* 1 pt progressed to metastatic urothelial carcinoma despite clinical complete response in the bladder.

Consistent, Favorable and Well-Tolerated Safety Profile from BOND-003 Cohort P

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=56)	
	Any Grade (%)	Grade ≥ 3
Patients with ≥ 1 TRAE	40 (71.4%)	0 (0)
Treatment-Related AE reported in > 10% patients		
Bladder Spasm	26 (46.4%)	0 (0)
Dysuria	22 (39.3%)	0 (0)
Pollakiuria	14 (25.0%)	0 (0)
Urgency	11 (19.6%)	0 (0)

- Most AEs were Grade 1-2
- **0% Grade ≥ 3 TRAEs, Serious TRAE, deaths**
- **No dose delays, missed doses due to TRAEs**
- **No treatment related discontinuations**
- 98.2% received all protocol defined treatments

Safety data cutoff as of 01SEP2025

BOND-003 Cohort P: Conclusions

BOND-003 COHORT P

- Topline results with cretostimogene in BOND-003 Cohort P consistently demonstrate
  - Strong HG-EFS at 3, 6, and 9 mo
  - Responses maintained across HGTa and higher-risk, HGT1, populations
  - Well-tolerated safety profile
- Longer-term treatment and follow up ongoing

Initiated BLA Submission to US FDA for HR BCG-UR NMIBC with CIS +/- Ta/T1!

Breakthrough Therapy Designation

Fast Track Designation

Acknowledgements

Top 30 Abstracts

All Bladder Cancer Patients and Their Families

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BOND-003 COHORT P

BCAN 20 Years of Impact

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Thank You & Questions

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