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 NON-MUSCLE INVASIVE BLADDER CANCER

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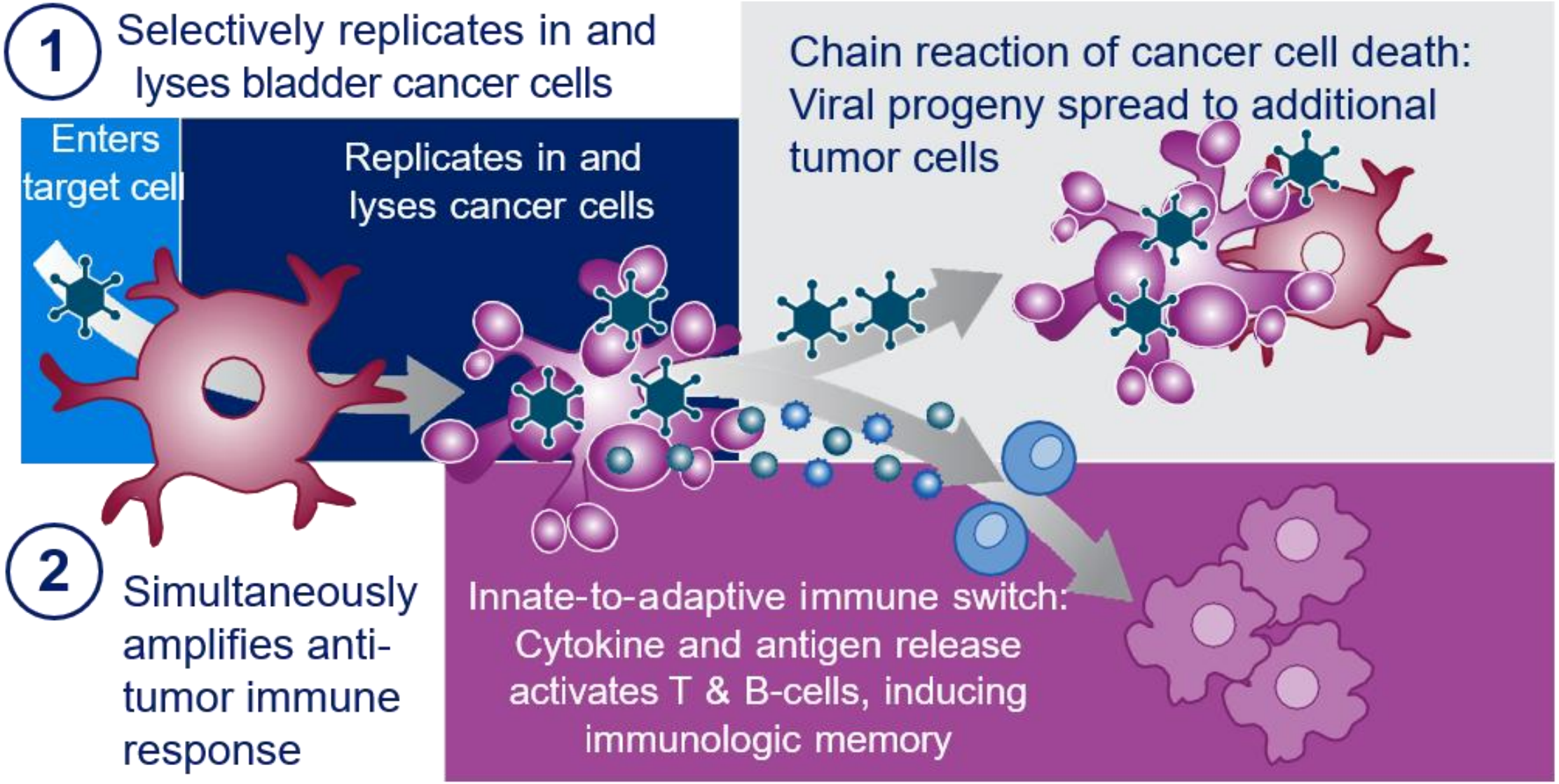
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DISCLOSURES

- Nothing to disclose

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ONCOLYTIC IMMUNOTHERAPY: CRETOSTIMOGENE GRENADENOREPVEC'S DUAL MECHANISM OF ACTION



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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 [8,9]	TAR-200[10]
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

Data are presented for benchmarking purposes only; differences in trial design, patient populations, and endpoints preclude direct cross-trial comparison.

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-Guérin; BCG-UR: BCG unresponsive; CIS: carcinoma in situ; FDA: US Food and Drug Administration; HG: high grade; HR: high risk; NMIBC: non muscle invasive bladder cancer; Ta/T1: papillary tumor stages Ta and T1

1 Clark, PE et al., AUA/SUO guideline: 2026 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. Chang S, et al. *J Urol*. 2026;215(1):44-56. 10. Daneshmand S, et al. Presented at SUO 2025 Annual Meeting.

BOND-003 COHORT C: PHASE 3 CRETOSTIMOGENE MONOTHERAPY FOR HIGH-RISK BCG-UNRESPONSIVE NMIBC WITH CIS

BOND-003 COHORT C

FDA Fast Track Designation

FDA Breakthrough Therapy Designation

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 assessment[1]

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; Ta/T1: papillary tumor stages Ta and T1

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.

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BOND-003 COHORT P- PAPILLARY ONLY (HG TA/T1), BCG-UR, HR-NMIBC

N=56 patients

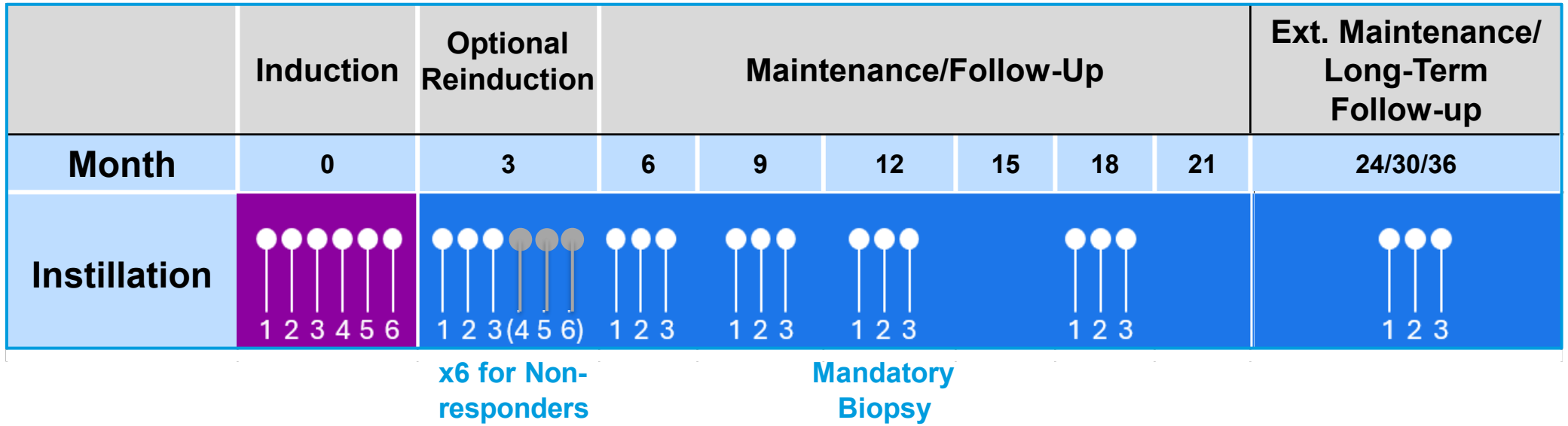
- Age ≥ 18 years
- Pathologically confirmed HR BCG-UR NMIBC HG Ta/T1 without CIS
- Completely resected prior to treatment

Primary Endpoint

- HG-EFS

Secondary Endpoints

- RFS, PFS, CFS, CSS



BCG-UR: Bacillus Calmette-Guérin unresponsive; CFS: cystectomy-free survival; CIS: carcinoma in situ; CSS: cancer-specific survival; HG: high grade; HG-EFS: high-grade event-free survival; HR: high risk; NMIBC: non-muscle invasive bladder cancer; PFS: progression-free survival; RFS: recurrence-free survival; Ta/T1: papillary tumor stages Ta and T1

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BOND-003 COHORT P PATIENT BASELINE CHARACTERISTICS

Patients in Safety Dataset	N=56	%
Gender		
Male	44	78.6
Female	12	21.4
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	37	66.1
HG T1	19	33.9
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 33.9% HG T1 at baseline

HG: high grade; NMIBC: non-muscle invasive bladder cancer; US: United States

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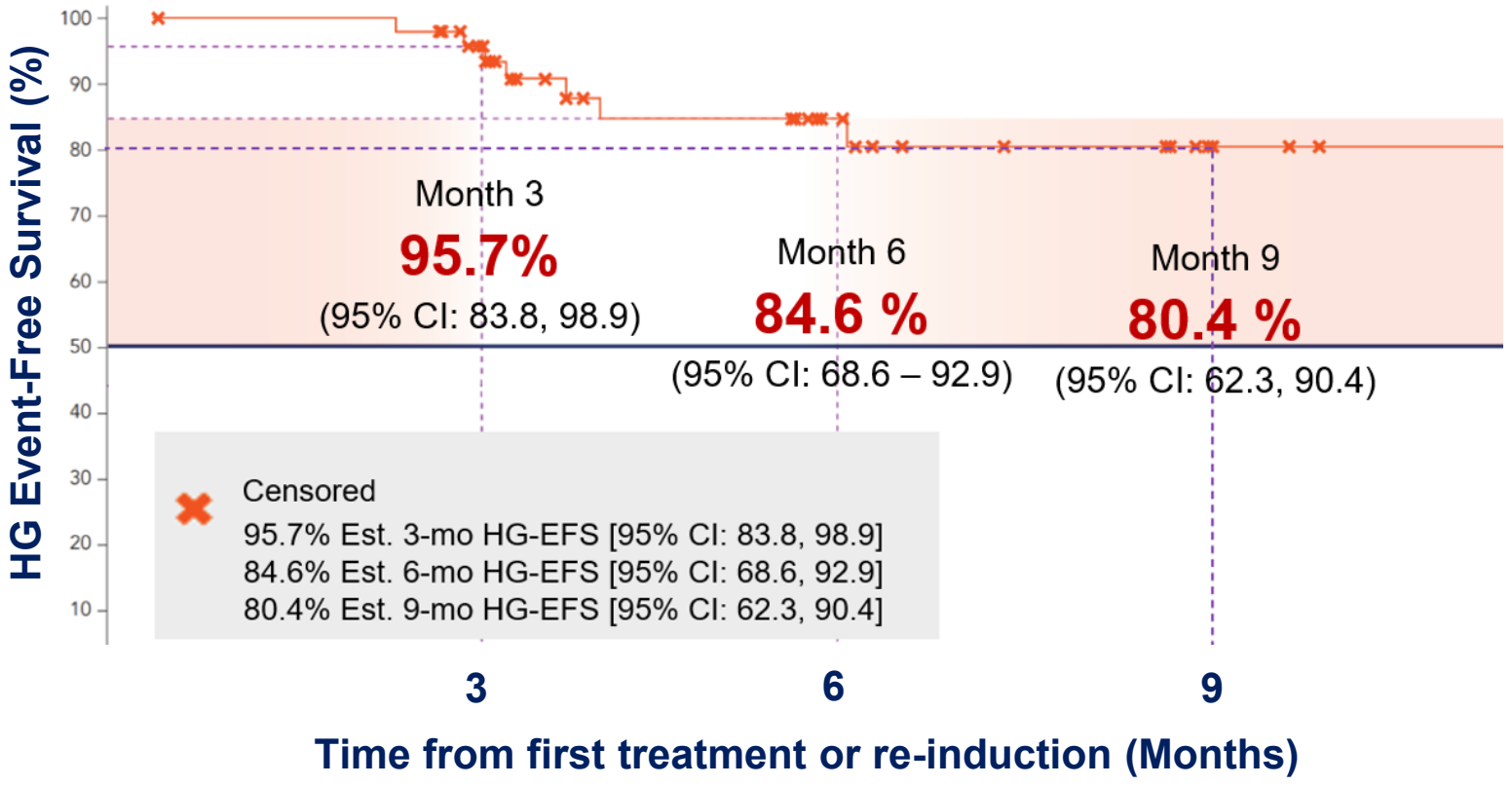
TOPLINE RESULTS: BOND-003 COHORT P HR, PAPILLARY-ONLY BCG-UNRESPONSIVE NMIBC

- Median follow-up: 6.0 mos
- 8 patients re-induced at 3 mos
- Consistent and high HG-EFS:

HG-T1	HG-Ta
100% (3 mo)	92.8% (3 mo)
100% (6 mo)	75.9% (6 mo)
87.5% (9 mo)	75.9% (9 mo)

- No patients underwent RC
- No progression to MIBC

Kaplan-Meier Estimate for High Grade Event-Free Survival



BCG: Bacillus Calmette-Guérin; HG-EFS: high-grade event-free survival; HR: high risk; MIBC: muscle invasive bladder cancer; NMIBC: non-muscle invasive bladder cancer; RC: radical cystectomy

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CONSISTENT, FAVORABLE AND WELL-TOLERATED SAFETY PROFILE

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

AE: adverse event; MedDRA: Medical Dictionary for Regulatory Activities; TRAE: treatment-related adverse event

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BOND-003 COHORT P: CONCLUSIONS





- Topline results with cretostimogene in BOND-003 Cohort P 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

HG-EFS: high-grade event-free survival; HGT1: high-grade T1; HGTa: high-grade Ta

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BOND-003 COHORT P

BCAN 20 Years of Impact

CG ONCOLOGY

THANK YOU

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

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