CG ONCOLOGY

Attacking Bladder Cancer
for a Better Tomorrow™

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2024 ASCO® ANNUAL MEETING

nature medicine

CORE-001

Final Results of CORE-001: A Phase-2, Single Arm Study of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in Patients with BCG-Unresponsive, High-Risk NMIBC with Carcinoma In Situ

Roger Li, Paras Shah, Tyler Stewart, Trinity Bivalacqua, Donald Lamm, Daniel Geynisman, Joshua Meeks, Edward Uchio, Joseph Jacob, Rian Dickstein, Shane Pearce, James Burke and Gary Steinberg

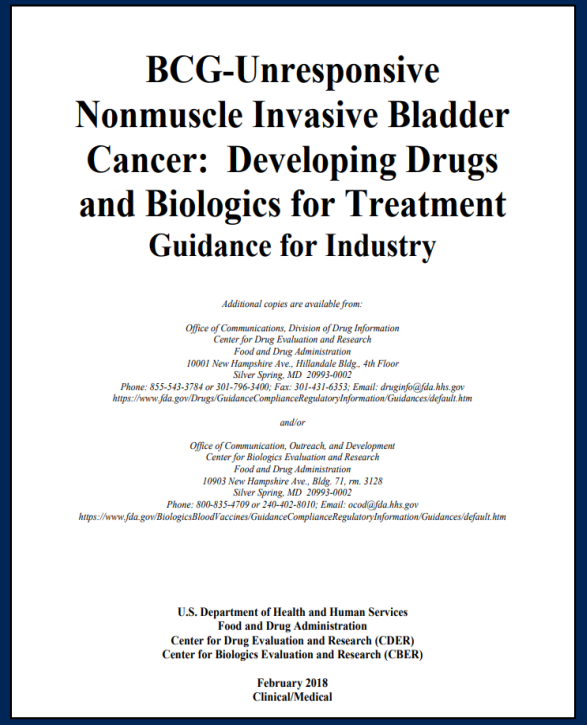
Roger Li, M.D.

Presented at ASCO Annual Meeting; June 2, 2024; Chicago, IL

Unmet Medical Need in BCG-Unresponsive NMIBC

- Standard of care for High-Risk NMIBC is TURBT followed by intravesical BCG[1,2]
  - Despite initial response rates, BCG fails approximately 50-60% of patients[3,4]
  - These patients are at risk for disease progression, 20–40% develop MIBC, of which, half eventually succumb to bladder cancer [2, 5, 6]

- 2018 FDA Guidance: BCG-Unresponsive NMIBC definition[7]
  - Persistent or recurrent CIS +/- Ta/T1 within 12 months of adequate BCG therapy
  - Recurrent HG Ta/T1 disease within 6 months of adequate BCG therapy
  - HG T1 disease at the first evaluation after induction BCG course



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

February 2018
Clinical/Medical

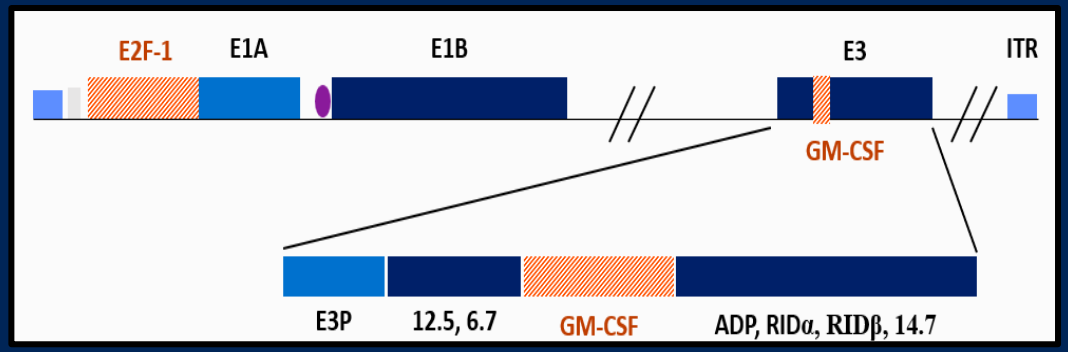
There is a critical unmet need for highly effective, well-tolerated, durable treatment options for patients with BCG-UR HR NMIBC

[1] Holzbeierlein J, et al. J Urol. 2024;10.1097. [2] NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. V3.2024. [3] Rouanne M, et al. J Clin Invest. 2022;132(12):e145666. [4] Sylvester RJ, et al. Eur Urol. 2006;49(3):466-5. [5] Van den Bosch S, et al. Eur Urol. 2011;60: 493–500. [6] Babjuk, M. et al. Eur. Urol. 2022; 81:75–94. [7] FDA Guidance Document: BCG-Unresponsive Nonmuscle Invasive Bladder Cancer, February 2018.

Background: Cretostimogene Grenadenorepvec

What is Cretostimogene?

- Oncolytic Immunotherapy (OIT)
  - Conditionally replicating, oncolytic adenovirus
  - Encodes GM-CSF
  - Insertion of human E2F-1 promoter
- Binds to Coxsackie Adenovirus Receptor (CAR)
  - Robust expression in all stages of bladder cancer
- Viral replication results in tumor lysis, release of GM-CSF, further viral progeny, and additional tumor lysis



Monotherapy Experience:

- Studies in heavily pretreated HR NMIBC with CR at any time rates of 65-75%, with low AE profile[1,2]
- Intravenous pembrolizumab is FDA approved with a 41% CR in BCG-UR NMIBC and a 12-month CR rate of ~20%[3]

[1]Packiam VT, et al. Urol Oncol. 2018;36(10):440-7 [2]Tyson, et al. AUA 2024 [3]Keytruda. Package insert. Merck & Co., Inc.; 2014.

CORE-001: Phase-2 Cretostimogene + Pembrolizumab for BCG-Unresponsive, High-Risk NMIBC with CIS (NCT04387461)

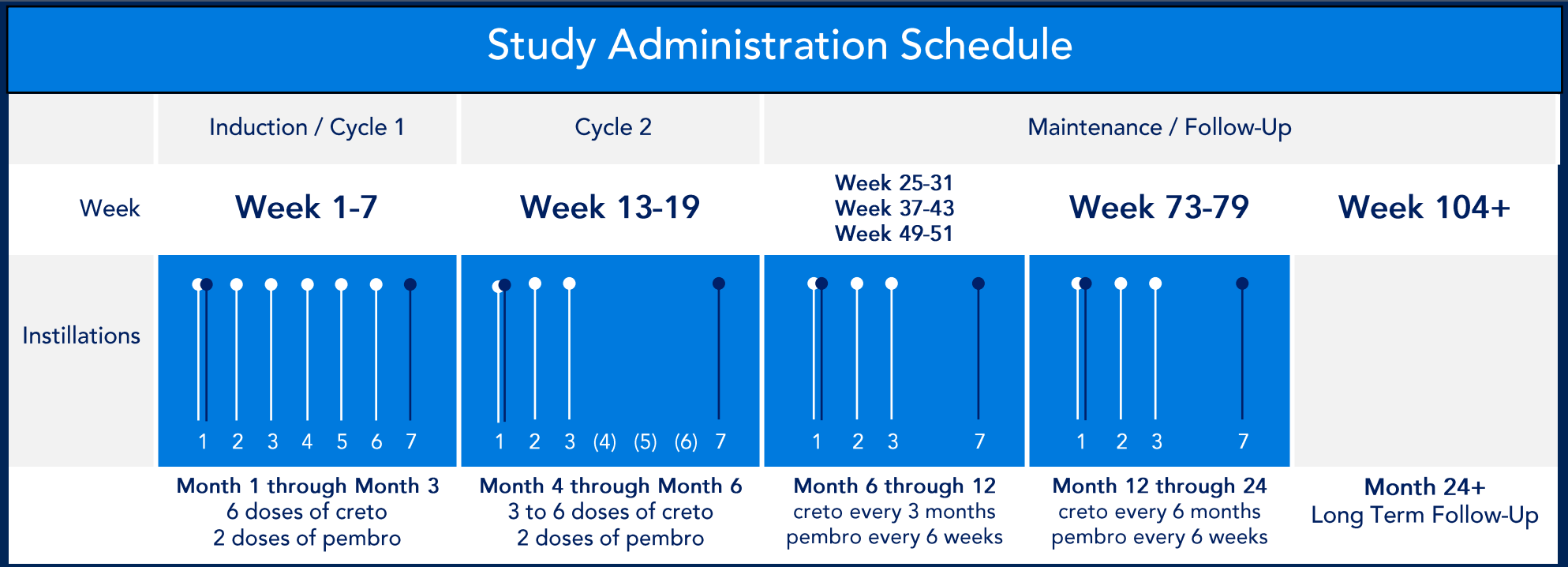
N = 35 BCG-UR NMIBC **Design:** Single-arm, intravesical cretostimogene + intravenous pembrolizumab **Trial Type:** Open label

Regimen:
Cretostimogene induction[1]
Weekly x 6
Maintenance courses[2]
Weekly x 3 for Complete Responders

Primary Endpoint: CR at 12 months

Secondary Endpoints: CR at any time, DoR, Safety

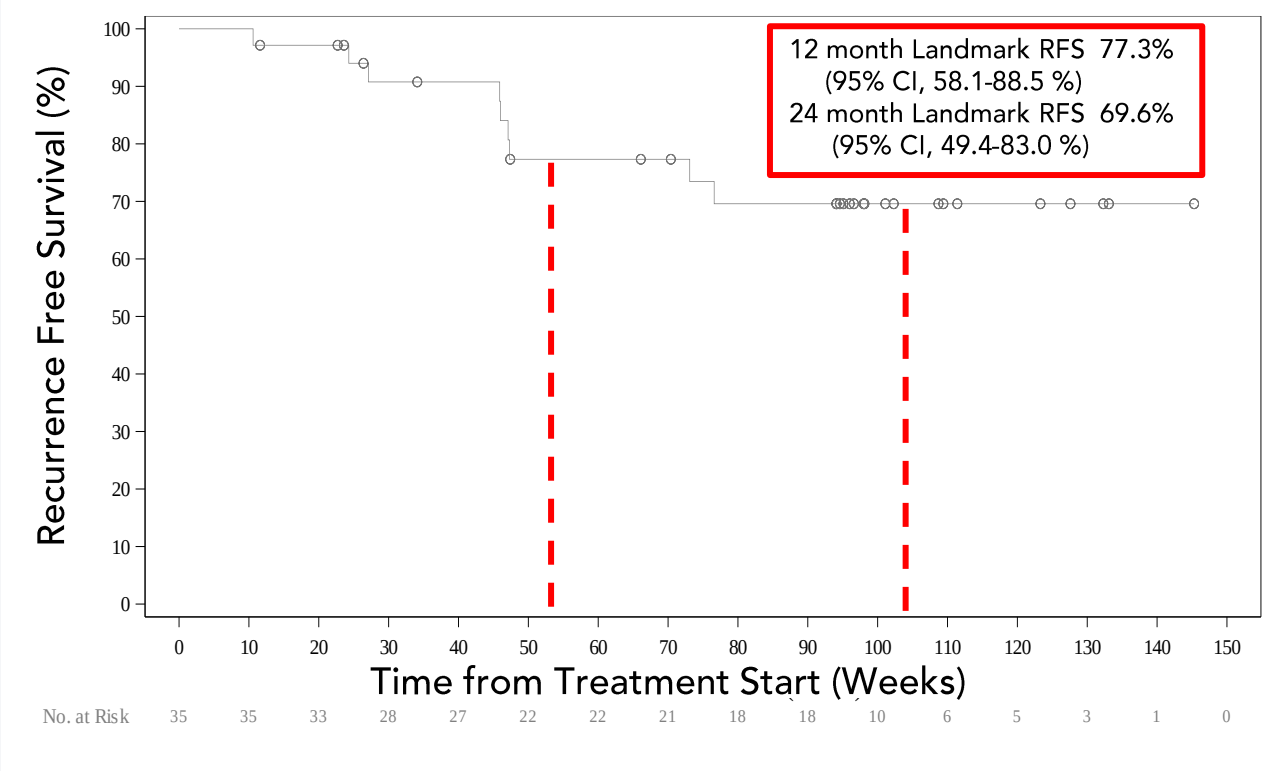
Study Administration Schedule



Response assessment: Quarterly centrally reviewed cytology & cystoscopy (with for cause biopsy). 12 month assessment included mandatory bladder mapping biopsy

[1] Second induction course of weekly x 6 for non-responders at month 3. [2] Maintenance course for complete responders starts at month 3 every 3 months for 1st year, and every 6 months for 2nd year

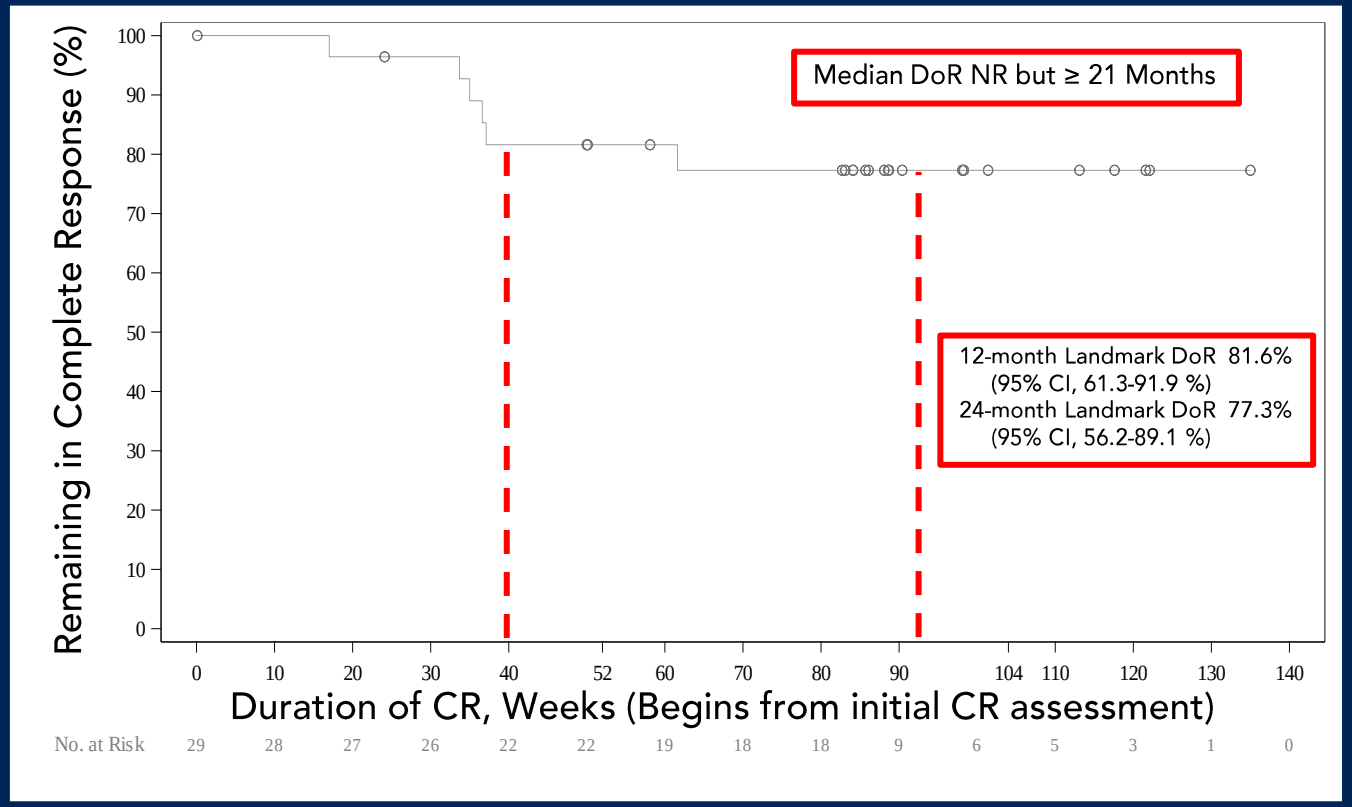
Cretostimogene + Pembro with Durable Complete Responses



- Demographics are consistent with generalizable bladder cancer cohort
- 82.8% CR at any time
  - (29/35, 95% CI 70.4-95.3%)
- 57.1% CR at 12 months
  - (ITT; 20/35, 95% CI 39.5–73.2%)
- 54.3% CR at 24 months
  - (ITT; 19/35, 95% CI 36.9-70.8%)
- 12 month Landmark RFS – 77.3%
  - (95% CI, 58.1-88.5 %)
- 24 month Landmark RFS- 69.6%
  - (95% CI, 49.4-83.0 %)

The data cut off was May 17, 2024.

Cretostimogene + Pembro with Durable Complete Responses



- Median Follow-up 26.5 months
- 12-month Landmark DoR – 81.6%
  - (95% CI, 61.3-91.9 %)
- 24-month Landmark DoR – 77.3%
  - (95% CI, 56.2-89.1 %)
- 95.1% of patients in CR at 12 months, in CR at 24 months
- **100% PFS**
  - No patients with MIBC/mUC
  - Compares favorably: 94% nadofaragene[1], 91% pembrolizumab[2], 90% N803+BCG[3]
- **80.0% CFS at 24 months**

The data cut off was May 17, 2024.
1 Boorjian, Lancet Oncol; 2021, 2 Keytruda. Package insert. Merck & Co., Inc.; 2014, 3 Anktiva. Package. Insert. Altor BioScience, LLC,; 2024

Favorable Safety Profile- No Overlapping or Synergistic Toxicity

System organ class, *n* (%)/preferred term, *n* (%)	Maximum severity					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total (*N*=35)
Participants reporting at least one study drug-related treatment-emergent AE	9 (25.7)	18 (51.4)	5 (14.3)	0	0	32 (91.4)
Bladder spasm	13 (37.1)	4 (11.4)	0	0	0	17 (48.6)
Fatigue	11 (31.4)	2 (5.7)	0	0	0	13 (37.1)
Dysuria	8 (22.9)	1 (2.9)	0	0	0	9 (25.7)
Pollakiuria	8 (22.9)	1 (2.9)	0	0	0	9 (25.7)
Hematuria	5 (14.3)	1 (2.9)	0	0	0	6 (17.1)
Micturition urgency	4 (11.4)	2 (5.7)	0	0	0	6 (17.1)
Diarrhea	4 (11.4)	0	1 (2.9)	0	0	5 (14.3)
Nocturia	3 (8.6)	1 (2.9)	0	0	0	4 (11.4)
Hypothyroidism	1 (2.9)	3 (8.6)	0	0	0	4 (11.4)
Urinary tract infection	3 (8.6)	1 (2.9)	0	0	0	4 (11.4)
Blood alkaline phosphatase increased	0	0	1 (2.9)	0	0	1 (2.9)
Ejection fraction decreased	0	0	1 (2.9)	0	0	1 (2.9)
Neutrophil count decreased	0	0	1 (2.9)	0	0	1 (2.9)
Adrenal insufficiency	0	0	1 (2.9)	0	0	1 (2.9)
Immune-mediated hepatitis	0	0	1 (2.9)	0	0	1 (2.9)

Data are *n* (%). The table presents study drug-related AEs that occurred in at least 10% or more of all treated patients (*n*=35) and all study drug-related grade 3 events. AEs include all events that occurred or worsened after the first dose of cretostimogene or pembrolizumab. There were no grade 3–5 cretostimogene drug-related AEs. There were no grade 4–5 pembrolizumab drug-related AEs.

- AEs attributed to creto were low grade and self-limited
- No grade 3-5 creto related AEs
- irAEs exclusively associated with pembro
- 5 discontinuations prior to 12-month timepoint, all unrelated
- No treatment-related deaths

The data cut off was May 17, 2024.

Conclusion

- Cretostimogene plus pembrolizumab achieved a favorable benefit/risk profile in patients with BCG-UR NMIBC
- Strong CR at any time (83%), CR at 12 months (57%) and robust DoR in responders at 24 months (95%)
- Translational correlates from CORE-001 and monotherapy BOND-003 will generate key insights regarding risks of recurrence in BCG-UR HR NMIBC
- Future clinical trials will evaluate cretostimogene monotherapy, and rational combinations, as a backbone therapy for patients with High-Risk NMIBC
- CORE-001 manuscript now in press at Nature Medicine (https://doi.org/10.1038/s41591-024-03025-3)

Acknowledgements

All Bladder Cancer Patients and Their Families

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- Pat Keegan
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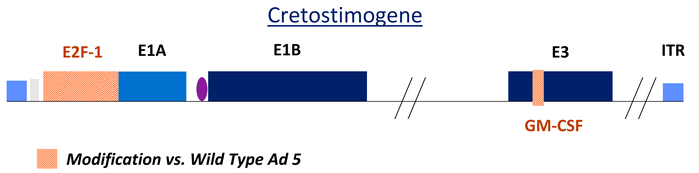
#4601

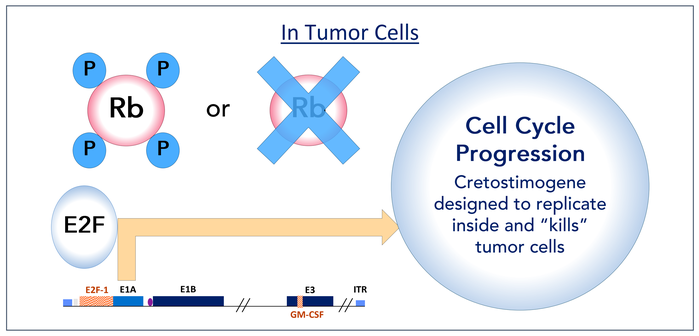
Final Results of CORE-001: A Phase-2, Single Arm Study of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in Patients with BCG-Unresponsive, High-Risk NMIBC with Carcinoma In Situ

Roger Li, MD,[1] Paras Shah, MD,[2] Tyler Stewart, MD,[3] Trinity Bivalacqua, MD,[4] Donald Lamm, MD,[5] Daniel Geynisman, MD,[6] Joshua Meeks, MD,PhD[7] Edward Uchio, MD,[8] Joseph Jacob, MD,[9] Rian Dickstein, MD,[10] Shane Pearce, MD,[11] James Burke, MD,[12] and Gary Steinberg, MD [13]

BACKGROUND

- Cretostimogene is a conditionally replicating, intravesically delivered adenovirus
- Oncolytic immunotherapy: cretostimogene is engineered to lyse bladder cancer cells and produce GM-CSF, stimulating the immune system via a dual mode of action
- In High-Risk NMIBC, cretostimogene monotherapy shows Complete Response (CR) rates between 65-75% [1-3]
- Favorable safety profile with mostly grade 1-2 AE [1-3]
- Intravenous pembrolizumab is FDA approved in BCG-UR NMIBC with a 41% CR any time and 12-month CR of ~20% [4]
- CORE-001 is a proof-of-concept, Phase 2 study evaluating the combination of cretostimogene and pembrolizumab in BCG-UR HR NMIBC

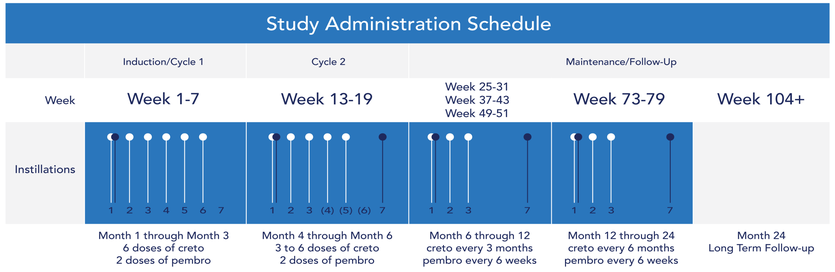




References: [1] Packiam, *Uro Onc;* 2018, [2] Li, *AUA Meeting;* 2022, [3] Tyson, *AUA Meeting;* 2024, [4] Keytruda. Package insert. Merck & Co., Inc.; 2014, [5] Boorjian, *Lancet Oncol;* 2021, [6] Anktiva. Package. Insert. Altor BioScience, LLC,; 2024

CORE-001

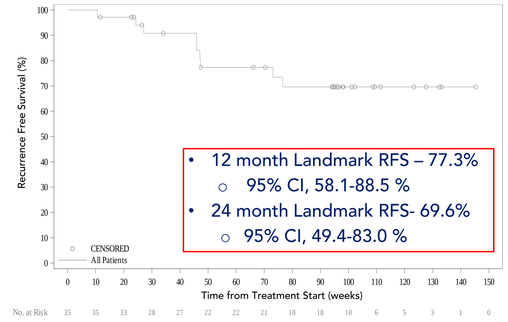
- 82.9% (29/35); CR at Any Time
- 57.1% (20/35); CR at 12 months
- 54.3% (19/35); CR at 24 months
- 95.1% of CRs at 12 months remain in CR at 24 months
- No progression to MIBC or mUC
- Favorable AE profile



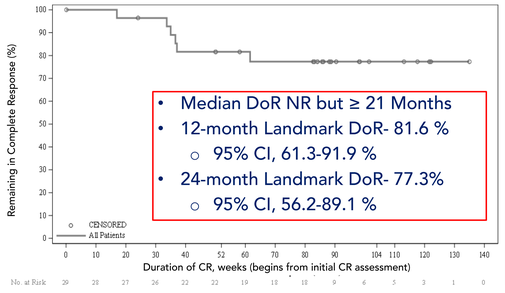
Response assessment: quarterly centrally reviewed cytology & cystoscopy (with for cause biopsy). 12 mon assessment included mandatory bladder mapping biopsy

[1]Moffitt Cancer Center, Tampa, FL, [2]Mayo Clinic, Rochester, MN, [3]UC San Diego, La Jolla, CA, [4] University of Pennsylvania, Philadelphia, PA, [5] BCG Oncology, Phoenix, AZ, [6] Fox Chase Cancer Center, Philadelphia, PA, [7] Northwestern University, Chicago, IL, [8]UC Irvine, Irvina, CA, [9]SUNY Upstate, Syracuse, NY, [10] Chesapeake Urology, Hanover, MD, [11] Spokane Urology, Spokane, WA, [12]Billings Clinic, Billings, MT, [13]Rush University, Chicago, IL

RESULTS



- Of 35 patients in the ITT population, 82.9% had CR at any time
- 20/35 (57.1%, 95% CI 39.5–73.2%) had CR at 12 months
- 19/35 (54.3%, 95% CI 36.9-70.8%) had CR at 24 months
- 100% PFS, no MIBC or mUC
  - Compares favorably: 94% nadofaragene[5], 91% pembrolizumab[4], 90% N803+BCG[6]
- AE profile: No ≥ Grade 3 creto-related AEs. No Tx-related discontinuations



Future Directions

- The long-term durability demonstrated in CORE-001 may represent a novel bladder-sparing strategy in HR NMIBC
- Future clinical trials will evaluate cretostimogene monotherapy, and rational combinations, as a backbone therapy for patients with HR NMIBC
- Manuscript now in press at *Nature Medicine*
- https://doi.org/10.1038/s41591-024-03025-3

The data cut off was May 17, 2024.

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