

Attacking Bladder Cancer for a Better Tomorrow™

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Investment Summary

Cretostimogene grenadenorepvec is an <u>oncolytic immunotherapy</u> with backbone therapy potential targeting multi-billion dollar market opportunities in NMIBC:

- Monotherapy achieved 75.2% (79/105) Complete Response at any time and compares favorably to approved and other investigational agents in lead indication BCG-Unresponsive, High-Risk NMIBC
- Generally well-tolerated with no Grade 3 or higher treatment-related AEs
- Combination with pembrolizumab achieved 83% (29/35) CR at any time, 57% CR at 12-month landmark (78% CR by Kaplan-Meier estimate) and 54% CR at 24-month landmark (70% CR by Kaplan-Meier estimate)

Multiple near-term clinical milestones:

- Pivotal Phase 3 monotherapy results from BOND-003 Cohort C expected by the end of 2024
- Active recruitment in Phase 3 Intermediate-Risk NMIBC trial (PIVOT-006) in collaboration with SUO-CTC
- Launch CORE-008, a multi-cohort study in High-Risk NMIBC planned in 2H'24
- Initiated Expanded Access Program in BCG-Unresponsive, High-Risk NMIBC in 2Q'24 to provide real-world patients with access to cretostimogene

Strong financial position:

Cash runway expected to fund operations through 2027



Comprehensive Programs in High-Risk and Intermediate-Risk NMIBC Addressing a Multi-Billion Dollar Market Opportunity

COMPOUND/INDICATION	PHASE 1	PHASE 2	PHASE 3	ANTICIPATED MILESTONES
Cretostimogene Monotherapy BCG-Unresponsive, High-Risk NMIBC (BOND-003)				BOND-003 Cohort C pivotal data in 2H'24
Cretostimogene + Pembrolizumab BCG-Unresponsive, High-Risk NMIBC (CORE-001)				CORE-001 24-month data at ASCO 2024
Cretostimogene Monotherapy Intermediate-Risk NMIBC (PIVOT-006)				PIVOT-006 active recruitment; complete enrollment in 1H'26
Cretostimogene (Mono/Combo) High-Risk NMIBC (CORE-008) ¹				Initiate CORE-008 in 2H'24

Expected cash runway through 2027

¹ Planned clinical trials to be conducted under existing Investigational New Drug application (IND) previously approved by the FDA. Preliminary and unaudited estimate subject to revision based on further review.

Timing and achievement of milestone events are based on Company estimates and subject to risks and uncertainties. Actual results may be materially different than projected. The BLA filing is subject to completion and positive results of pivotal trials and FDA feedback.

Current Program





Executive Leadership Team

Deep Industry Experience with Track Record of Success in Drug Development







Our Vision

We see a world where urologic cancer patients can benefit from our innovative immunotherapies to live with dignity and have an enhanced quality of life.

Our Mission

We are focused on developing bladder-sparing therapeutics for patients afflicted with bladder cancer.



Attacking Bladder Cancer for a Better Tomorrow™



Bladder Cancer is a Significant Unmet Medical Need Well Positioned for Innovation and Disruption

A Very Common Cancer

83,000+ people will be diagnosed with bladder cancer this year¹

725,000+ people estimated living with

bladder cancer in 2020 in the United States⁸ Highly Recurrent Disease With Few Treatment Options

~15%-61%

of high-risk patients will recur within 1 year⁷



Bladder Cancer is one of the most expensive cancers to treat⁹



POG

¹ ACS (American Cancer Society) 2024 Cancer Facts and Figures Annual Report. ² Chang et al 2016. J Urol. 196:1021-1029. ³ Mossanen et al. World J Urol. 2019;37(10):2059-2065. ⁴ Berger et al. Can Urol Assoc J. 2018;13(7):E190-e201. ⁵ Sadowski et al. Urol Oncol. 2018;36(3):89.e87-89.e11. ⁶ Pak et al. Urology. 2017;103:117-123. ⁷ Sylvester et al. Eur Uro. 2006 Mar;49(3):466-5; discussion 475-7. ⁸ SEER Cancer Stat Facts: Bladder Cancer. https://seer.cancer.gov/statfacts/html/urinb.html. ⁹ Abdalla Aly, et al. J Clin Pathw. 2020 May; 6(4): 51-60.

NMIBC Represents a Multi-Billion Institution Dollar Market Opportunity in Bladder Cancer

~75% of Newly Diagnosed Bladder Cancer Cases are NMIBC

~25% of Newly Diagnosed Bladder Cancer Cases are MIBC

> Muscle Invasive Bladder Cancer

NMIBC



The Patient Journey

Patient presents to primary care and/or urologist with symptoms (hematuria, urinary frequency)

Testing

Work-up may include cystoscopy, urine cytology, and imaging (CT scan, MRI)

Suspicion of Cancer



TURBT, followed by tumor ^V staging and grading



Nadofaragene, N-803 + BCG

9

¹TURBT = Transurethral Resection of Bladder Tumor. ² Due to BCG shortage, NCCN guidelines no longer recommend BCG therapy for Intermediate-Risk patients.

FDA Guidance on BCG-Unresponsive NMIBC De-Risks Development & Regulatory Pathway to BLA Approval

Single-arm trials with complete response rate as primary endpoint in the context of duration of response may be appropriate for a full approval.

BCG-unresponsive disease defined as either:

- Persistent or recurrent CIS alone or with recurrent Ta/T1 disease within 12 months of adequate BCG therapy
- Recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG therapy, or
- T1 high-grade disease following a BCG induction course.

Adequate BCG therapy is defined as at least 5 doses of induction course plus at least 2 doses of maintenance therapy, or at least 5 doses of induction plus at least 2 doses of second induction.

- 2018 FDA Guidance for BCG-Unresponsive NMIBC

Three Therapeutic Agents Approved for Full Approval Following Issuance of FDA Guidance*

Pembrolizumab Approved in January 2020

Nadofaragene Approved in December 2022

N-803 plus BCG combo Approved in April 2024

Patient aversion to radical cystectomy associated with significant change in daily routine, surgeryrelated complications, and mortality rate drives regulatory and sponsor development pathways.



Oncolytic Immunotherapy: Cretostimogene's Dual Mechanism of Action





Cretostimogene Selectively Targets Rb-E2F Pathway Defective Cancers



- E2F is a master regulator of gene expression and Cell Cycle Progression
- In human cancers, which consistently have retinoblastoma (Rb) pathway-defective cells, Rb cannot bind to E2F due to reasons including:
 - Rb is hyper-phosphorylated (P)
 - Rb is deleted / silenced
- As a result, Cretostimogene selectively replicates inside tumor cells with dysfunctional Rb pathways to cause selective cancer cell lysis and immunogenic cell death

Cretostimogene is Intravesically Administered into the Bladder, Similar to Standard-of-Care BCG Therapy Which Urology Practices Perform Regularly

Procedure Can Be Prepared and Administered By: Medical Assistant, Nurse, Nurse Practitioner, Physician Assistant, or Urologist



Ease of Delivery and Administration for Patients, Physicians, and Practice Providers

	Delivery and Administration
Cold chain and stability	Commercial product will be shipped via Just-In-Time delivery with multi-day stability in the box until administration
Time required for thaw	~10 minutes
Time required for preparation	~10 minutes
Prepared and administered by	Medical Assistant, Nurse, Nurse Practitioner, Physician Assistant, or Urologist via urinary catheter
Biosafety handling	Any site (community or academic) that administers BCG or intravesical chemotherapy can prepare cretostimogene
Monitoring time after administration	No monitoring requirement for commercial setting; 30 minutes in clinical trials setting

Cretostimogene



Our Goal is to Establish Cretostimogene as Backbone Therapy for High-Risk and Intermediate-Risk NMIBC Patients

All Bladder Cancer (U.S. Incidence ~83,000 Patients/Year; Prevalence ~725,000 Patients)



BOND-003



Phase 3 Cretostimogene Monotherapy for BCG-Unresponsive, High-Risk NMIBC (NCT04452591)

BCG-Unresponsive NMIBC	Cretostimogene Single-Arm, Open-Label, Intravesical Administration	CR at Any Time (CIS) EFS (Ta/T1)
Trial Design	Study Design / Regimen	Additional Endpoints
 Pathologically confirmed BCG- Unresponsive, High-Risk NMIBC CIS or Ta/T1 Have all Ta/T1 disease resected prior to treatment Trial designed to be compliant with 2018 FDA guidance 	 Cohort C = BCG-unresponsive, High-Risk NMIBC CIS with or without Ta/T1 (n=112) Induction course = Weekly x 6 (1x10¹² vp/mL) Second induction course¹ = Weekly x 6 (1x10¹² vp/mL) for non-responders Maintenance courses = Weekly x 3 (1x10¹² vp/mL) for complete responders every 3 months for first 12 months, every 6 months for next 24 months 	 Cohort C DoR CR at 12 months PFS Cohort P
 Mandatory bladder mapping at 12-months² 	 Cohort P = BCG-unresponsive, High-Risk NMIBC Ta/T1 without CIS (up to n=75) Same as Cohort C 	RFSPFS



BOND-003 Patient Demographics & Baseline Characteristics

Subjects in Efficacy 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	93 83.0	
BCG History: Number of Prior Instillations		
Median (Range)	12 (7 – 66)	
High-Risk NMIBC T-Stage at Study Entry		
CIS with T1	6	5.3
CIS with Ta HG	16	14.3
CIS	90	80.4

- Majority of patients are:
 - Male (74%)
 - White (61%)
 - o > 65 years (83%)
- Study included highly pretreated population
 - Patients with prior intravesical chemotherapy and systemic immunotherapy were allowed on study

Cretostimogene Monotherapy Results in Cohort C: Largest Dataset in BCG-Unresponsive, High-Risk NMIBC



BOND-003

Landmark Analysis	Actual CR Rate, % (95% CI)
6-month	64.8% (54.8, 73.7) 68 out of 105 patients
12-month	43.3% (33.1, 54.2) 39 out of 90 patients

Landmark analysis based on actual landmark CR rate assessed in clinical trial, not Kaplan-Meier estimate.

- As of data cutoff, there are 15 patients in CR pending further assessment and evaluation at 12-month landmark timepoint
- All complete responses are centrally confirmed¹
- Landmark analysis at all timepoints compare favorably to approved agents

Efficacy data cutoff as of April 1, 2024. Efficacy analysis are centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance. ¹ 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.



AUA 2024: Updated Results from BOND-003 Cohort C

Cretostimogene Monotherapy for BCG-Unresponsive, High-Risk NMIBC

→ Ongoing Response
 Complete Response

- Recurrence / Non-Response
- Second Induction

🗱 Discontinued Study

BOND-003

- Re-induction allowed per protocol and cretostimogene's mechanism of action as an oncolytic immunotherapy agent¹
- 54% of re-induction patients converted to CR
- 96.7% PFS at 12-months and 92.4% CFS at 12-months compares favorably to both approved and investigational agents

Efficacy data cutoff as of April 1, 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.



Cretostimogene Has Been Generally Well-Tolerated

Preferred Term	Cretostimogene (n=112)			
(MedDRA v.26.1)	Any Grade (%)	Grade ≥ 3		
Patients with \geq 1 TRAE	70 (62.5%)	0 (0)		

Treatment-Related AE reported in >10% patients

BOND-003

Bladder Spasm	26 (23.2%)	0 (0)
Pollakiuria	22 (19.6%)	0 (0)
Dysuria	17 (15.2%)	0 (0)
Micturition Urgency	17 (15.2%)	0 (0)
Hematuria	16 (14.2%)	0 (0)

- No Grade ≥ 3 treatment-related AEs or deaths reported
- Most AEs were Grade 1-2
- 2 patients (1.8%) had serious treatment-related AEs (Grade 2)¹
- 1 patient discontinued treatment due to unrelated AE²
- 94.5% of patients completed all protocol-mandated treatments and had a 100% instillation success rate



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

BCG-Unresponsive NMIBC	Cretostimogene Single-Arm, Open-Label, IVe Creto + IV Pembrolizumab	CR at 12-months
Trial Design	Study Design / Regimen	Additional Endpoints
 Pathologically confirmed high-risk NMIBC BCG- unresponsive CIS with or without Ta/T1 Have all Ta/T1 disease resected prior to treatment Trial designed and compliant with 2018 FDA guidance 	 Cretostimogene Induction = Weekly x 6 (1x10¹² vp/mL) Second induction course¹ = Weekly x 3 or 6 (1x10¹² vp/mL) for responders, 6 for non-responders Maintenance courses² = Weekly x 3 (1x10¹² vp/mL) for complete responders 	 CR at Any Time DoR CR at 24-months PFS Safety
 Mandatory bladder mapping at 12-months³ 	 Pembrolizumab = Every 6 weeks (400 mg) through Year 2 	

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. ³ All patients required to undergo mandatory systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR.



Cretostimogene Combo with Pembrolizumab: Potential Class-Leading Response

Overall Complete Response

	100 -	82.9%
		(95% Cl, 66% - 93%)
ate (%)	75 -	
I CK K	50 -	CR
Uveral	25 -	(n=29)
	0 -	

CORE-001

Landmark Analysis	Actual CR Rate, % (95% CI)	CR by KM Estimate, % (95% CI)
12-month	57.1% (39.5, 73.2) 20 of 35 patients	77.3% (58.1, 88.5)
24-month	54.3% (36.9, 70.8) 19 of 35 patients	69.6% (49.4, 83.0)

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

- 95% of patients in a CR at 12-months (19 of 20) maintained a CR for another 12 months
- 100% PFS at 24-months with 0 patients progressing to muscle-invasive disease
- 80.0% CFS at 24-months; 100% CFS for patients in CR
- Median follow-up 26.5 months
 - Median DoR not met, > 21 months

(n=35)



CORE-001

Favorable Safety Profile with No Overlapping or Synergistic Toxicity in Combination of Cretostimogene and Pembrolizumab

Professed term n (%)	Maximum Severity					
Freierred term, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
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)

 AEs attributed to cretostimogene were low grade and selflimited

 No Grade 3-5 cretostimogene treatment-related AEs

- irAEs exclusively associated with pembrolizumab
- 5 treatment discontinuations observed prior to 12-month timepoint, all unrelated AEs
- No treatment-related deaths

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 treatment-related AEs. There were no grade 4-5 pembrolizumab treatment-related AEs.



Landscape

Pioneering Class-Leading Oncolytic Immunotherapy with Differentiated Clinical Profile Against Approved and Investigational NMIBC Agents¹

Trial	BOND-003	CORE-001	QUILT 3.032	NCT02773849	KEYNOTE-057	SunRISe-1	LEGEND
Intervention	Cretostimogene	Cretostimogene + Pembrolizumab	N-803 + BCG	Nadofaragene	Pembrolizumab	TAR-200	EG-70
Mechanism	Oncolytic Immunotherapy	Oncolytic Immunotherapy + Checkpoint Inhibitor	IL-15 Superagonist + BCG combo	Gene Therapy Secreting IFN	Checkpoint Inhibitor	Local Delivery of Gemcitabine via In-Dwelling Device	RIG-I Agonist + IL-12
RoA	Intravesical	Intravesical + Intravenous	Intravesical	Intravesical	Intravenous	Transurethral Procedure	Intravesical
Stage	Phase 3 Enrollment Complete	Phase 2 Complete	Approved	Approved	Approved	Phase 2 Ongoing	Phase 1/2 Ongoing
Sample Size	N=112	N=35	N=77	N=98	N=96	N=85	N=<24 (Phase 1) N=~100 (Phase 2)
CR at Any Time	75% (79/105) [95% Cl: 65% - 83%]	83% (29/35) [95% Cl: 70% - 95%]	62.3% (48/77) [95% Cl: 51% - 73%]	51% (50/98) ³ [95% CI: 41% - 61%]	41% (39/96) [95% Cl: 31% - 51%]	83% (48/58) [95% Cl: 70% - 91%]	73% (16/22) ⁴ [95% Cl: Not Reported]
CR at 12 Mo	43% (39/90) ⁴	57% (20/35)	36% (28/77) ²	24% (25/103)	19% (18/96)	39% (12/31) ⁴	Not Reported
CR at 24 Mo	Pending Assessment	54% (19/35)	25% (19/48) ²	19% (20/103)	Not Reported	Not Reported	Not Reported
DoR ≥ 12 Mo (Non-KM)	Pending Assessment	65%	58%	46%	46%	Not Reported	Not Reported
DoR ≥ 12 Mo (KM Estimate)	Pending Assessment	82%	Not Reported	Not Reported	Not Reported	75%	Not Reported
Safety Profile	0% Grade 3+ TRAE 0% treatment-related discontinuation	0% Grade 3+ creto-related AEs irAEs exclusively pembro-associated; 5 unrelated treatment discontinuations	16% SAE, including fatal adverse reaction of cardiac arrest in one patient on treatment; 7% treatment-related discontinuation	4% Grade 3+ TRAE 3% treatment-related discontinuation	11% Grade 3 TRAE 2% Grade 4 TRAE 11% treatment-related discontinuation	8.2% Grade 3 treatment-related AEs 4.7% serious TRAE 4.7% treatment-related discontinuation	5% Grade 3+ TEAE Discontinuation not disclosed

¹ These data are not based on head-to-head or comparator studies. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies. From published data. ² Derived from ANKTIVA® plus BCG Package Insert (April 2024) using DOR ≥ 12 months and DOR ≥ 24 months to estimate 12 months and 24 months landmark CR rate. ³ ADSTILADRIN® Package Insert (December 2022) and Summary Basis for Regulatory Action. ⁴ LifeSci Capital Analyst Report – May 3, 2024.

References: Merck: (FDA & ODAC presentation slides, NDA/BLA# 125514s-066 for pembrolizumab (https://www.fda.gov/media/133956/download), Balar, AB et al. Lancet Onc. Epub ahead of print. 2021 May 26.); FerGene: (Boorjian et al. Lancet Oncol. 2021 Jan;22(1):107-117. Epub 2020 Nov 27) (Narayan et al. Journal of Urology. April 2024 doi:10.1097/JU.00000000000002020). ImmunityBio (ANKTIVA® plus BCG Package Insert; FDA Approval Letter). Janssen (SunRISe-1 – AUA 2024), CG Oncology (BOND-003 – AUA 2024, Abstract #24-11358; CORE-001 – ASCO 2024 – Abstract #4601).



PIVOT-006

Phase 3 Adjuvant Cretostimogene Following TURBT Versus Surveillance Following TURBT for Intermediate-Risk NMIBC

Intermediate-Risk NMIBC (Actively Enrolling)	Cretostimogene vs Surveillance/TURBT Randomized (1:1), Two Arms, Open-Label (n=364)	RFS Rate
Population	Study Design / Regimen	Additional Endpoints
 Pathologically confirmed Intermediate-Risk NMIBC Recurrent LG Ta < 12mo Solitary LG Ta > 3cm LG Ta multifocal HG Ta ≤ 3cm LG T1 All disease removed by TURBT at baseline 	 Arm A = Cretostimogene following TURBT Induction course = Weekly x 6 (1x10¹² vp/mL) Maintenance courses¹ = Weekly x 3 (1x10¹² vp/mL) for complete responders Arm B = Surveillance following TURBT Patients with disease recurrence eligible to receive cretostimogene 	 RFS at 12-month and 24-month PFS Safety



CG Oncology Highlights

Potential backbone oncolytic immunotherapy targeting a multi-billion dollar market opportunity in lead indication with significant unmet need

Opportunity to expand into additional billion-dollar bladder indications

ONCOLOGY

2

3

Attacking Bladder Cancer for a Better Tomorrow™

Demonstrated clinical utility and observed tolerability drives further combination development strategies

Highly concentrated U.S. customer base enables focused execution in sales and marketing for commercialization

Experienced leadership team, seasoned CMC advisory board, and quality Life Sciences-focused investors



Attacking Bladder Cancer for a Better Tomorrow[™]

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