



Attacking Bladder Cancer  
for a Better Tomorrow™



# Disclaimer and Forward-Looking Statements

We caution you that this presentation contains forward-looking statements about us and our industry. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene and any future product candidates, the timing and likelihood of regulatory filings and approvals for cretostimogene and any future product candidates, our ability to commercialize cretostimogene and any future product candidates, if approved, the pricing and reimbursement of cretostimogene and any future product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and potential to enter into any future strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions.

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# Investment Summary

**Cretostimogene grenadenorepvec is an oncolytic immunotherapy 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	MILESTONES
<b>Cretostimogene Monotherapy</b> BCG-Unresponsive, High-Risk NMIBC (BOND-003)				BOND-003 Cohort C pivotal data expected in 2H'24
<b>Cretostimogene + Pembrolizumab</b> BCG-Unresponsive, High-Risk NMIBC (CORE-001)				CORE-001 24-month data at ASCO 2024
<b>Cretostimogene Monotherapy</b> Intermediate-Risk NMIBC (PIVOT-006)				PIVOT-006 in active recruitment; complete enrollment expected in 1H'26
<b>Cretostimogene (Mono/Combo)</b> High-Risk NMIBC (CORE-008) <sup>1</sup>				Initiate CORE-008 in 2H'24

Expected cash runway through 2027

<sup>1</sup> 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  
 Planned Studies

# Executive Leadership Team

Deep Industry Experience with Track Record of Success in Drug Development



**Arthur Kuan**  
Chairman & CEO

Business Insider's 30 People Under 40 Who Are Transforming Healthcare

2020 Forbes 30 Under 30 featured honoree in healthcare



**Ambaw Bellete**  
President & COO

30+ Years in Biotech & Life Sciences with multiple BLA approvals & launch experience  
Chairman of the Board for OncoSTING  
Board member of Axiom Reach Foundation



**Vijay Kasturi, M.D.**  
Chief Medical Officer

25+ Years as GU Medical Oncologist  
Managed Launch Plan for BAVENCIO®



**Swapnil Bhargava, Ph.D.**  
Chief Technical Officer

Supported multiple INDs, BLAs, and modalities to the clinic and market  
(TIVDAK®, PADCEV®, and ADCETRIS®)



**Corleen Roche**  
Chief Financial Officer

30+ Years in Biotech & Life Sciences  
CFO to publicly-traded companies with extensive commercial experience  
(PREVNAR 13®, ZARXIO®, GLATOPA™)



**Joshua Patterson, Esq.**  
General Counsel & CCO

20+ Years as In-House Counsel in Biopharmaceutical Industry  
Over \$2.25B in transaction experience



# 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 year<sup>1</sup>

**725,000+**

people estimated living with bladder cancer in 2020 in the United States<sup>8</sup>

## Highly Recurrent Disease With Few Treatment Options

**~15%-61%**

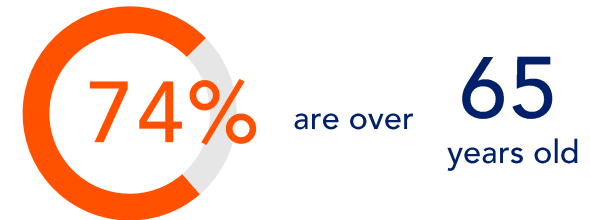
of high-risk patients will recur within 1 year<sup>7</sup>



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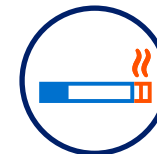
Bladder Cancer is one of the most expensive cancers to treat<sup>9</sup>

## Patients are from High-risk Populations



**73** years is the median age

### Risk factors



Smoking



Exposure to carcinogens including agent orange



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

~75% of Newly Diagnosed Bladder Cancer Cases are NMIBC

~25% of Newly Diagnosed Bladder Cancer Cases are MIBC

Non-Muscle Invasive Bladder Cancer  
NMIBC

Muscle Invasive Bladder Cancer  
MIBC

Inside of the bladder wall

Bladder wall

Outside of the bladder wall

Lamina Propria

Inner Muscle

Deep Muscle

CIS

Carcinoma in Situ (CIS)

Ta

Non-Invasive Papillary Carcinoma

T1

Tumor Invades Connective Tissue

T2a

Tumor Invades Superficial Muscle

T2b

Tumor Invades Deep Muscle

T3

Tumor Invades Perivesical Tissue

T4

Tumor Invades Adjacent Tissue and Organs



# The Patient Journey

## 1 Symptoms

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

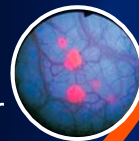
## 2 Testing

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

Suspicion of Cancer

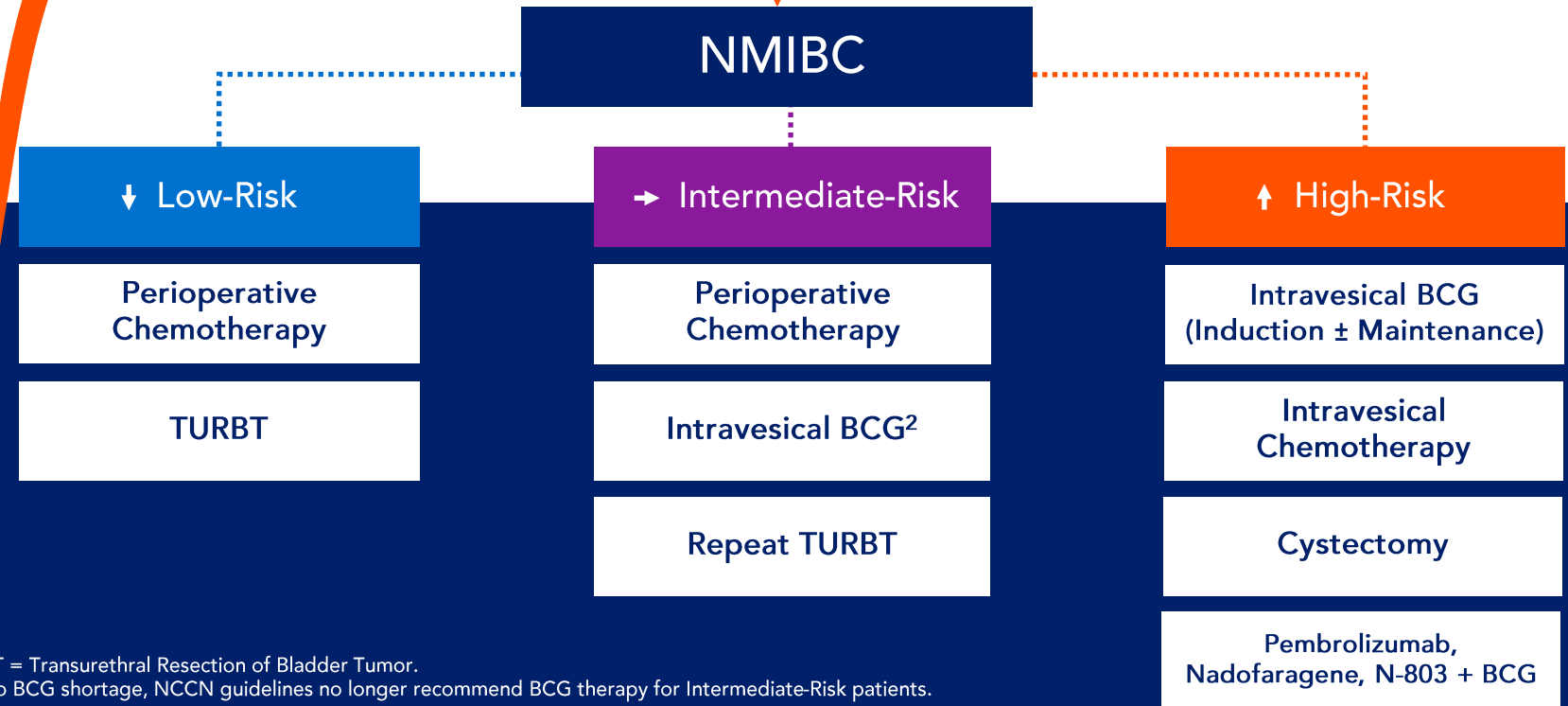
## 3 TURBT<sup>1</sup>

TURBT, followed by tumor staging and grading



## 4 Ongoing Treatment

Require surveillance and/or treatment every 3 to 6 months for 2 to 5 years



<sup>1</sup> TURBT = Transurethral Resection of Bladder Tumor.

<sup>2</sup> 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, surgery-related complications, and mortality rate drives regulatory and sponsor development pathways.

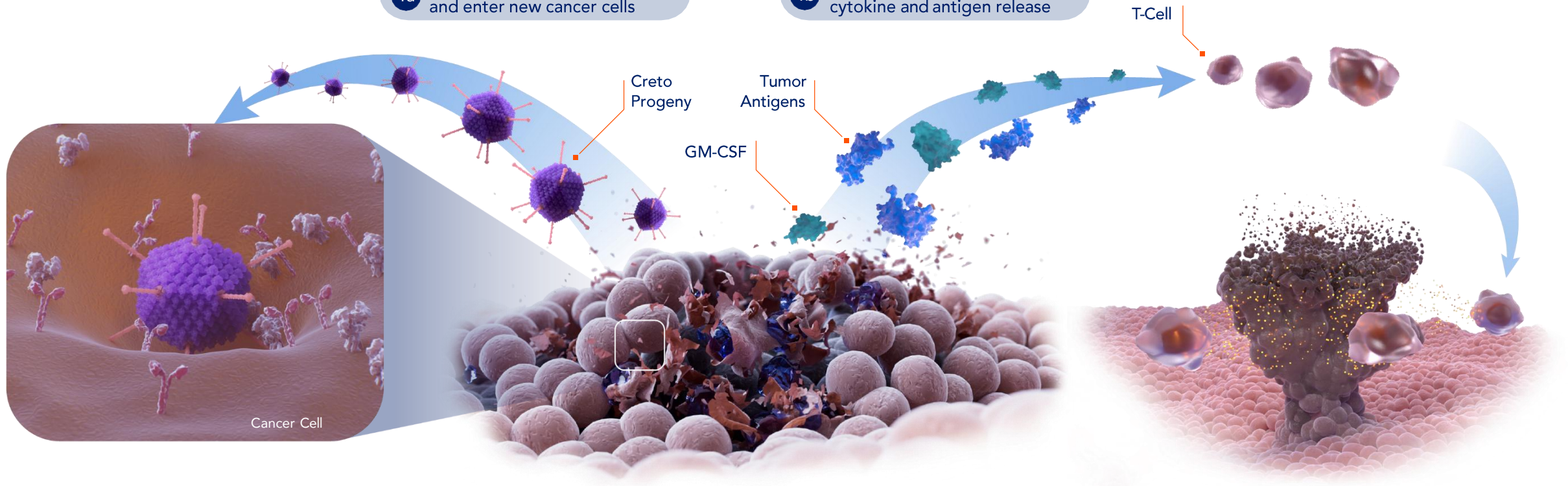
# Oncolytic Immunotherapy: Cretostimogene's Dual Mechanism of Action

1 Cretostimogene selectively replicates in and kills cancer cells

2 Immune cells attack and kill additional cancer cells

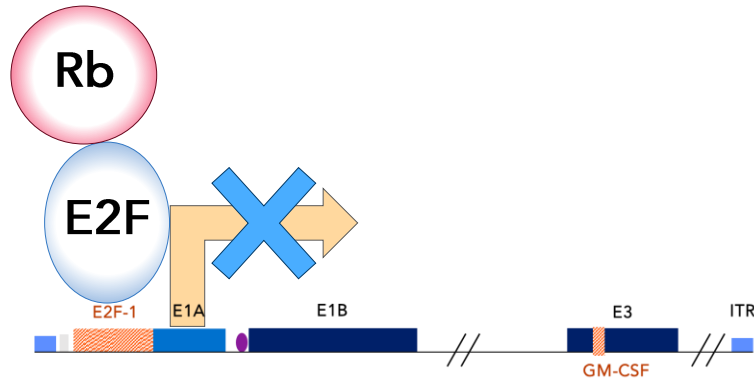
1a Progeny viruses are released and enter new cancer cells

1b Cretostimogene stimulates cytokine and antigen release

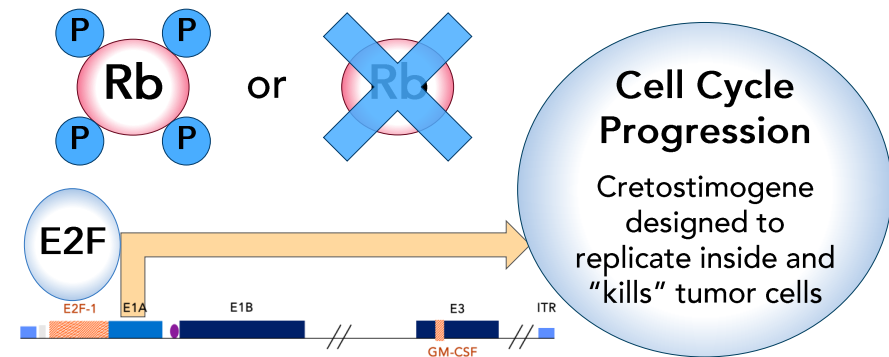


# Cretostimogene Selectively Targets Rb-E2F Pathway Defective Cancers

Cretostimogene grenadenorepvec  
in Normal Cells



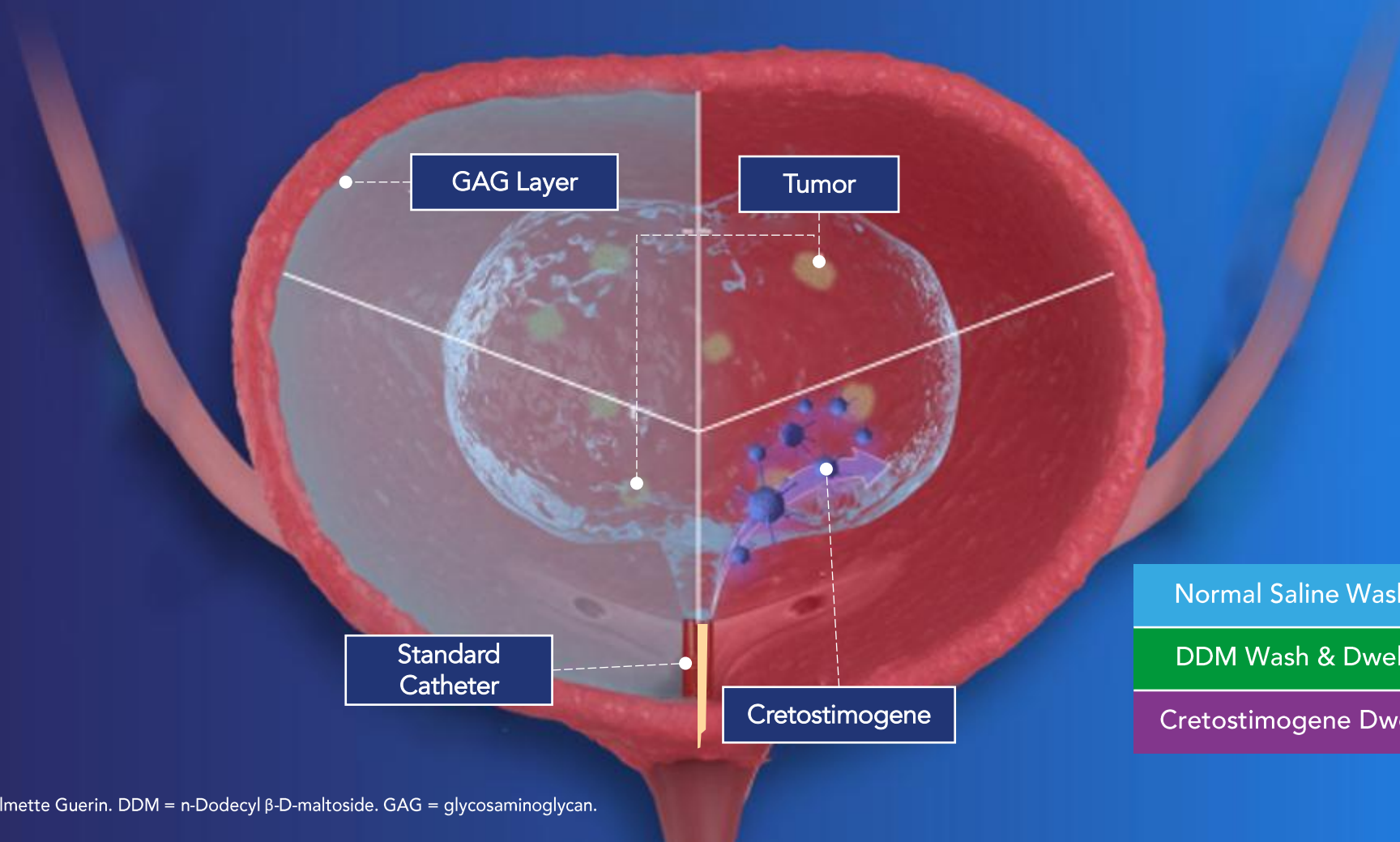
Cretostimogene grenadenorepvec  
in Tumor Cells



- 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



Normal Saline Wash	~5 minutes
DDM Wash & Dwell	~15 to 20 minutes
Cretostimogene Dwell	~45 to 60 minutes

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

	Delivery and Administration
Cold chain and stability at 2-8°C for at least 3 weeks	Commercial product will be shipped via Just-In-Time delivery with multi-day stability in the box; and at least 3 weeks at 2-8°C in a regular fridge until administration
Prepared and administered by	Medical Assistant, Nurse, Nurse Practitioner, Physician Assistant, or Urologist via urinary catheter
Biosafety handling	Any site that administers BCG or intravesical chemotherapy can prepare cretostimogene
Monitoring time after administration	No monitoring requirement expected for commercial setting; 30 minutes in clinical trials setting

# 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)

NMIBC (75%) (Non-Muscle Invasive Bladder Cancer)

Intermediate Risk (30%)

High Risk (40%)

TURBT  
(Transurethral Resection of the Bladder Tumor)

BCG-Naïve

CORE-008\*  
Multi-Cohort Study



BCG-Exposed

BCG-Unresponsive

PIVOT-006

Phase 3 Monotherapy



CORE-008\*

Multi-Cohort Study



BOND-003

Phase 3 Monotherapy



CORE-001

Phase 2 Checkpoint Combo



CORE-008\*

Multi-Cohort Study



Current Program

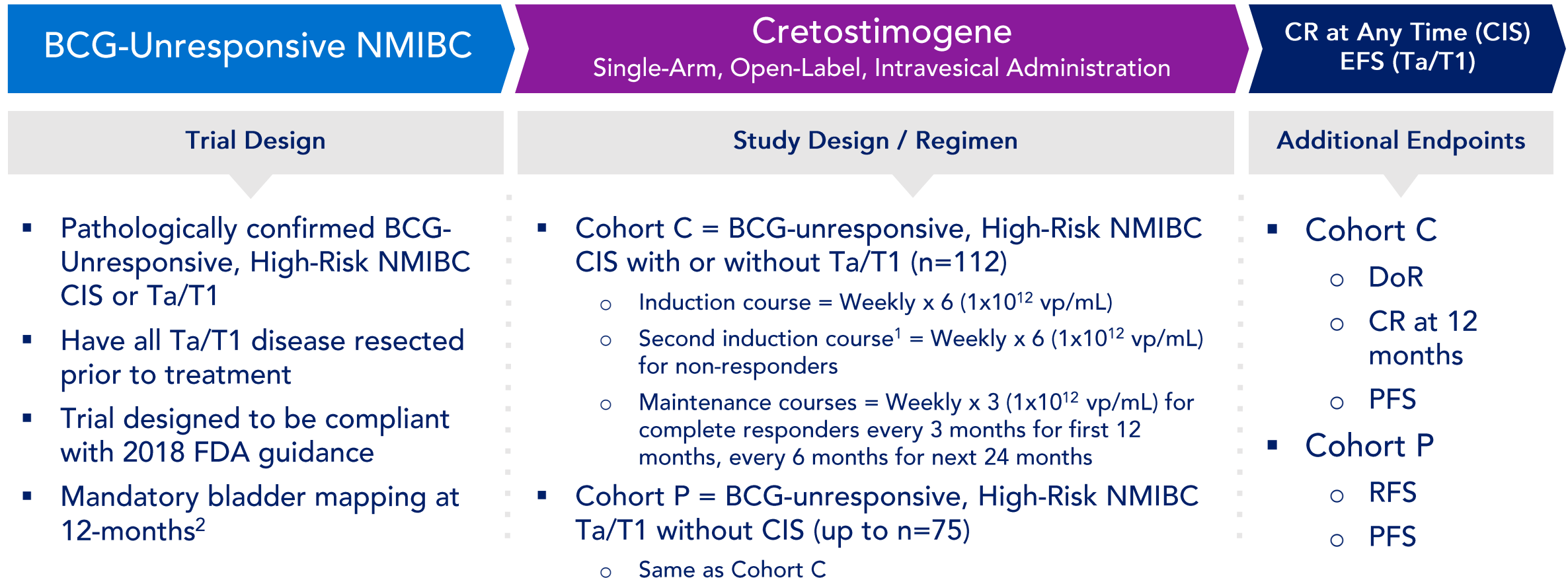


Planned Studies

\* CORE-008 is a multi-cohort planned study to evaluate cretostimogene in High-Risk NMIBC.



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



RFS = recurrence free survival. PFS = progression free survival

Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years, as well as mandatory bladder mapping at month 12.

<sup>1</sup>Second induction course of weekly x 6 for non-responders at month 3. <sup>2</sup>All patients required to undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR.

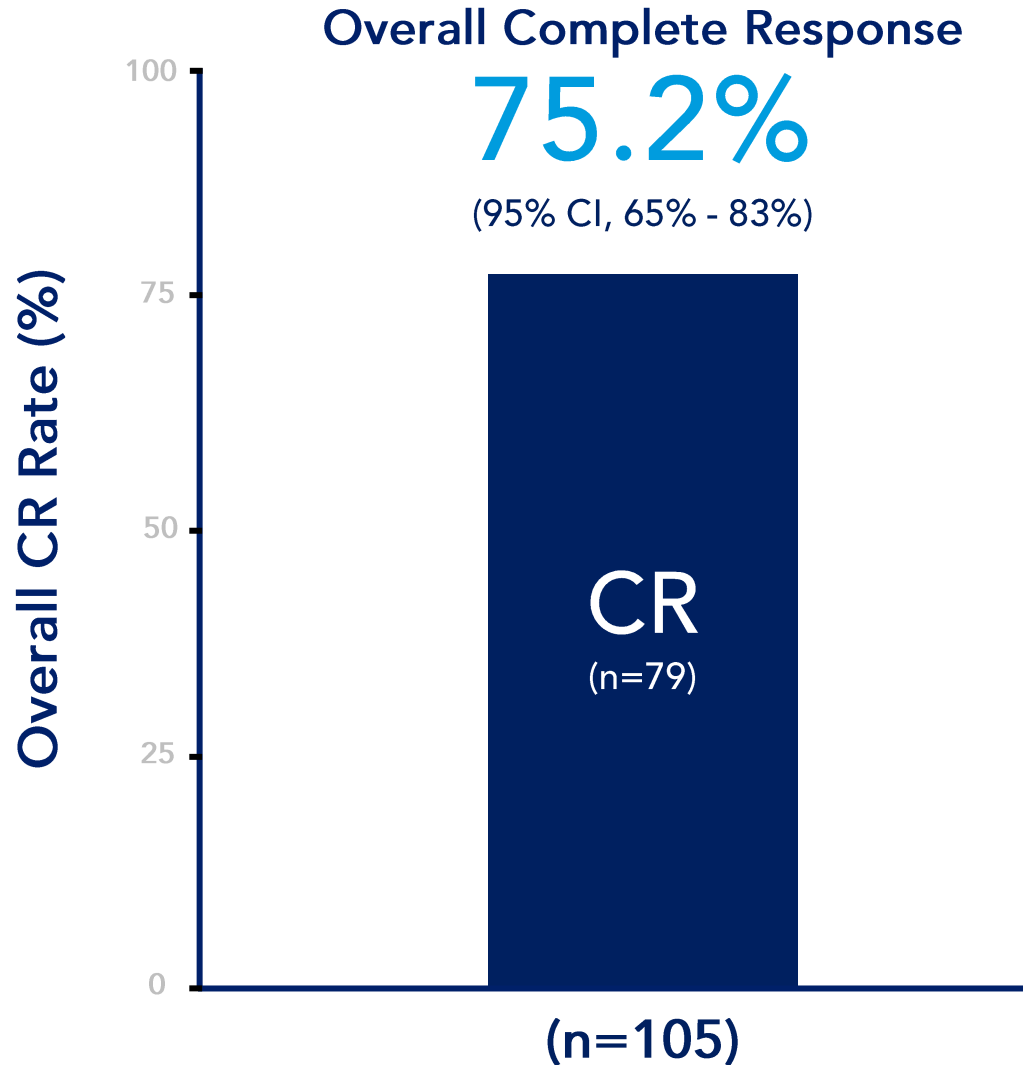


# Patient Demographics & Baseline Characteristics

Subjects in Efficacy Dataset	N=112	%
<b>Gender</b>		
Male	83	74.1
Female	29	25.9
<b>Age (Years)</b>		
Mean (SD)	72.9 (9.19)	
Median (Range)	74.0 (43-90)	
<b>Age (Categories)</b>		
< 65	19	17.0
> 65	93	83.0
<b>BCG History: Number of Prior Instillations</b>		
Median (Range)	12 (7 – 66)	
<b>High-Risk NMIBC T-Stage at Study Entry</b>		
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%)
  - > 65 years (83%)
- Study included highly pre-treated 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



CR 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.*

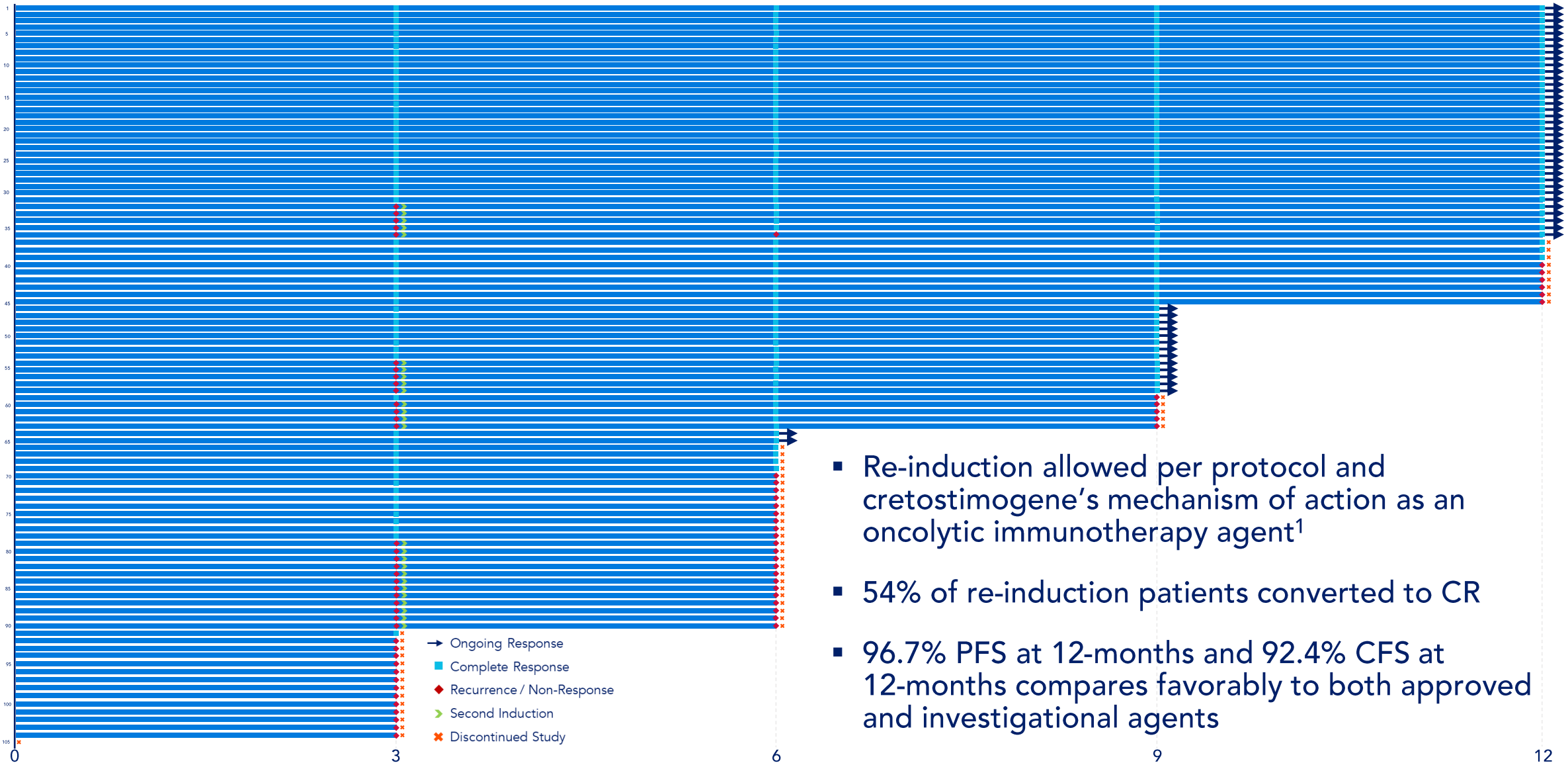
- As of data cutoff, there are 15 patients in CR pending further assessment and evaluation at 12-month landmark timepoint
- All complete responses are centrally confirmed<sup>1</sup>
- Landmark analysis at all timepoints compare favorably to approved agents

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.

<sup>1</sup> 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



- Re-induction allowed per protocol and cretostimogene’s mechanism of action as an oncolytic immunotherapy agent<sup>1</sup>
- 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

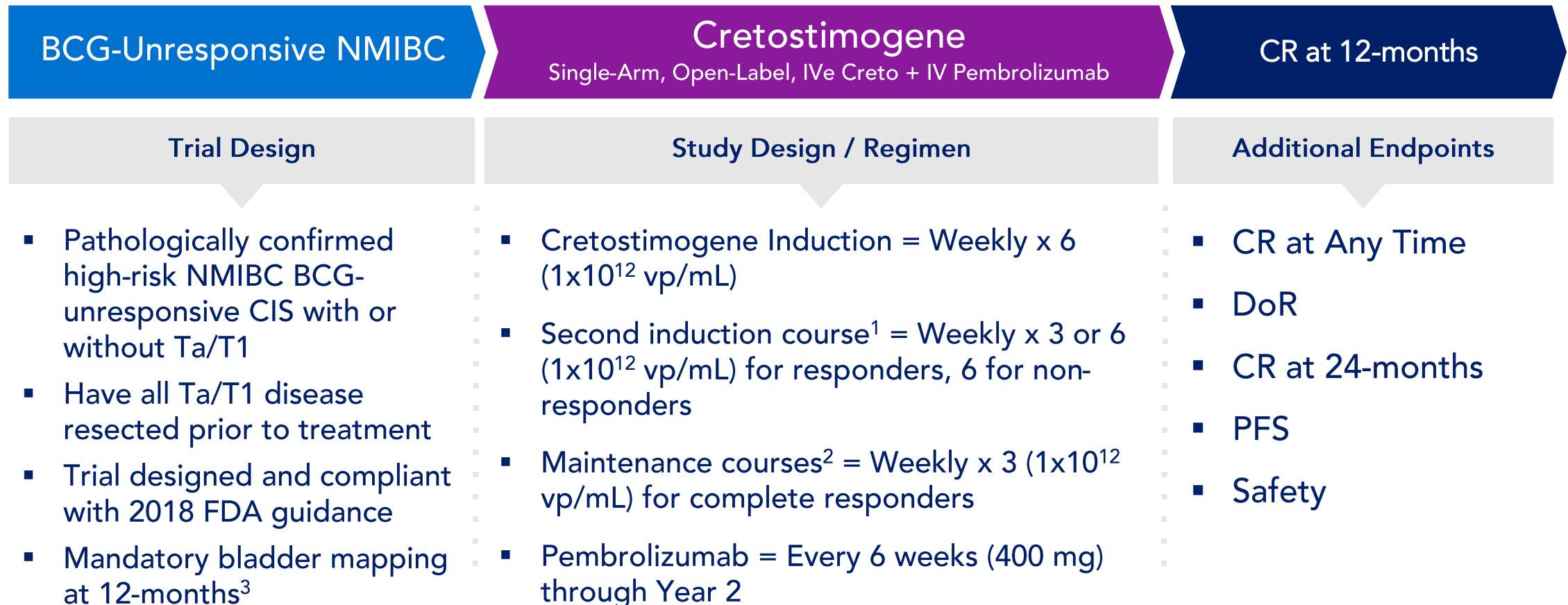
Efficacy data cutoff as of April 1, 2024. <sup>1</sup> Per 2018 FDA Guidance Document on BCG-Unresponsive NMIBC (page 6), sponsors should consider and discuss with the Agency a patient’s disease history, type of disease present at 3 months, and the mechanism of action of the investigational drug regarding patients with CIS who do not achieve a CR at their 3-month assessments.

# Cretostimogene Has Been Generally Well-Tolerated

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade ≥ 3
Patients with ≥ 1 TRAE	70 (62.5%)	0 (0)
Treatment-Related AE reported in >10% patients		
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)<sup>1</sup>
- 1 patient discontinued treatment due to unrelated AE<sup>2</sup>
- 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)A



CR = complete response. DoR = duration of response. PFS = progression free survival.

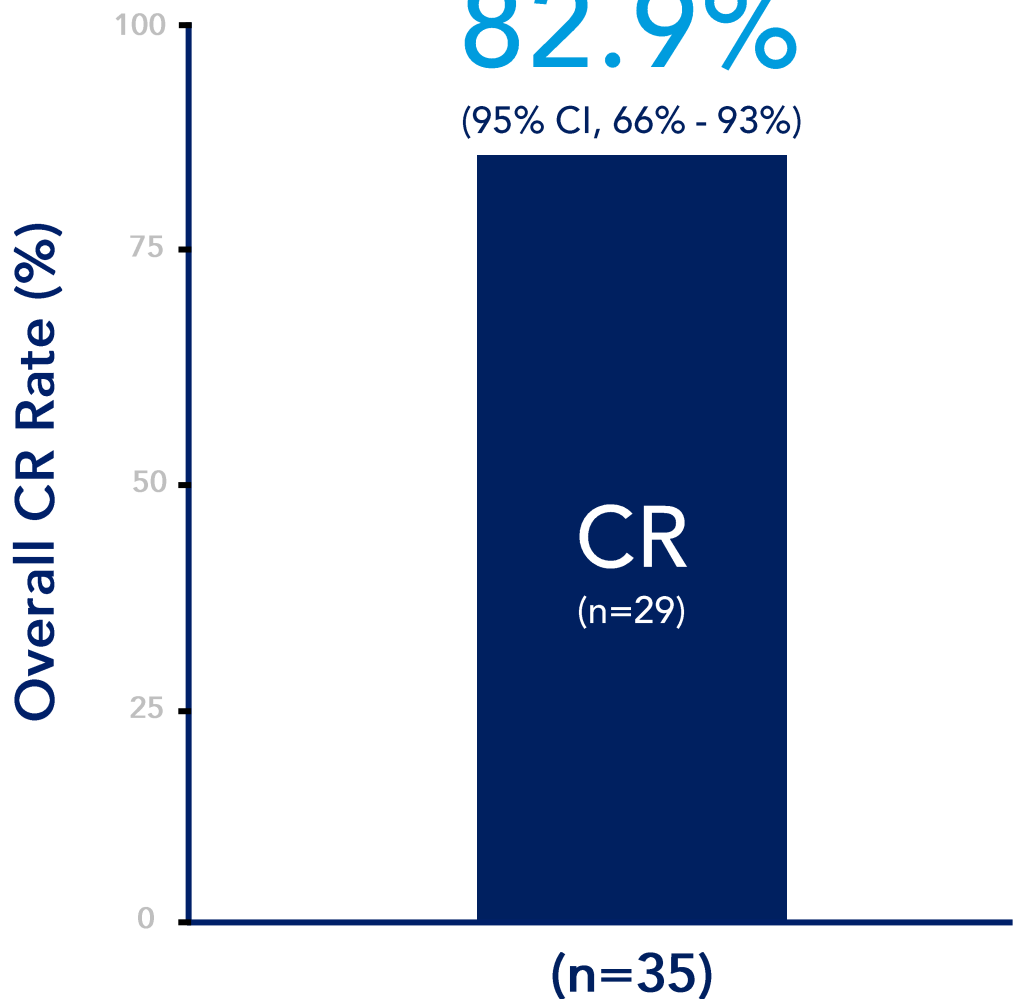
<sup>1</sup> Second induction course of weekly x 6 for non-responders at month 3. <sup>2</sup> Maintenance course for complete responders starts at month 3 every 3 months for 1st year, and every 6 months for 2nd year. <sup>3</sup> All patients required to undergo mandatory, systematic bladder mapping 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

**82.9%**

(95% CI, 66% - 93%)



CR 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<sup>1</sup>.*

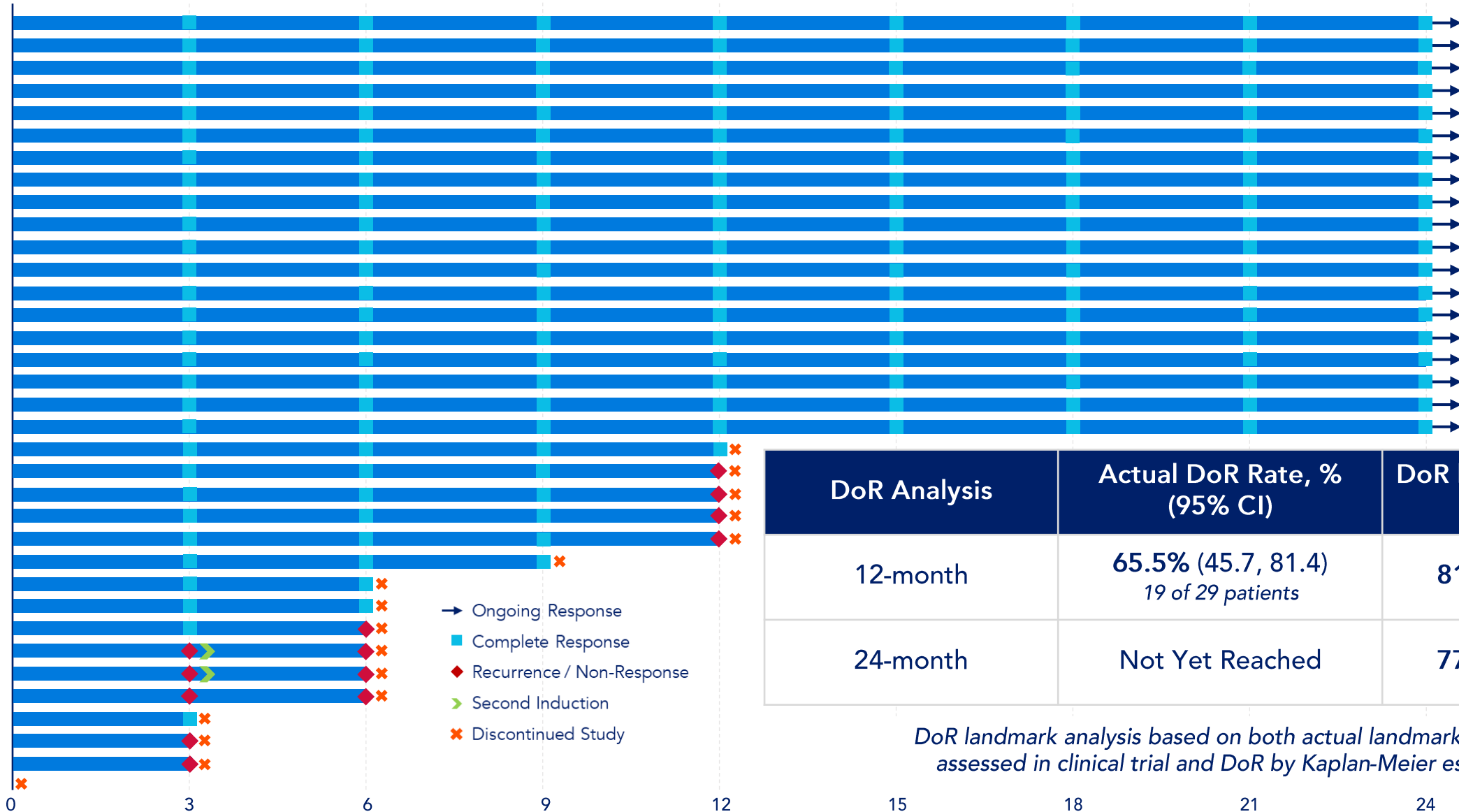
- 95% of patients in a CR at 12-months (19 of 20) maintained a CR for another 12 months
- 100% PFS at 24-months with 0 patients progressing to muscle-invasive disease
- 80.0% CFS at 24-months; 100% CFS for patients in CR
- Median follow-up 26.5 months
  - Median DoR not met, > 21 months

Efficacy data cutoff as of May 17, 2024. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance.

<sup>1</sup> CR by Kaplan-Meier estimate is based on HG RFS.

# ASCO 2024: Updated Long-Term Durability Data

## Cretostimogene + Pembrolizumab Combo for BCG-Unresponsive, High-Risk NMIBC



Efficacy data cutoff as of May 17, 2024.

DoR Analysis	Actual DoR Rate, % (95% CI)	DoR by KM Estimate, % (95% CI)
12-month	65.5% (45.7, 81.4) <i>19 of 29 patients</i>	81.6% (61.3, 91.9)
24-month	Not Yet Reached	77.3% (56.2, 89.1)

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

Complete Response Assessment (Months)

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

Preferred term, n (%)	Maximum Severity					
	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)

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.

- AEs attributed to cretostimogene were low grade and self-limited
- 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



## Landscape

# Pioneering Class-Leading Oncolytic Immunotherapy with Differentiated Clinical Profile Against Approved and Investigational NMIBC Agents<sup>1</sup>

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	<b>75% (79/105)</b> [95% CI: 65% - 83%]	<b>83% (29/35)</b> [95% CI: 70% - 95%]	62.3% (48/77) [95% CI: 51% - 73%]	51% (50/98) <sup>3</sup> [95% CI: 41% - 61%]	41% (39/96) [95% CI: 31% - 51%]	84% (71/85) [95% CI: 74% - 91%]	71% (15/21) [95% CI: Not Reported]
CR at 12 Mo	<b>43% (39/90)<sup>5</sup></b>	<b>57% (20/35)</b>	36% (28/77) <sup>2</sup>	24% (25/103)	19% (18/96)	39% (12/31) <sup>5</sup>	Not Reported
CR at 24 Mo	Pending Assessment	<b>54% (19/35)</b>	25% (19/77) <sup>2</sup>	19% (20/103)	9% (9/96) <sup>4</sup>	Not Reported	Not Reported
DoR ≥ 12 Mo (Non-KM)	Pending Assessment	<b>65%</b>	58%	46%	46%	Not Reported	Not Reported
DoR ≥ 12 Mo (KM Estimate)	Pending Assessment	<b>82%</b>	Not Reported	Not Reported	Not Reported	66%	Not Reported
Safety Profile	<b>0% Grade 3+ TRAE</b> <b>0% treatment-related discontinuation</b>	<b>0% Grade 3+ creto-related AEs</b> <b>irAEs exclusively pembro-associated;</b> <b>5 unrelated treatment discontinuations</b>	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	9.4% Grade 3 treatment-related AEs 5.9% serious TRAE 5.9% treatment-related discontinuation	4.2% Grade 3 TRAE 0% treatment-related discontinuation

<sup>1</sup> 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. <sup>2</sup> 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. <sup>3</sup> ADSTILADRIN® Package Insert (December 2022) and Summary Basis for Regulatory Action. <sup>4</sup> Derived from GU ASCO 2021, Balar et al presentation DOR ≥ 24 months to estimate 24-months landmark CR rate. <sup>5</sup> Goldman Sachs Equity Research – May 6, 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.; 2021 ASCO GU presentation); 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.0000000000004020). ImmunityBio (ANKTIVA® plus BCG Package Insert; FDA Approval Letter). Janssen (SunRISe-1 – ESMO 2024). enGene (Corporate Presentation and Press Release – September 2024). CG Oncology (BOND-003 – AUA 2024, Abstract #24-11358; CORE-001 – ASCO 2024 – Abstract #4601).

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

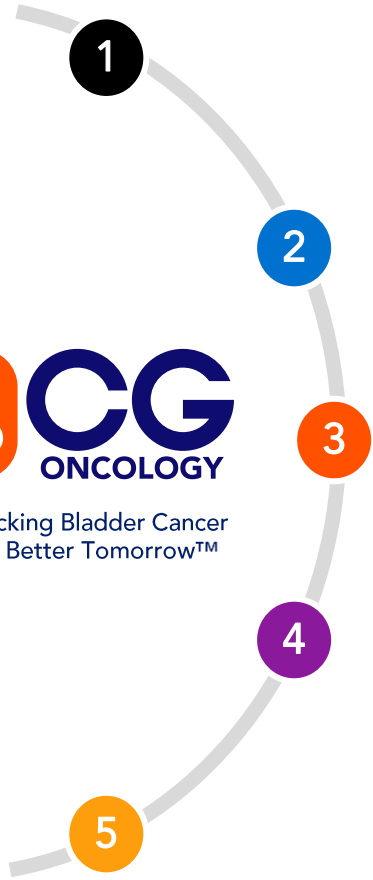
Intermediate-Risk NMIBC (Actively Enrolling)	Cretostimogene vs Surveillance/TURBT Randomized (1:1), Two Arms, Open-Label (n=364)	Primary Endpoint: RFS Rate
Population	Study Design / Regimen	Additional Endpoints
<ul style="list-style-type: none"> <li>▪ Pathologically confirmed Intermediate-Risk NMIBC                             <ul style="list-style-type: none"> <li>○ Recurrent LG Ta &lt; 12mo</li> <li>○ Solitary LG Ta &gt; 3cm</li> <li>○ LG Ta multifocal</li> <li>○ HG Ta ≤ 3cm</li> <li>○ LG T1</li> </ul> </li> <li>▪ All disease removed by TURBT at baseline</li> </ul>	<ul style="list-style-type: none"> <li>▪ Arm A = Cretostimogene following TURBT                             <ul style="list-style-type: none"> <li>○ Induction course = Weekly x 6 (1x10<sup>12</sup> vp/mL)</li> <li>○ Maintenance courses<sup>1</sup> = Weekly x 3 (1x10<sup>12</sup> vp/mL) for complete responders</li> </ul> </li> <li>▪ Arm B = Surveillance following TURBT                             <ul style="list-style-type: none"> <li>○ Patients with disease recurrence eligible to receive cretostimogene</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ RFS at 12-month and 24-month</li> <li>▪ PFS</li> <li>▪ Safety</li> </ul>

RFS = recurrence free survival. PFS = progression free survival.

Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years; mandatory, site-directed biopsy at month 12.

<sup>1</sup> Maintenance course for complete responders weekly x 3 at month 3 and month 6, and once every 3 months at month 9 and month 12.

# CG Oncology Highlights



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

2 Opportunity to expand into additional billion-dollar bladder indications

3 Demonstrated clinical utility and observed tolerability drives further combination development strategies

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

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



Attacking  
Bladder Cancer  
for a Better  
Tomorrow™

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