



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.

The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in our business, including, without limitation: we currently depend entirely on the success of cretostimogene, which is our only product candidate and is based on a novel approach to the treatment of cancer; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; results from earlier clinical trials and preclinical studies not necessarily being predictive of future results; unfavorable results from clinical trials; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; preliminary or interim data results are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and more patient data become available; our dependence on third parties in connection with manufacturing, shipping and clinical and preclinical testing; regulatory developments in the United States and foreign countries; our ability to obtain, maintain and enforce intellectual property protection for cretostimogene; we may use our capital resources sooner than we expect; we face significant competition; and other risks described in our filings with the SEC, including under the heading "Risk Factors" in the final prospectus dated January 24, 2024 we filed with the SEC and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

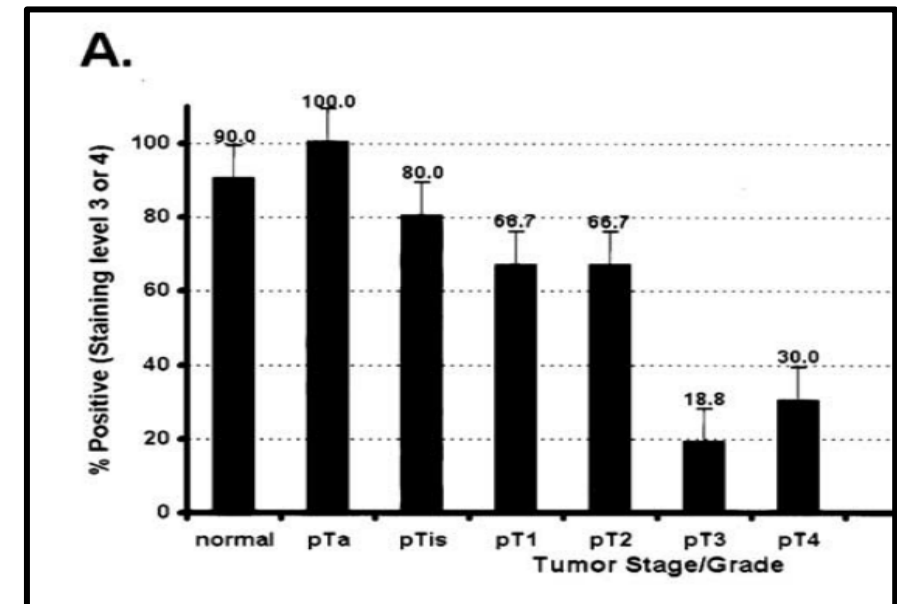
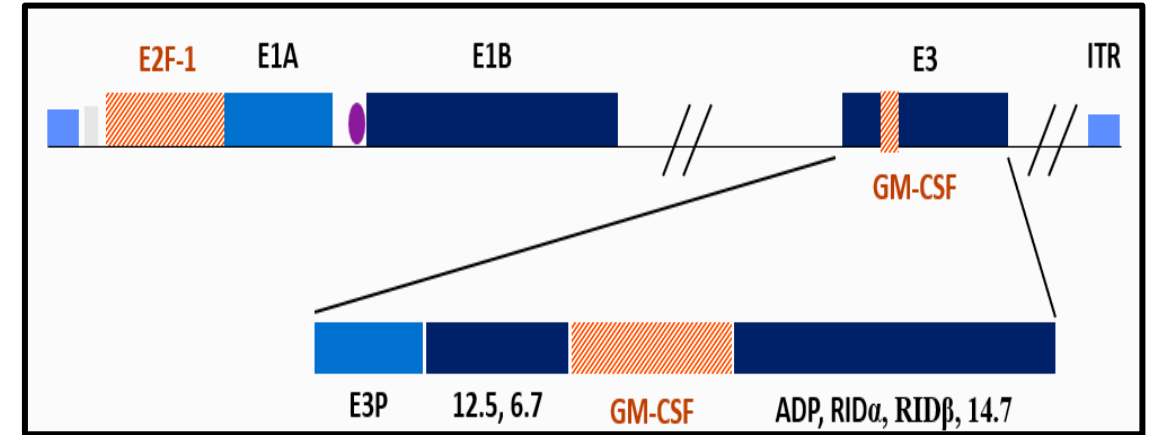
This presentation concerns products that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. It is currently limited by federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

Cretostimogene grenadenorepvec is an investigational engineered oncolytic immunotherapy (OIT). It is an investigational drug and is not approved by any regulatory agency. Its safety and efficacy has not been established. In BCG-unresponsive, Non-Muscle Invasive Bladder Cancer (NMIBC), cretostimogene has shown clinical benefit and has been generally well-tolerated as both a monotherapy and in combination with other therapies in clinical trials.

Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this presentation appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights to these trademarks and tradenames.

# What is Cretostimogene Grenadenorepvec?

- Conditionally replicating adenovirus
  - Highly immunogenic
- Oncolytic immunotherapy
  - 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



# Oncolytic Immunotherapy: Selective Oncolysis and Potent Anti-Tumor Immune Response

Spreads to additional tumor cells  
inducing a chain reaction of further  
cancer cell death

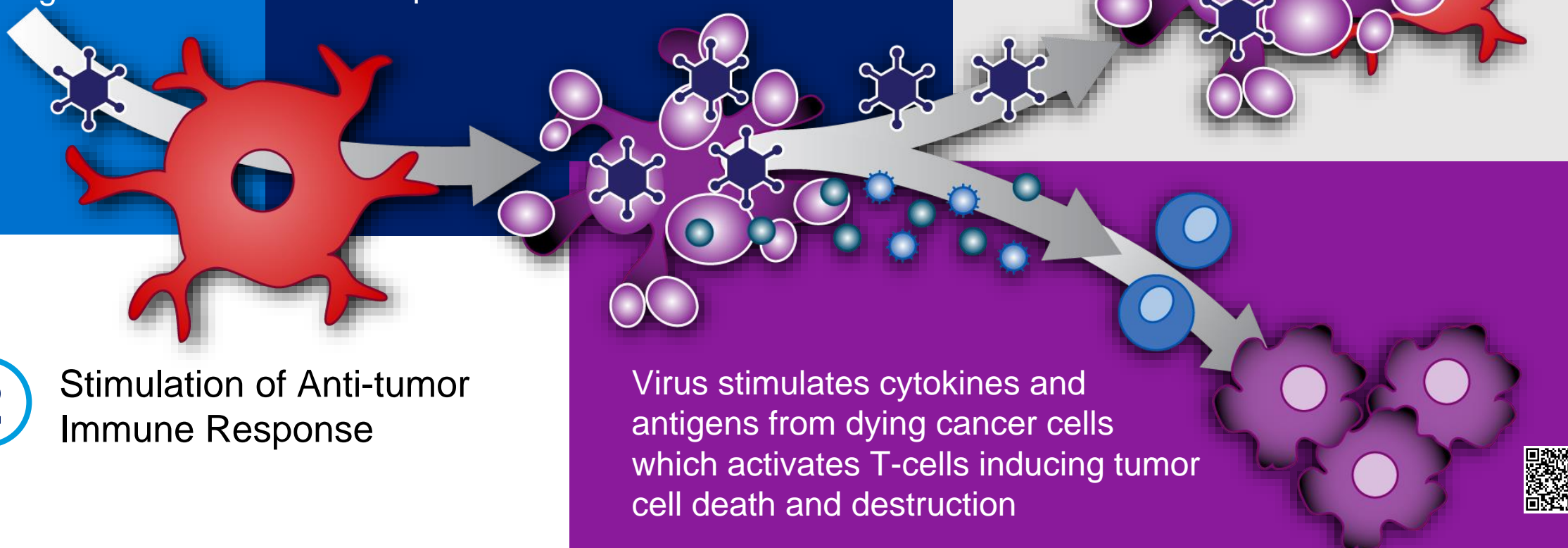
**1** Targets and Destroys  
Cancer Cells

Enters target cell

Replicates and kills the cell

**2** Stimulation of Anti-tumor  
Immune Response

Virus stimulates cytokines and  
antigens from dying cancer cells  
which activates T-cells inducing tumor  
cell death and destruction



# BOND-003: Phase-3 Single Arm, BCG-UR NMIBC with CIS

## Cohort C Population (N=112):

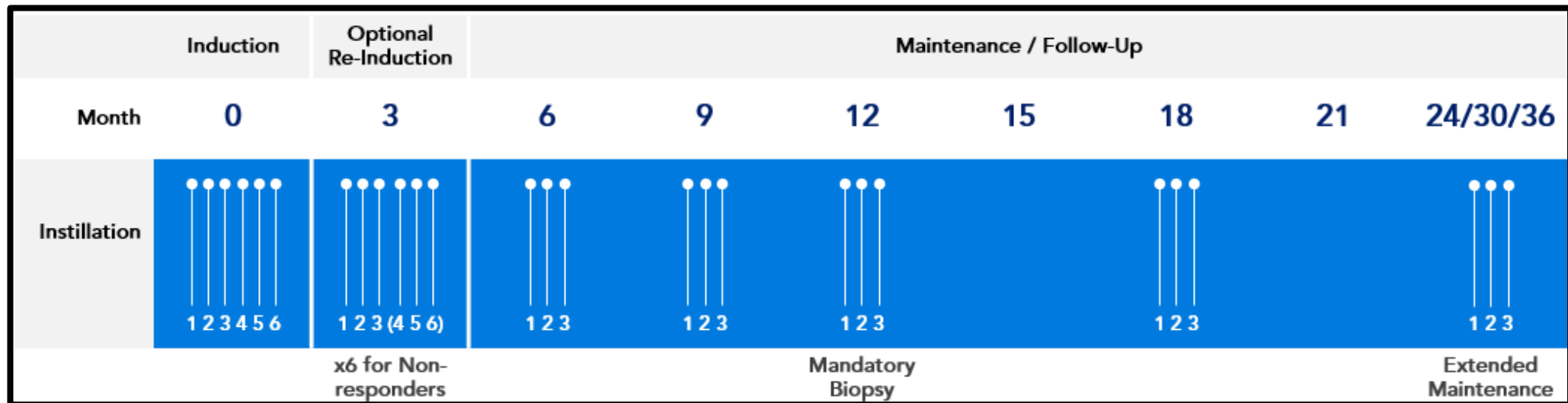
- Age  $\geq$  18 yo
- ECOG PS 0-2
- Pathologically confirmed BCG-UR HR NMIBC with CIS +/- papillary disease

## Primary Endpoint:

- CR at any time

## Secondary Endpoints:

- Duration of Response
- CFS, PFS, RFS



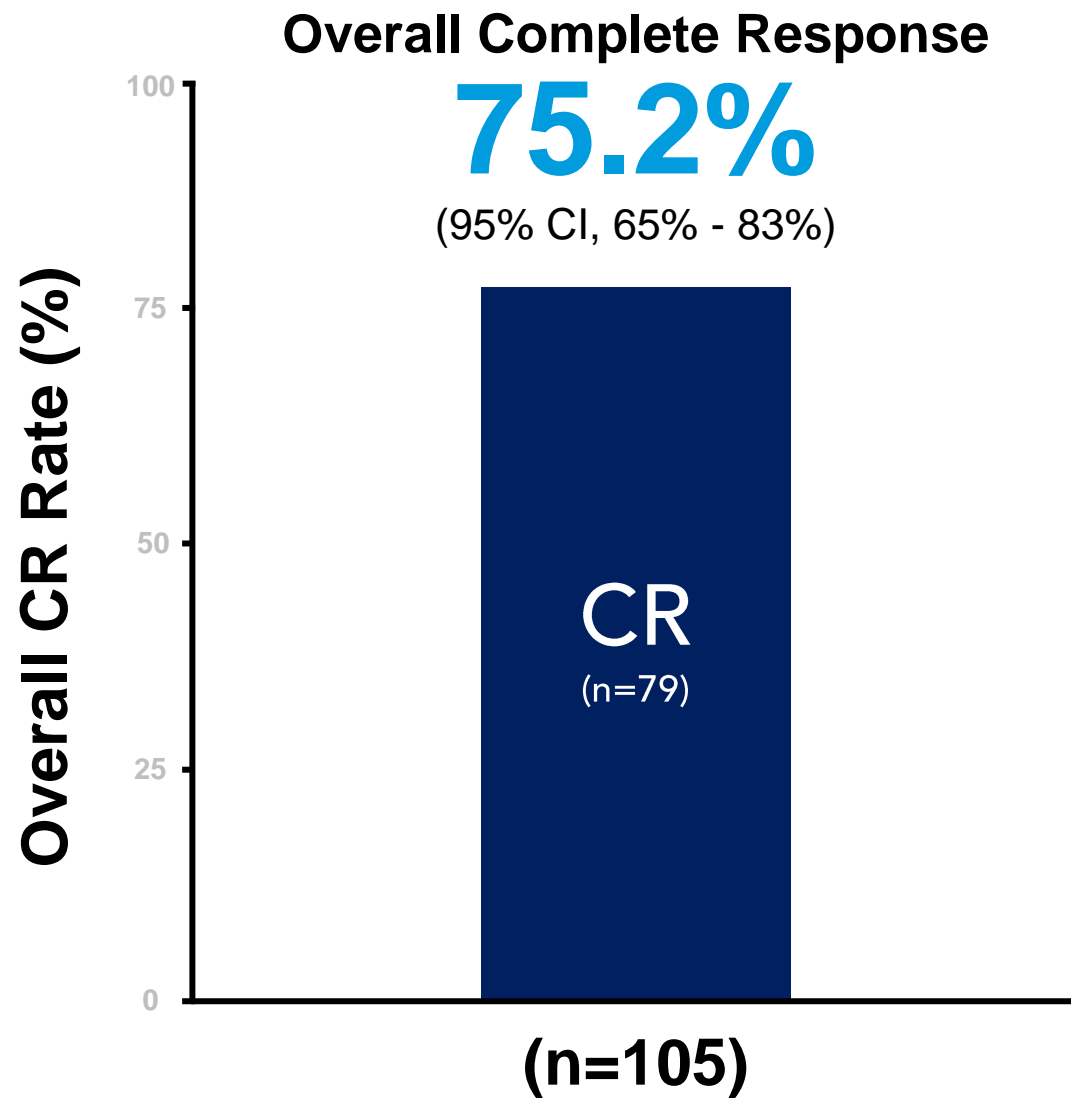


# BOND-003: Patient Demographics (Cohort C)

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%)
- Highly pre-treated population
  - Includes patients with prior intravesical chemotherapy and systemic immunotherapy

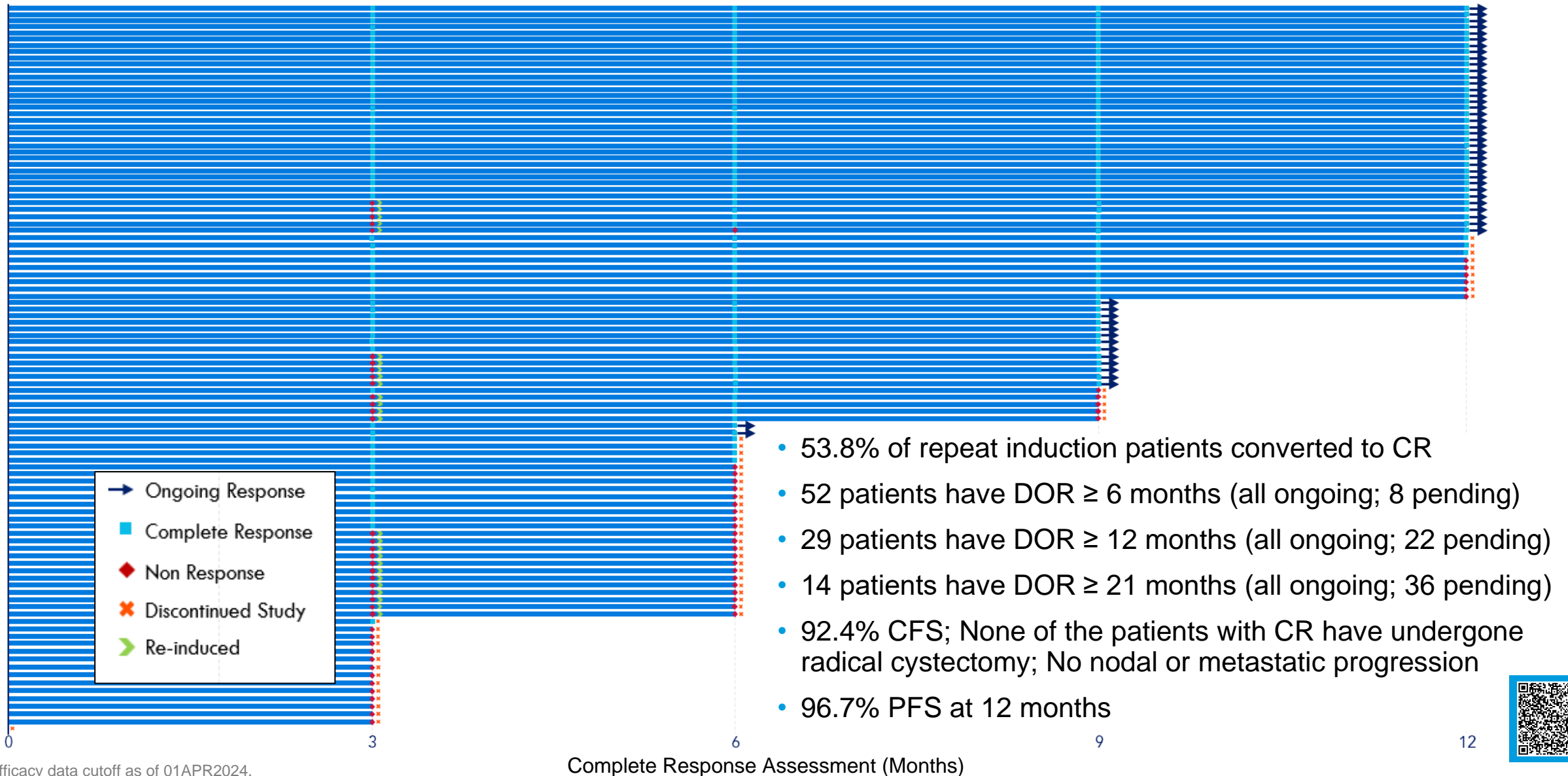
# Cretostimogene Monotherapy Results: 75.2% CR at Any Time



Efficacy data cutoff as of 01APR2024  
Efficacy analysis centrally confirmed. All pts have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance



# Cretostimogene Has Shown Durable Responses Over Time





# Cretostimogene Has Been Generally Well-Tolerated

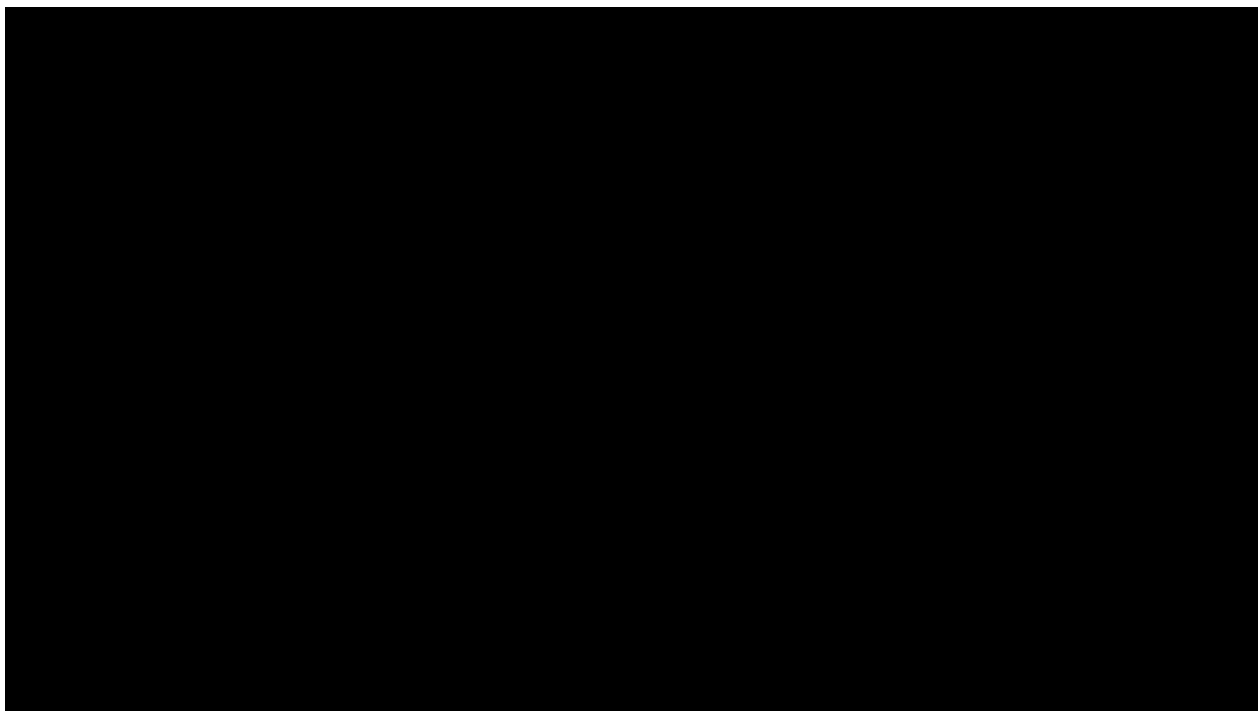
Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade ≥ 3
<b>Patients with ≥ 1 TRAE</b>	70 (62.5%)	0 (0)
<b>Treatment-Related AE reported in &gt; 10% patients</b>		
Bladder Spasm	26 (23.2%)	0 (0)
Pollakiuria	22 (19.6%)	0 (0)
Dysuria	17 (15.2%)	0 (0)
Micturition Urgency	17 (15.2%)	0 (0)
Hematuria	16 (14.2%)	0 (0)

- Most AEs were Grade 1-2
- No grade ≥ 3 treatment-related AEs or deaths reported
- 2 patients (1.8%) had serious treatment-related AEs (Grade 2)\*
- 1 patient discontinued treatment due to unrelated AE\*\*
- 94.5% completed all expected treatments

\* Treatment-related SAEs were Cystitis noninfective (Grade 2) and clot retention (Grade 2).  
 \*\* Unrelated AE leading to treatment discontinuation was Hematuria (Grade 2).



# Experience with Cretostimogene



- Familiar and convenient instillation process/schedule for practices
  - Thaw time up to 10 minutes
- Administered by allied healthcare professionals (MAs, RNs)
- Generally well-tolerated regimen
- 100% of patients with successful instillation on BOND-003
- Streamlined instillation process for future cohorts and studies



# Cretostimogene Has Potential to Become Backbone Therapy in NMIBC Treatment Landscape<sup>1</sup>

Trial	BOND-003	CORE-001 <sup>2</sup>	QUILT 3.032	NCT02773849	KEYNOTE-057
Intervention	Cretostimogene	Cretostimogene + Pembrolizumab	N-803 + BCG	Nadofaragene	Pembrolizumab
Mechanism	Oncolytic Immunotherapy	Oncolytic Immunotherapy + Checkpoint Inhibitor	IL-15 Superagonist + BCG	Gene Therapy Secreting IFN	Checkpoint Inhibitor
RoA	Intravesical	Intravesical + Intravenous	Intravesical	Intravesical	Intravenous
Stage	Phase 3 Enrollment Complete	Phase 2 Ongoing	Approved April 22, 2024	Approved	Approved
Sample Size	N=112	N=35	N=77	N=98	N=96
CR Any Time	<b>75% (79/105)*</b>	85% (29/34)*	62% (48/77)	51% (50/98)	41% (39/96)
DOR ≥ 12 Mo	<b>83% (29/35)*</b>	88% (14/16)*	58% (28/48)	46% (23/50)	46% (18/39)
Safety Profile	0% Grade 3 TRAE 0% Grade 4 TRAE <b>0% treatment-related discontinuation</b>	Creto-related: 0% Grade 3 TRAE <b>4 pembro-related discontinuation of pembrolizumab<sup>2</sup></b>	<b>16% SAE</b> , including fatal adverse reaction of cardiac arrest in one patient on treatment; <b>7% treatment-related discontinuation<sup>3</sup></b>	4% Grade 3+ TRAE <b>3% treatment-related discontinuation<sup>4</sup></b>	11% Grade 3 TRAE 2% Grade 4 TRAE <b>11% treatment-related discontinuation<sup>5</sup></b>

\* Pending additional assessment and evaluation at subsequent timepoints

<sup>1</sup>. Not based on head-to-head or comparator studies. Differences exist between trial designs and participants; caution should be exercised when comparing these data. <sup>2</sup>. Interim efficacy data (03MAR2023) and safety data (31JAN2024) at AUA 2023; <sup>3</sup>. ANKTIVA® Package Insert; <sup>4</sup>. ADSTILADRIN® Package Insert and Boorjian, Lancet Oncol. 2021 <sup>5</sup>. KEYTRUDA® Package Insert and Balar, Lancet Oncol. 2021

# Fast Track & Breakthrough Therapy Designations Granted for Cretostimogene Monotherapy in BCG-UR CIS +/- Papillary Disease!



# Next Phase of BOND-003 Trial (Cohort P)

Trial Extension & Addition of BCG-UR Papillary Only Cohort

## Treatment Extension

### Maintenance Extension:

Complete Responders eligible for maintenance through Year 3

### Maintenance Dosing:

Weekly x 3 Q3M in Year 1  
Weekly x 3 Q6M in Year 2 and Year 3

## Addition of Papillary Cohort (n~75)

### Dosing Schedule:

Standard Cretostimogene induction and maintenance schedule

### Summary of Changes:

Patients will have the option for repeat induction, if in non-response at 3 Months



Visit the AUA Learning Lab on Sunday, May 05 @ 10:56 AM for more information on **BOND-003 Cohort P**



# Cretostimogene Expanded Access Program (EAP)

## Program Objectives

- Available for a broader range of patients with CIS-containing BCG-UR NMIBC
- Prioritize geographically and ethnically diverse population of real-world patients
- CG Oncology will provide supply of cretostimogene

## Dosing Regimen

**Induction Course:**  
Weekly x 6

**Second Induction:**  
Weekly x 6 for non-responders

**Maintenance Course:**  
Weekly x 3 Q3M for Year 1  
Weekly x 3 Q6M for Year 2

## Data Collection

- Safety
- Efficacy
- PROs





# Further Steps: SUO-CTC Supported Clinical Trials

## PIVOT-006: Phase-3 Adjuvant Cretostimogene Versus Surveillance in IR-NMIBC

- >90 sites participating
- Patients dosed!
- Dr. Robert Svatek Global PI
  - *AUA Learning Lab- May 5, 10:24 AM*

## CORE-008: Phase-2 Multi-arm, Multi-cohort Cretostimogene in HR-NMIBC

- Cohort A: BCG-Naïve
- Cohort B: BCG-Exposed
- Additional cohorts under design



# Acknowledgements

**All Bladder Cancer Patients and Their Families**

**The Study Coordinators and Nurses**

## Key Collaborators

Edward Uchio, UC Irvine, CA  
Jong-kil Nam, Pusan University, South Korea  
Don Lamm, BCG Oncology, AZ  
Trinity Bivalacqua, UPenn, PA  
Neal Shore, CURC, SC  
Wassim Kassouf, McGill University, Quebec  
Gary Steinberg, Rush University, IL  
Peter Black, UBC, British Columbia  
Ashish Kamat, MDACC, TX  
Hiroshi Kitamura, University of Toyama, Japan  
Roger Li, Moffitt Cancer Center, FL

## CG Oncology

Andy Darilek  
Nataliya Hnat  
James Burke  
Calvin Lai  
Jee-Hyun Kim  
Angelica Craighead  
Kara Sabourin  
John McAdory  
Michael Lambert  
Shelja Patel  
Pat Keegan  
Vijay Kasturi



This research is funded by CG Oncology, Inc..





Attacking  
Bladder Cancer  
for a Better  
Tomorrow™

Thank You!

