

Interim Data Presentation from the ADVANCED-2 Trial of TARA-002 in Patients with NMIBC

American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium

February 2026

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Agenda



Jesse Shefferman
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Executive Officer



Carla Beckham, MD, PhD
Lead Medical Director and Head of
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Urologist



Neal Shore, MD
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Introduction

Jesse Shefferman

Review of Updated TARA-002 Data

Carla Beckham, MD, PhD

KOL Discussion

Neal Shore, MD

Closing Remarks

Jesse Shefferman

Q&A

All

Key Clinical Updates

TARA-002 for Non-Muscle Invasive Bladder Cancer (NMIBC)



TARA-002 in NMIBC

1. Interim data from the **ADVANCED-2** trial of **TARA-002** in patients with **NMIBC**

- TARA-002 demonstrated 66% CR rate at any time, 68% 6-month landmark and 33% 12-month landmark CR rate in patients with BCG-Unresponsive NMIBC¹
- TARA-002 demonstrated 72% CR rate at any time, 67% 6-month landmark and 58% 12-month landmark CR rate in patients with BCG-Naïve NMIBC¹
- Favorable safety and tolerability profile observed with no Grade 3 or greater TRAEs

2. TARA-002 has anticipated low burden on physicians & patients

- No additional administration procedures or safety protocols required
- Rapid administration typically performed by nurse

3. Next steps

- Expect to complete enrollment in the BCG-Unresponsive registrational cohort of ADVANCED-2 in 2H'26
- Expect to initiate enrollment in the BCG-Naive NMIBC ADVANCED-3 registrational trial in 2H'26

Diversified Late-Stage Pipeline

	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Expected Status
ONCOLOGY						
 Indicates potential clinical programs yet to be initiated						
TARA-002 ADV-2	CIS ± Ta/T1 NMIBC BCG-Naïve [†]	ADVANCED-2 (Cohort A)				Fully enrolled
	CIS ± Ta/T1 NMIBC BCG-Unresponsive	ADVANCED-2 (Cohort B)				Full enrollment 2H'26
TARA-002 ADV-3	CIS ± Ta/T1 NMIBC BCG-Naïve ¹	ADVANCED-3 (BCG-Naïve RCT)				Trial initiation in 2H'26
TARA-002 NMIBC Expansion	HR NMIBC Ta / T1 PoC ²					
TARA-002 Systemic Administration*	HR NMIBC ²					
RARE DISEASES						
IV CHOLINE	Choline for parenteral support (PS) patients**	THRIVE-3				Interim data 2H'26
TARA-002	Lymphatic Malformations (LMs)***	STARBORN-1				Regulatory feedback 1H'26 Full enrollment 2H'26

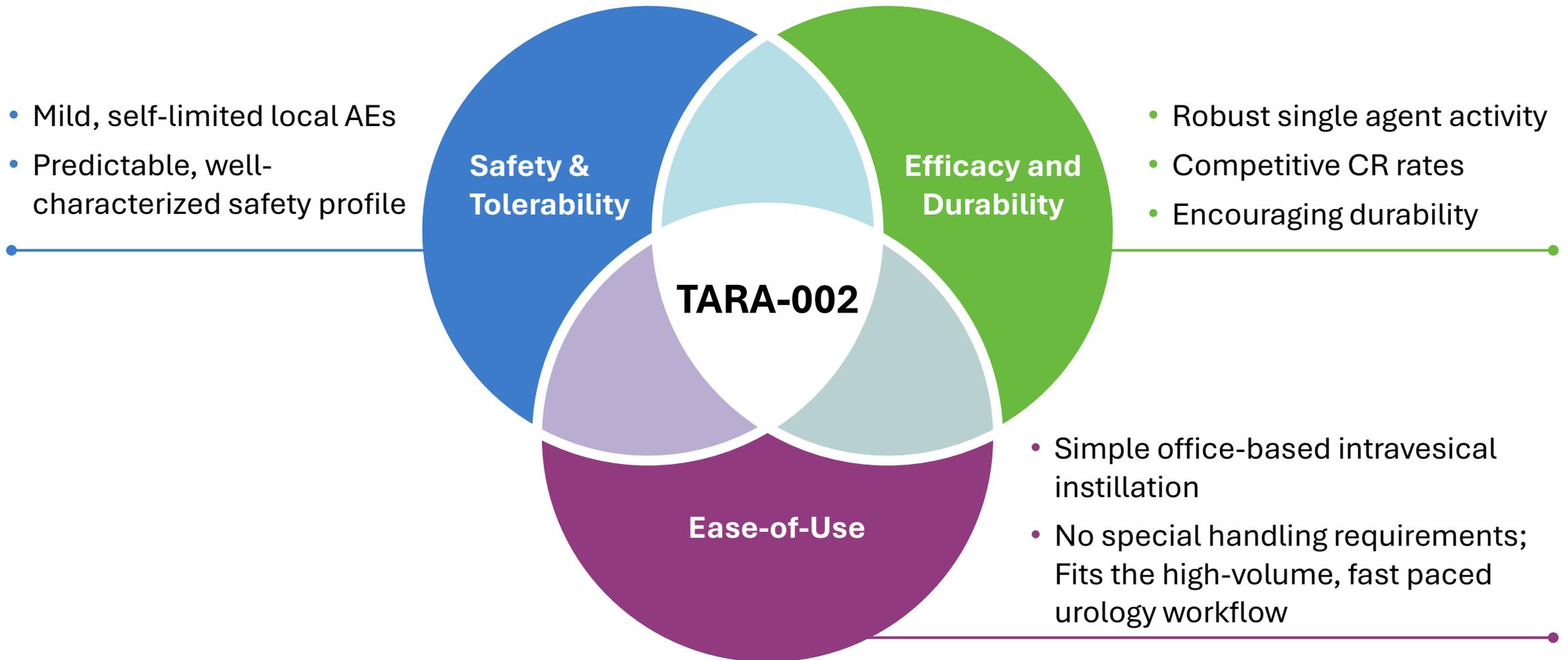
*Currently in pre-clinical studies to define dosing and, once protocol is confirmed, expect to initiate P2 trial cohort.

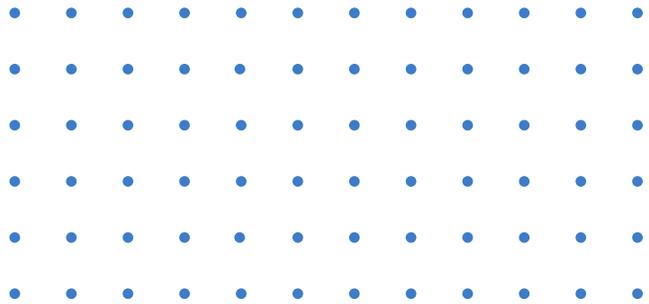
**IV Choline granted Orphan Drug Designations by the U.S. FDA for the prevention and/or treatment of choline deficiency in patients on long-term PN and Fast Track Designation as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

***TARA-002 granted Rare Pediatric Disease Designation as well as Breakthrough Therapy and Fast Track Designations by the U.S. FDA and Orphan Drug Designation by the European Commission for the treatment of LMs.

[†]Trial also includes BCG-Exposed patients; ¹Subject to regulatory clearance ²Potential expansion opportunity for NMIBC program

TARA-002 Target Product Profile Sits at the Intersection that NMIBC Patients and Urologists Prioritize

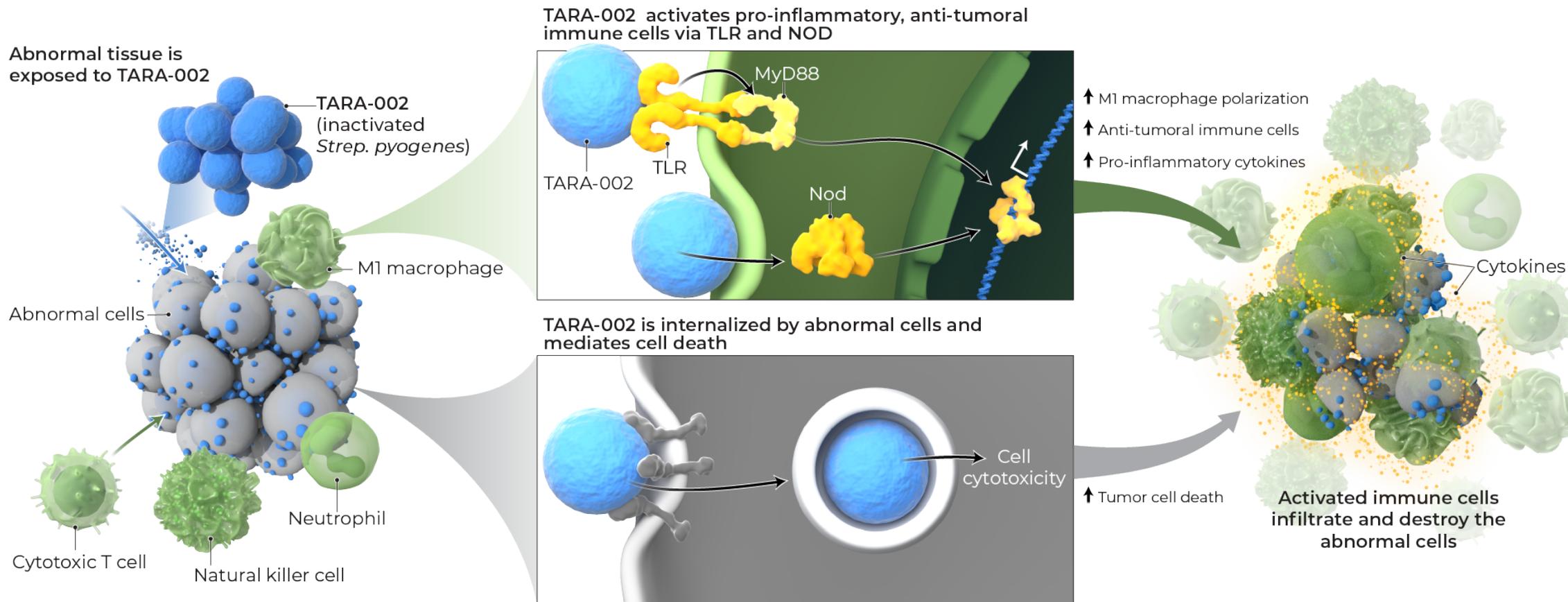




ADVANCED-2 RESULTS



TARA-002: A Unique TLR2/NOD2 Agonist Derived from *Streptococcus Pyogenes* that Brings a New Immunologic Mechanism to NMIBC Beyond BCG



TARA-002 ignites both innate and adaptive immunity through dual TLR2/NOD2 activation, driving potent local anti-tumor / cystic responses via fully inactivated bacteria⁽¹⁾⁽²⁾⁽³⁾

TARA-002 in NMIBC: ADVANCED-2 Clinical Trial Design

Primary endpoint of high-grade complete response (CR) at any time up to 6 months; Key secondary endpoint of 12-month DOR



REGISTRATIONAL DESIGN*: BCG-Unresponsive (CIS ± Ta/T1)



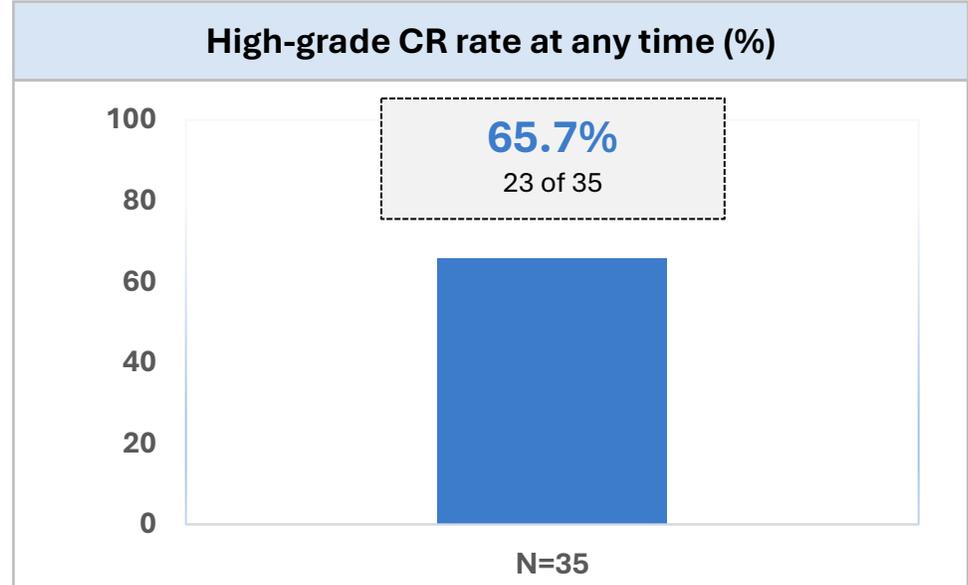
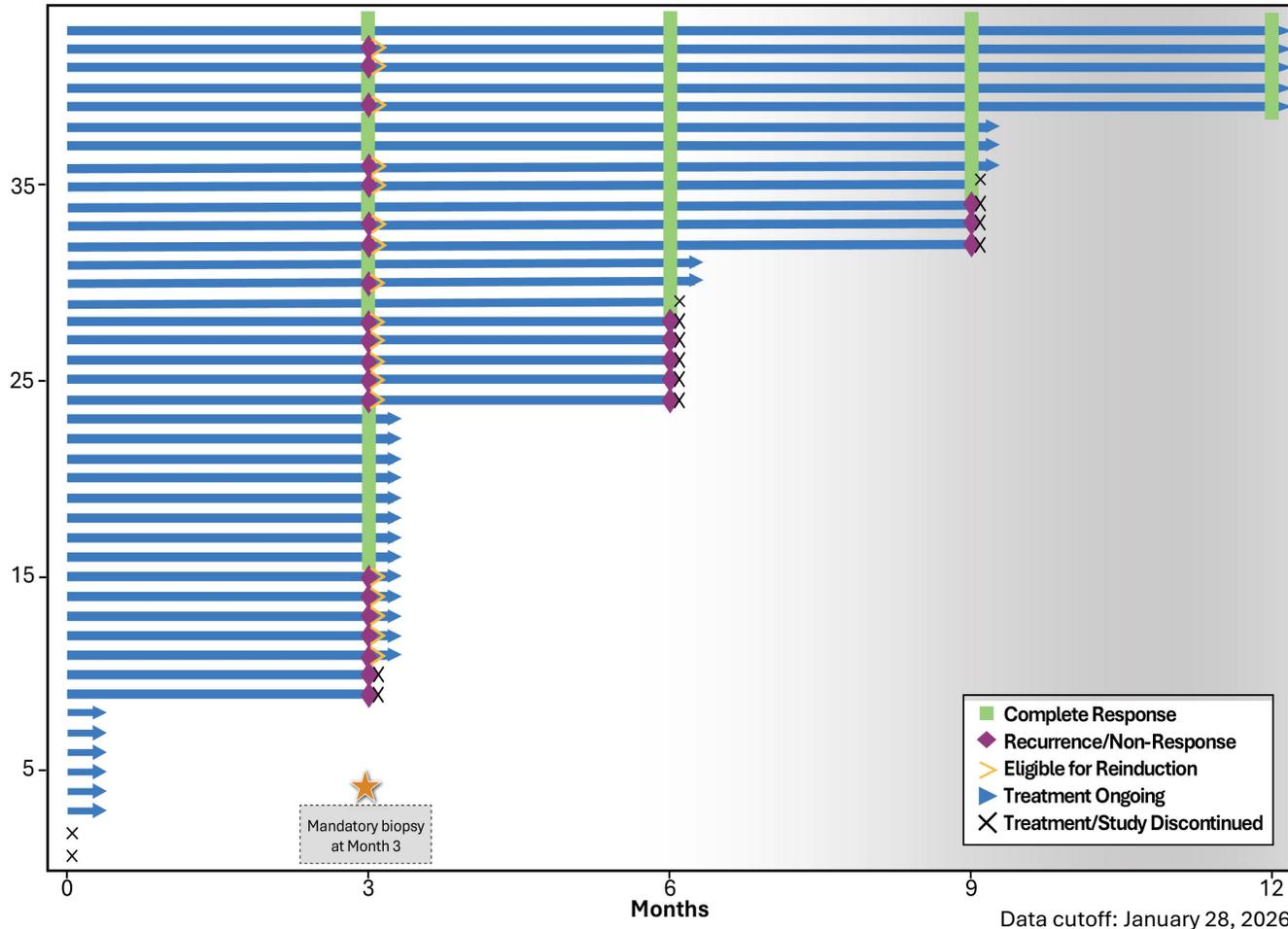
BCG Naïve (CIS ± Ta/T1)



CT.gov identifier: NCT05951179

Abbreviations: CR = complete response; CIS = carcinoma in situ
 *Aligned with the FDA's 2024 BCG Unresponsive NMIBC: Developing Drugs and Biologics for Treatment Guidance for Industry.
 **Enrollment complete
[†]Residual CIS and/or recurrence of HGTA; [^]3 weekly instillations every 3 months through month 18 and then at month 24

TARA-002 Monotherapy Demonstrates 68% CR at 6 Months with Durable Response Among BCG-Unresponsive Participants



Landmark	High-grade CR rate (%)
Month 6	68.2 (15 of 22)
Month 12	33.3 (5 of 15)
Reinduction Salvage	61.5 (8 of 13)

71%*
(95% CI, 46.7, 95.5)
Maintained CR for ≥ 6 Mo

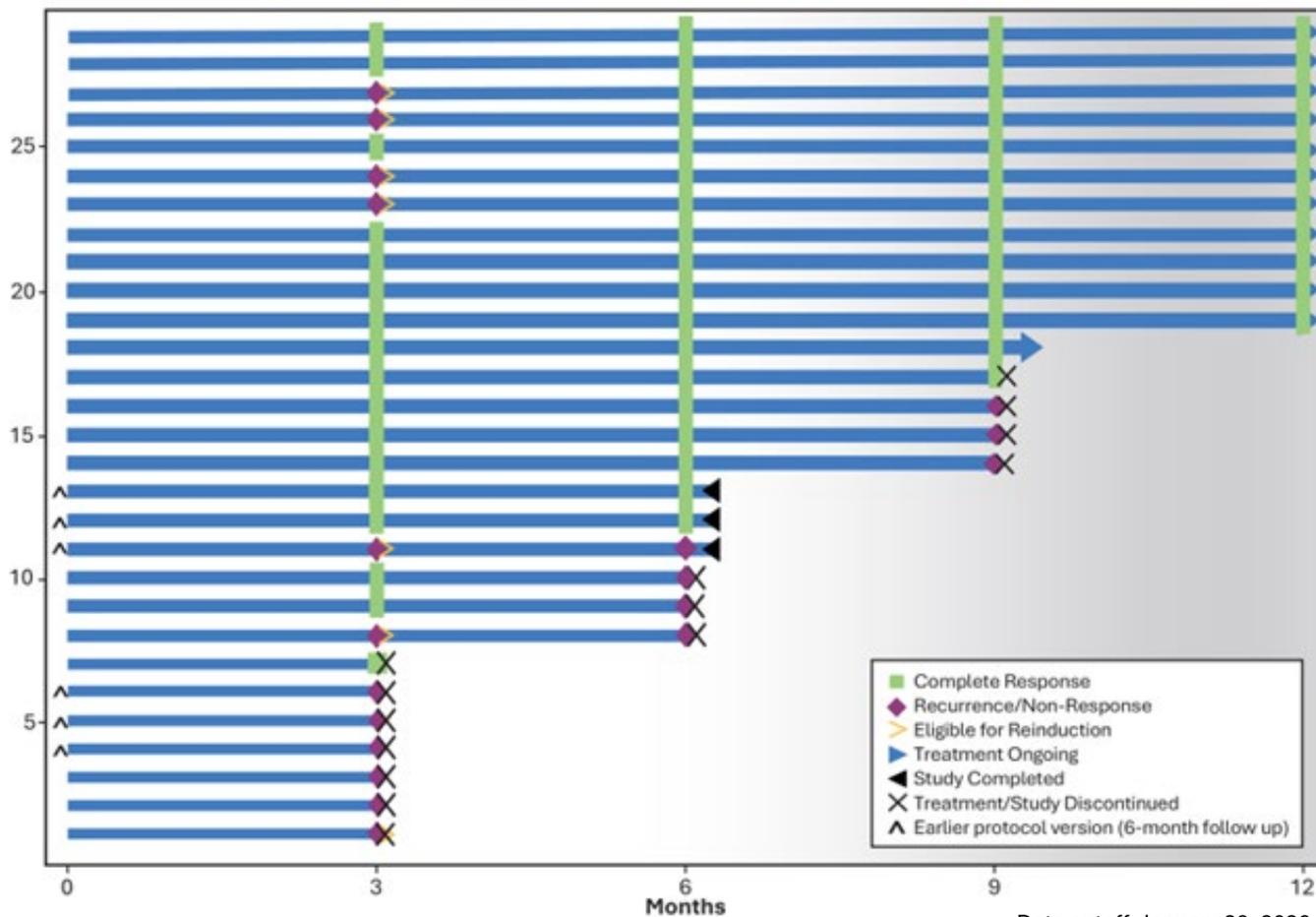
100%
Maintained CR from
9 Mo -12 Mo (5 of 5)

Abbreviations: CR = complete response

High-grade CR is based on central pathology including a mandatory biopsy at Month 3

Notes: Evaluable participants include those who had at least one dose of study drug before the response assessment time point and completed at least one response assessment; CR rates at each landmark time point include all participants who were either evaluable at that time point or had experienced disease progression or treatment failure prior to the scheduled visit. Two participants at Month 3 and 1 participant at Month 12 are pending central confirmation of response.

TARA-002 Monotherapy Demonstrates 67% CR at 6 Months with Durable Response Among BCG-Naïve Participants



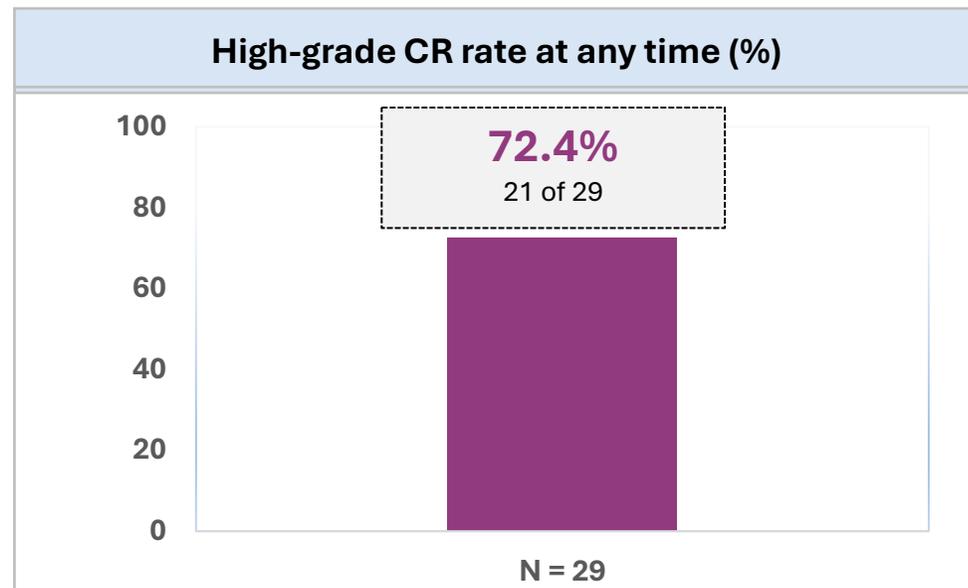
Data cutoff: January 28, 2026

Abbreviations: CR = complete response

High-grade CR is based on central pathology.

Notes: Evaluable participants include those who had at least one dose of study drug before the response assessment time point and completed at least one response assessment; CR rates at each landmark time point include all participants who were either evaluable at that time point or had experienced disease progression or treatment failure prior to the scheduled visit

^ Participants enrolled under an earlier protocol version with 6-month duration; therefore, they are not included in CR analyses from Month 9 onward.



Landmark	High-grade CR rate (%)
Month 6	66.7 (18 of 27)
Month 12	57.9 (11 of 19)
Reinduction Salvage	66.6 (4 of 6)

73%*
(95% CI, 52.9, 93.4)
Maintained CR for ≥ 6 Mo

100%
Maintained CR from
9 Mo -12 Mo (11 of 11)

*Based on Kaplan-Meier (KM) probability of maintaining a CR

TARA-002 in NMIBC Demonstrated a Favorable Safety and Tolerability Profile with No Grade 3 or Greater TRAEs Across BCG Exposures

N = 74	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
TRAEs, n (%)	19 (26)	19 (26)	4 (5)	0	0
TRAEs ≥5%, n (%)					
Dysuria	10 (14)	10 (14)	0	0	0
Bladder spasm	7 (9)	4 (5)	3 (4)	0	0
Fatigue	5 (7)	4 (5)	1 (1)	0	0
Micturition urgency	4 (5)	4 (5)	0	0	0
SAEs, n (%)	11 (15)	0	3 (4)	10 (14)	1 (1)
Related SAEs, n (%)	0	0	0	0	0
TRAEs leading to Study Drug Withdrawal, n (%)	0	0	0	0	0

Abbreviations: TRAE = treatment related adverse event; SAE = serious adverse event

Data cutoff: January 28, 2026

NOTE: A total of 74 participants were exposed to at least one dose of TARA-002; 43 were BCG-unresponsive and 31 were BCG-naïve.

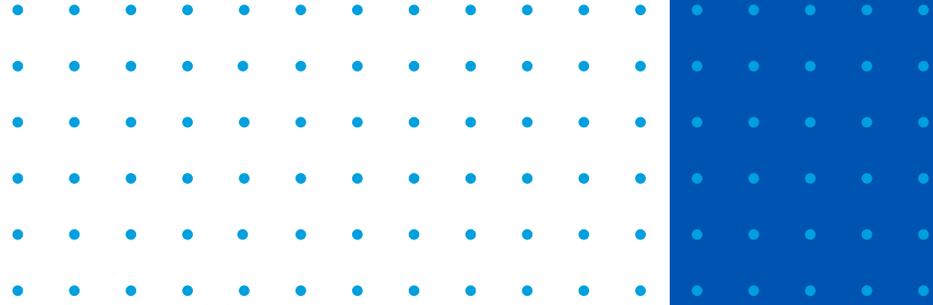
Severity of adverse event is based on NCI-CTCAE Version 5.0 or later.



KOL DISCUSSION

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CLOSING REMARKS

Q&A



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Nicacio, MD**
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Bill Conkling
Chief Commercial Officer

THANK YOU



APPENDIX



BCG-Unresponsive Cohort Demographics and Baseline Characteristics

Baseline Demographics	Cohort B N = 43
Age (years)	
Median (Min, Max)	75 (47, 92)
Sex, n (%)	
Male	31 (72.1)
Female	12 (27.9)
Race, n (%)	
Asian	5 (11.6)
Black or African American	1 (2.3)
White	35 (81.4)
Other	1 (2.3)
Not Reported	1 (2.3)

Baseline Characteristics	Cohort B N = 43
ECOG PS, n (%)	
0	39 (90.7)
1	4 (9.3)
2-5	0
Diagnosis, n (%)	
CIS (only)	40 (93.0)
CIS + Ta	3 (7.0)
CIS + T1	0
BCG Exposure, n (%)	
BCG-unresponsive	43 (100.0)

ECOG PS = Eastern Cooperative Oncology Group Performance Status.

Data cutoff: January 28, 2026

BCG-Naïve Cohort Demographics and Baseline Characteristics

Baseline Demographics	Cohort A N = 31
Age (years)	
Median (Min, Max)	71 (45, 89)
Sex, n (%)	
Male	25 (80.6)
Female	6 (19.4)
Race, n (%)	
Black or African American	1 (3.2)
White	29 (93.5)
Not Reported	1 (3.2)

Baseline Characteristics	Cohort A N = 31
ECOG PS, n (%)	
0	26 (83.9)
1	4 (12.9)
2	1 (3.2)
3-5	0
Diagnosis, n (%)	
CIS (only)	18 (58.1)
CIS + Ta	9 (29.0)
CIS + T1	4 (12.9)
BCG Exposure, n (%)	
Never exposed	24 (77.4)
BCG exposed >24 months	7 (22.6)

ECOG PS = Eastern Cooperative Oncology Group Performance Status.

Data cutoff: January 28, 2026