PROTARA
THERAPEUTICS

ADVANCED-2 TRIAL INTERIM RESULTS

December 2024

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PROTARA THERAPEUTICS

Promising NMIBC therapy & de-risked rare disease programs

Oncology

TARA-002 in NMIBC

- Positive interim results from ADVANCED-2 trial in NMIBC
- Unique product characteristics anticipated to drive significant adoption
- Potential to expand clinical program into BCG-naïve, combinations, systemic dosing and intermediate risk

Rare Disease

IV Choline for Parenteral Support

- Enrolling pivotal study with PK endpoint
- 30K patient population in the US[1]
- FDA Orphan Drug and Fast Track Designations

TARA-002 in LMs

- Dosing underway in Phase 2 STARBORN-1 trial
- TARA-002 predecessor is standard of care in Japan
- U.S. FDA granted Rare Pediatric Disease Designation – PRV eligible

PROTARA THERAPEUTICS

1. Data on file

Unique product characteristics anticipated to drive significant adoption

Encouraging interim ADAVNCED-2 data

- Compelling response rates in BCG-UN and BCG-naïve
- 100% durability observed from 3-to 6-months and 80% reinduction salvage rate seen across all patients

Favorable safety & tolerability

- To date, no Grade 2 or greater treatment-related adverse events
- To date, majority of adverse events are grade 1 and transient

Anticipated low burden on physicians & patients

- No additional administration procedures or safety protocols required
- Fast administration typically performed by nurse
- Dedicated to ensuring access with minimal burden

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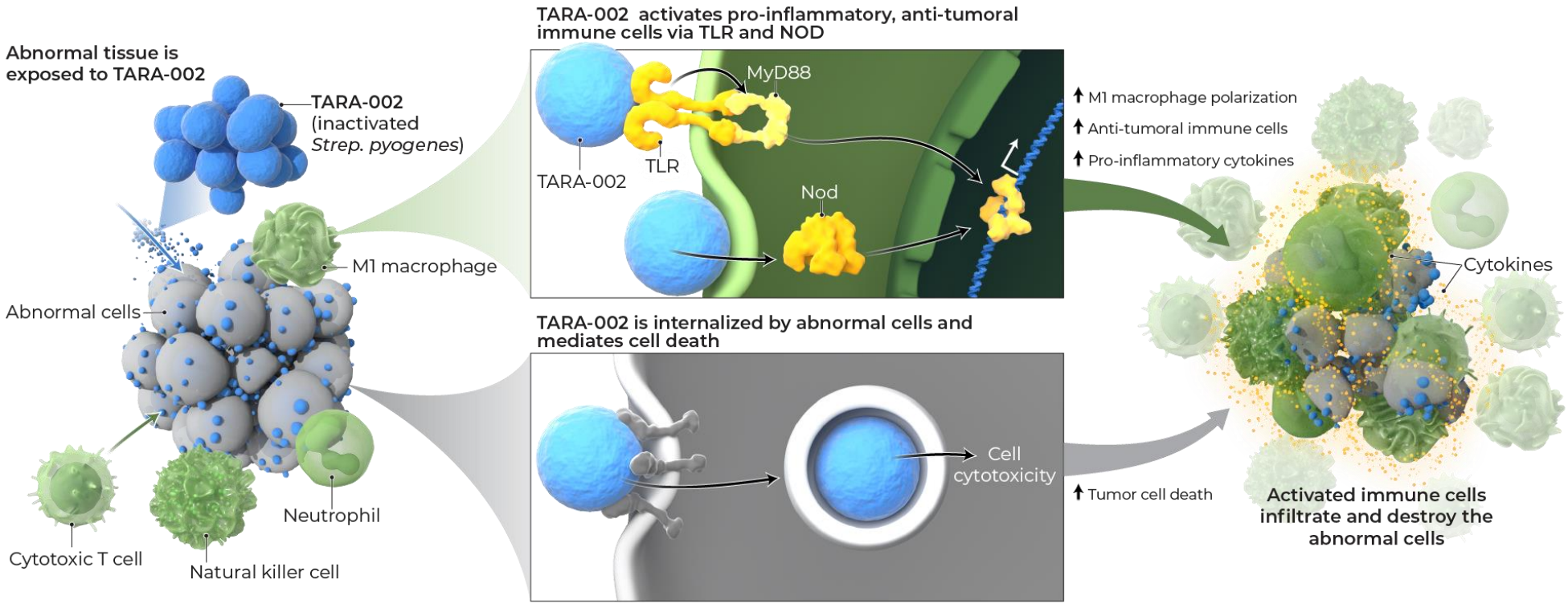
BROAD IMMUNOPOTENTIATION = POTENTIAL FOR DURABLE RESPONSE

Mechanism similar to BCG, unique to other agents in development

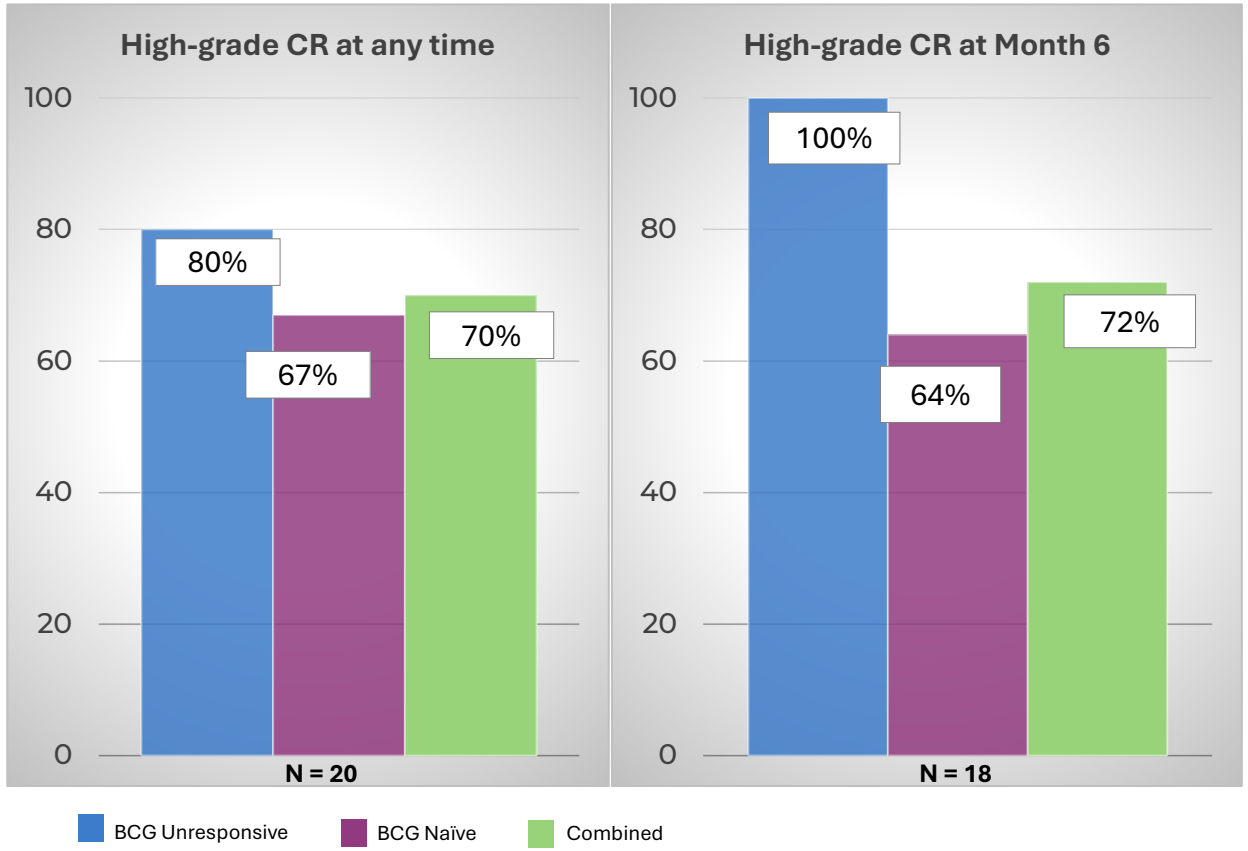
Activates Th1 Immune Cascade [1][2][3]

IL-1b IL-6 IL-12 TNF-α IFN-γ GM-CSF NK-Cells



1. Fujimoto T., et al. J Immunol. 1997: 5619. | 2. Ryoma Y, et al. Anticancer Res. 2004; 3295-3298. | 3. Zhao H, et al. Microbiol. Immunol. 1994; 183-190.

TARA-002 demonstrated 72% six-month CRR and 70% CRR at any time across BCG exposures

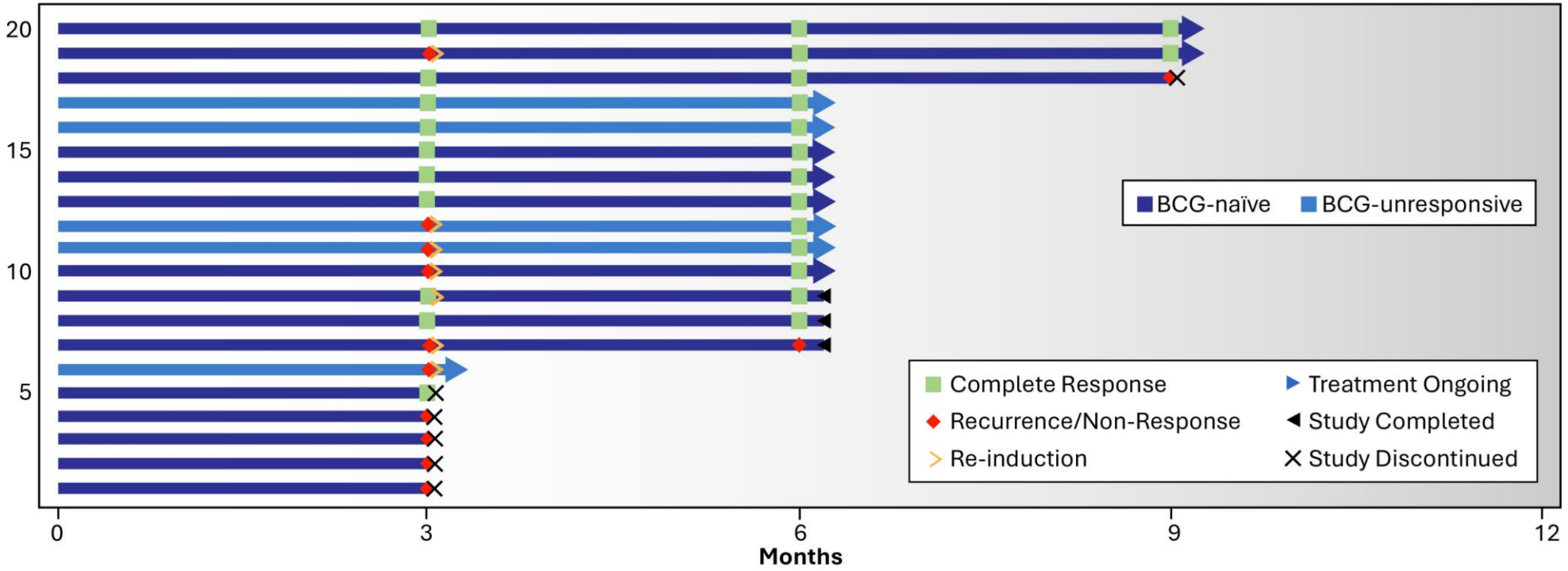


	BCG Un-responsive N = 5 (%)	BCG Naïve N = 15 (%)	Combined N = 20 (%)
High-grade CR at any time	4/5 (80.0)	10/15 (66.7)	14/20 (70.0)
High-grade CR at Timepoint			
Month 6	4/4 (100.0)	9/14 (64.3)	13/18 (72.2)
Month 9	N/A	2/3 (66.7)	2/3 (66.7)
High-grade CR at Month 6 by Baseline Dx			
CIS only	4/4 (100.0)	5/6 (83.3)	9/10 (90.0)
CIS + Ta/T1	N/A	4/8 (50.0)	4/8 (50.0)

Data cut-off date: 19 November 2024

Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ; Dx = diagnosis; NMIBC = non-muscle invasive bladder cancer
Notes: At the time of data cutoff, 20 subjects were evaluated for high-grade CR at Month 3 and later. Eighteen subjects were evaluated for high-grade CR at Month 6 and 3 subjects at Month 9; Evaluable subjects include those who had at least one dose of study drug before the response assessment of time point and were discontinued due to dx progression or treatment failure. Subjects who have not yet completed week 12 visit as of study cut off date are not included;
Central urine cytology is pending for 3 subjects at Month 6 and 1 subject at Month 9.

TARA-002 demonstrated 100% durability from 3 months to 6 months with a reinduction salvage rate of 80%[1]



Data cut-off date: 19 November 2024

Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ

NOTES: At the time of data cutoff, of the 24 subjects enrolled, 20 subjects were evaluated for high-grade CR at Month 3 and later. Eighteen subjects were evaluated for high-grade CR at Month 6 and 3 subjects at Month 9. Evaluable subjects include those who had at least one dose of study drug before the response assessment of time point and were discontinued due to diagnosis of progression or treatment failure. Subjects who have not yet completed the week 12 visit as of study cut of date were not included. Central urine cytology is pending for 3 subjects at Month 6 and 1 subject at Month 9.

1. 100% durability from 3 to 6 months in 9/9 patients; reinduction salvage rate of 80% in 4/5 patients

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TARA-002 demonstrated favorable safety and tolerability in interim analysis of ADVANCED-2 trial

AEs reflect urinary tract instrumentation effects and known safety profile of an immune-potentiating drug

N=24	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Number of Subjects with TEAEs, n^ (%)	16 (67)	11 (46)	7 (29)	3 (13)	0
Number of Subjects with Related TEAEs^, n (%)	6 (25)	6 (25)	0	0	0
Dysuria	3 (13)	3 (13)	0	0	0
Bladder Discomfort	1 (4)	1 (4)	0	0	0
Bladder Spasm	1 (4)	1 (4)	0	0	0
Chills	1 (4)	1 (4)	0	0	0
Fatigue	1 (4)	1 (4)	0	0	0
Hematuria	1 (4)	1 (4)	0	0	0
Micturition Urgency	1 (4)	1 (4)	0	0	0
Urinary Incontinence	1 (4)	1 (4)	0	0	0
Number of Subjects with Serious TEAEs+, n (%)	3 (13)	0	1 (4)	2 (8)	0
Number of Subjects with TEAEs leading to Study Drug Withdrawal, n (%)	0	0	0	0	0

Abbreviations: AE = adverse event; NMIBC = non-muscle invasive bladder cancer; TEAE = treatment emergent AE

^ Subjects may be counted in multiple categories

+ Non-drug related Serious TEAEs included urinary tract infection (UTI; N = 2) and urosepsis (N =1)

Note: the safety population includes any patients who have had at least 1 dose of TARA-002. The 24 patients in safety analysis include 3 patients who have not reached their week 12 assessment, and 1 patient withdrew consent prior to their week 12 assessment

Data cut-off date: 19 November 2024

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TARA-002 HAS A DIFFERENTIATED PROFILE IN NMIBC WITH ENCOURAGING INTERIM DATA

PROMISING CLINICAL DATA

- Positive interim results across BCG exposures

UNIQUE MOA

- Only broad immunopotentiator in the industry pipeline
- Non-clinical data points to encouraging durability
- No overlapping toxicities with other novel therapeutic in NMIBC

POTENTIAL EASE ON PROVIDERS & PATIENTS

- To date, no Grade 2 or greater treatment-related adverse events
- Simple, fast administration via catheter

OPPORTUNITIES TO EXPAND

- First to publish efficacy in BCG-naïve patients; assessing potential next steps
- Only novel agent with the ability to dose systemically – potentially replacing intravesical administration

RELIABLE MANUFACTURING

- Advanced, FDA-inspected, cGMP manufacturing with 20mm vial annual capacity
- Doubling time (2 hrs) vs. BCG (16 hrs) adds to TARA-002's benefit over BCG in the non-refractory setting
- Dedicated to ensuring access with minimal burden

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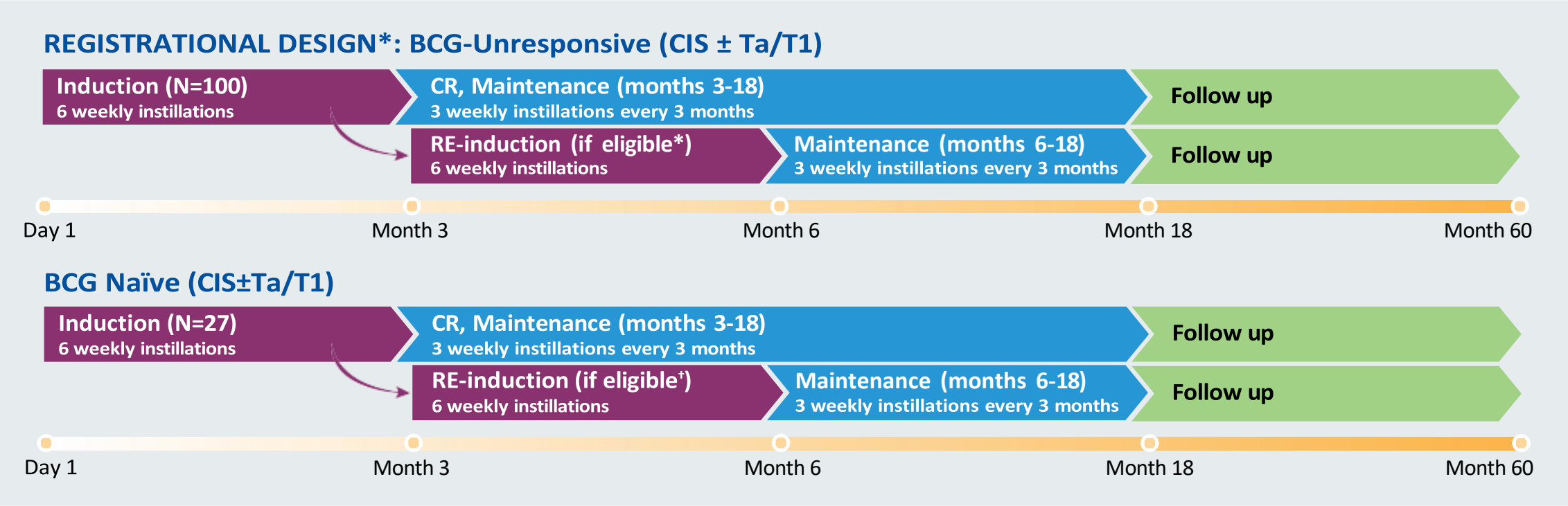
Q&A

APPENDIX

TARA-002 in NMIBC: ADVANCED-2 trial design

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



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.
†Residual CIS and/or recurrence of HGTa

Data cut-off date: 19 November 2024

ADVANCED-2 demographics and disease characteristics

	N = 24		N = 24
Age (years)		**Prior BCG Status, n (%)**	
Mean (SD)	71 (10.9)	BCG Naïve	17 (71)
Median	71	BCG Exposed	2 (8)
Min, Max	45, 92	BCG Unresponsive	5 (21)
Sex, n (%)		**Prior No. of BCG Doses, n (%)**	
Male	19 (79)	≥ 12 BCG doses	5 (21)
Female	5 (21)	< 12 BCG doses	2 (8)
Race, n (%)		**Prior non-BCG Treatment, n (%)**	
White	24 (100)	Gemcitabine/Docetaxel	2 (8)
Ethnicity, n (%)		Gemcitabine	1 (4)
Hispanic	1 (4)	Mitomycin	3 (12)
Non-Hispanic	23 (96)	Other	2 (8)
ECOG Score, n (%)		**Prior TURBT Status, n (%)**	
0	18 (75)	> 3 TURBTs	5 (21)
1	5 (21)	≤ 3 TURBTs	19 (79)
2	1 (4)		
Baseline Diagnosis, n (%)			
CIS only	14 (58)		
CIS + Ta	6 (25)		
CIS + T1	4 (17)		

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