ADVANCED-2 (Cohort A): Interim 12-Month Efficacy and Safety Data in BCG-Naïve Participants With High-Grade Non-Muscle Invasive Bladder Cancer

PROTARA THERAPEUTICS

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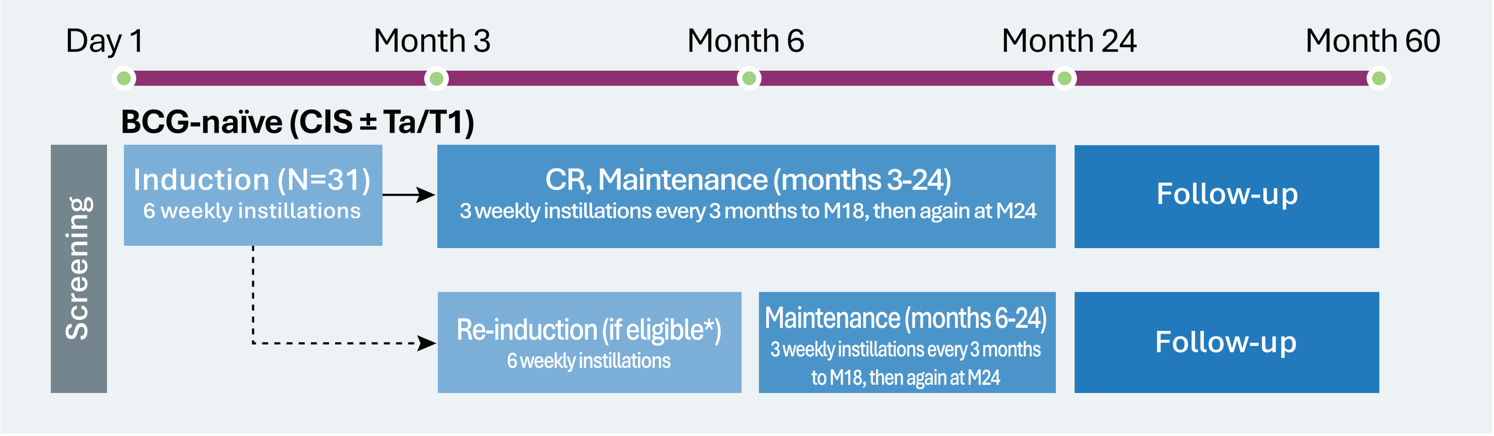
BACKGROUND

- There continues to be a significant unmet need for safe, effective, and bladder-sparing treatment options for patients with NMIBC
- TARA-002 is a TLR2/NOD2 agonist and novel immunopotentiator derived from *Streptococcus pyogenes* with a mechanism of action that includes the activation of innate and adaptive immune pathways within the bladder wall
- TARA-002 requires no special handling or thawing and can be rapidly administered via catheter by a healthcare professional in a routine office-based setting

METHODS

- ADVANCED-2 (NCT05951179) – Cohort A is a Phase 2, ongoing, open-label study of intravesical TARA-002 in adults ≥ 18 years with high-grade NMIBC with CIS ± Ta/T1 who have active disease and are BCG-naïve (defined as patients who have never been exposed and those who have not received intravesical BCG for at least 24 months)
- Endpoints:
  - Primary: High-grade complete response (CR) at any time according to central pathology
  - Key secondary: Duration of response (12 months)
- Data cutoff date of April 5, 2026
- Enrollment in this cohort is complete

ADVANCED-2 COHORT A (BCG-NAÏVE) STUDY SCHEMA



Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ; HGTa = high grade Ta tumor; T1 = carcinoma invading the lamina propria; Ta = non-invasive papillary carcinoma.
*Eligible for re-induction: Residual CIS and/or recurrence of HGTa

DISCLOSURES

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RESULTS

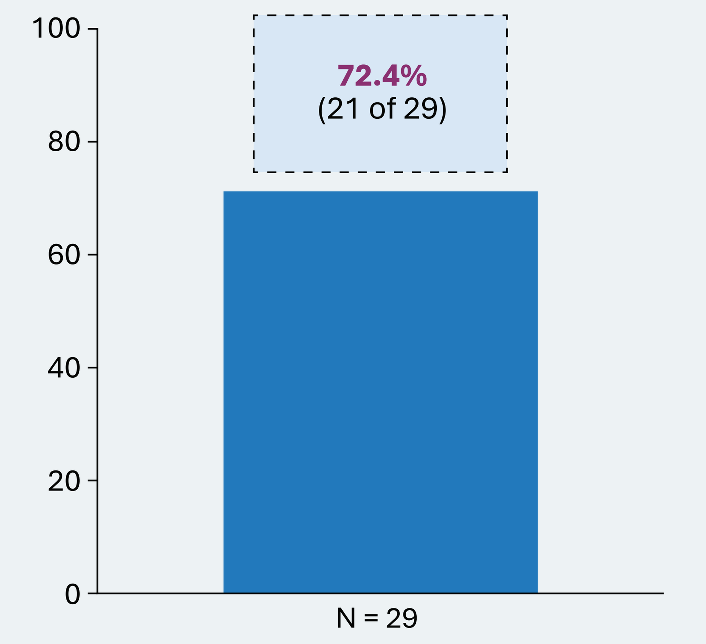
DEMOGRAPHICS AND BASELINE CHARACTERISTICS

		Cohort A N = 31
Age (years)	Median (Min, Max)	71 (45, 89)
Sex, n (%)	Male	25 (80.6)
Race, n (%)	White	29 (93.5)
ECOG PS, n (%)	0	26 (83.9)
Diagnosis, n (%)	CIS (only)	18 (58.1)

ECOG PS = Eastern Cooperative Oncology Group Performance Status.

TARA-002 MONOTHERAPY DEMONSTRATES STRONG EFFICACY AND DURABILITY IN BCG-NAÏVE PARTICIPANTS

High-grade CR Rate at any time (%)

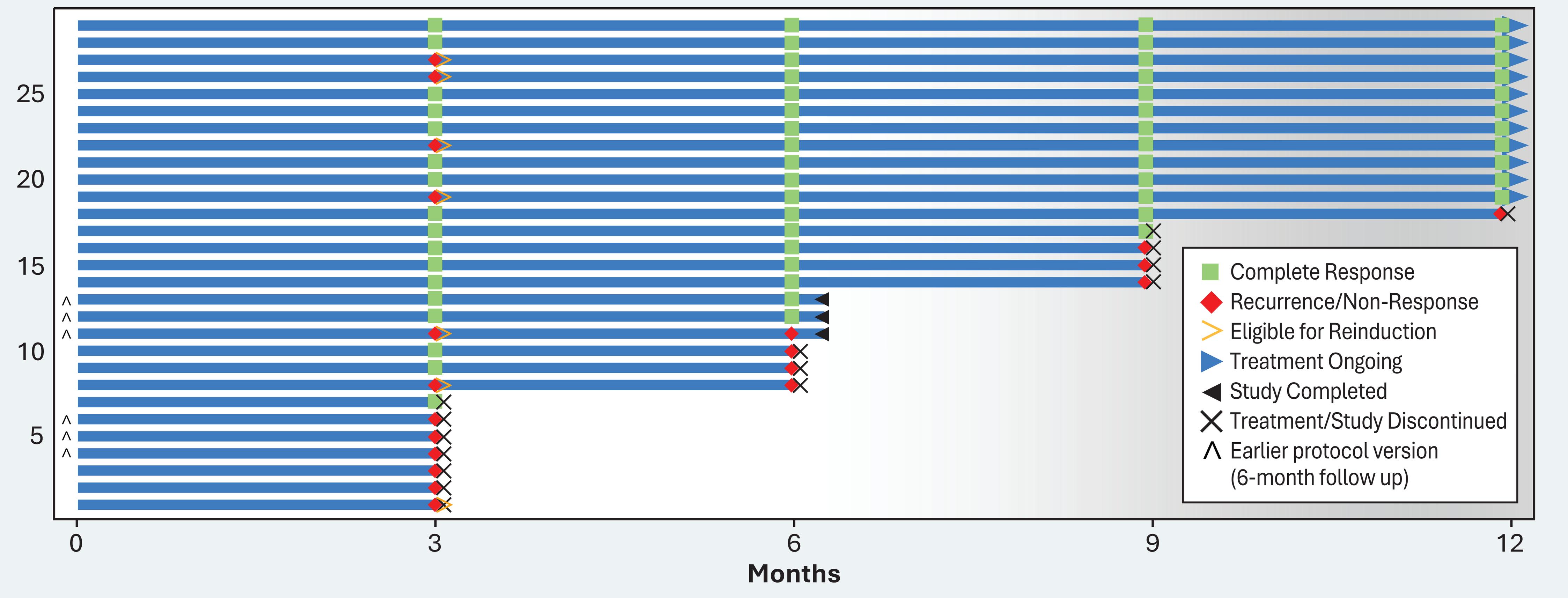


Landmark	High-grade CR Rate (%)
Month 6	66.7 (18 of 27)
Month 12	55.0 (11 of 20)

Abbreviations: CR = complete response
Note: 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 who have not yet completed the visit time point were not included.

- This dataset includes 31 enrolled participants of whom 29 were evaluable for efficacy with a median follow-up of 9.44 months (Min: 2.4, Max: 22.6)
- The CR rate was 66.7% (18 of 27) at six months and 55.0% (11 of 20) at 12 months
- Among responders:
  - The Kaplan-Meier (KM) estimated probability of maintaining a CR for six months was 73.1% (95% CI: 52.9, 93.4)
  - 91.7% (11 of 12) maintained their CR from 9 to 12 months
- 66.7% (4 of 6) of re-induced participants converted to a CR at six months
- The majority of treatment-related adverse events (TRAEs) were Grade 1 and transient. The most common TRAEs were dysuria, fatigue and hematuria.
- No participants experienced Grade 3 or greater TRAEs, related SAEs or TRAEs leading to study drug withdrawal

TARA-002 MONOTHERAPY DEMONSTRATES 55% HIGH-GRADE COMPLETE RESPONSE AT MONTH 12 IN BCG-NAÏVE PARTICIPANTS



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

TARA-002 IN NMIBC DEMONSTRATES A FAVORABLE SAFETY AND TOLERABILITY PROFILE WITH NO GRADE 3 OR GREATER TRAEs

N = 31	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
TRAEs, n (%)	8 (26)	8 (26)	1 (3)	0	0
SAEs, n (%)	4 (13)	0	0	4 (13)	0
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
Severity of adverse event is based on NCI-CTCAE Version 5.0 or later.

CONCLUSIONS

- In BCG-naïve high-grade NMIBC participants, TARA-002 demonstrated a high rate of complete response with a substantial proportion maintaining a durable response at Month 12
- Re-induction therapy successfully salvaged most initial non-responders, resulting in high conversion rates and durable responses
- TARA-002 was well tolerated; common urinary TRAEs reflect urinary tract instrumentation effects and systemic TRAEs were mild and easily managed
- These findings support continued investigation of TARA-002 in BCG-naïve high-grade NMIBC
- A Phase 3 randomized controlled study, ADVANCED-3 (NCT07480356), is planned to start this year

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