

ADVANCED-2: Preliminary Efficacy and Safety Data in BCG-naïve Participants with High-grade Non-muscle Invasive Bladder Cancer

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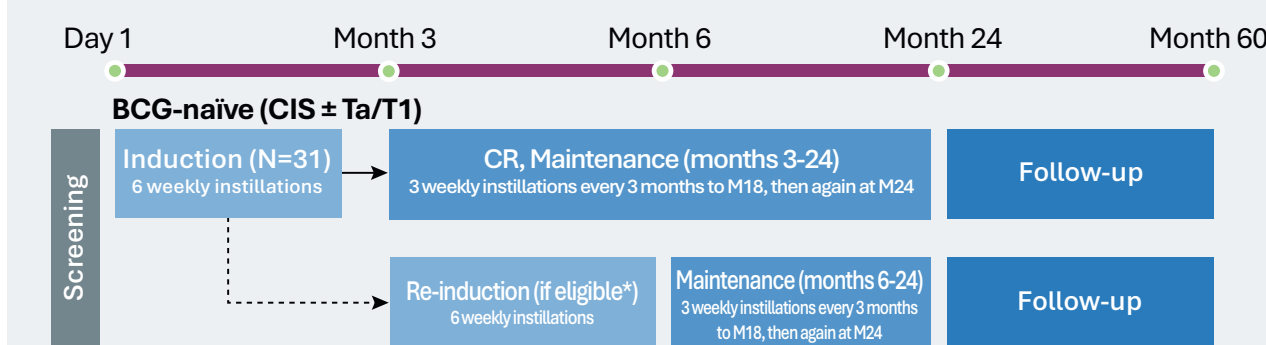
BACKGROUND

- There continues to be a significant unmet need for safe, effective, and bladder-sparing treatment options for patients with NMIBC, and this need is more pronounced in patients who are unable to access or receive BCG
- TARA-002 is a first-in-class TLR2/NOD2 agonist and novel immunopotentiator derived from inactivated *Streptococcus pyogenes* with a mechanism of action that includes the activation of innate and adaptive immune pathways within the bladder wall
- TARA-002 has shown safety and efficacy in patients with high-grade NMIBC in a BCG-unresponsive cohort and ease of use for providers

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)
- The data cutoff date is 7 November 2025
- Enrollment in this cohort is complete

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

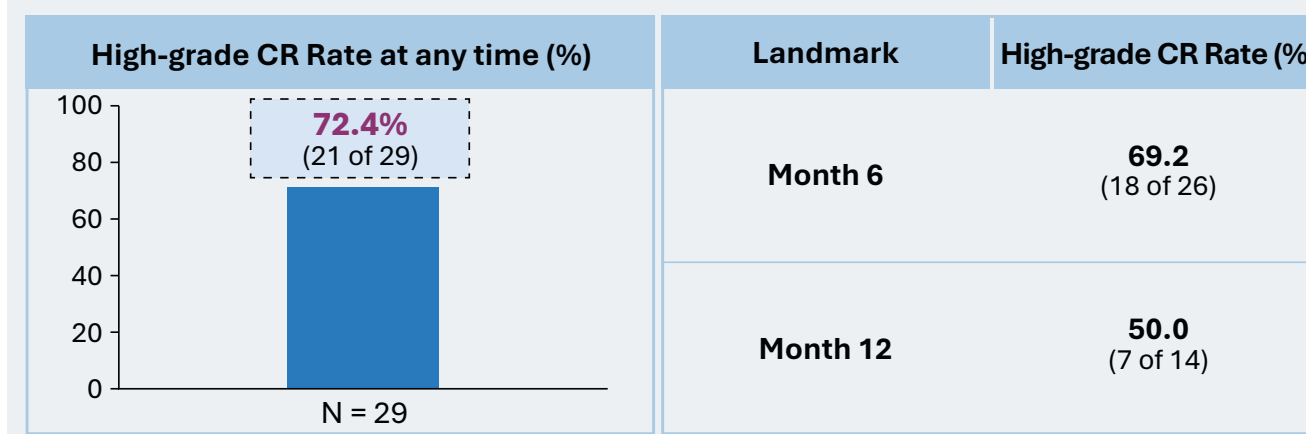


Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ; HG Ta = high grade Ta tumor; T1 = carcinoma invading the lamina propria; Ta = non-invasive papillary carcinoma.

*Eligible for re-induction: Residual CIS and/or recurrence of HG Ta

RESULTS

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



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 study includes 31 BCG-naïve participants with a median age of 71.0 years (Min: 45 years; Max: 89 years) and the majority of participants are male (80.6%, 25/31) and White (93.5%, 29/31)
- The rate of high-grade CR at any time was 72.4% (21 of 29)
- The rate of high-grade CR was 69.2% (18 of 26) at Month 6 and 50.0% (7 of 14) at Month 12
- Among initial responders, 87.5% (14 of 16) maintained their response through Month 6 and 100% (3 of 3) through Month 12
- Among the initial non-responders who underwent re-induction, 80% (4 of 5) converted to a CR by Month 6; all responders maintained CR through Month 12 (4 of 4)
- The majority of TRAEs were Grade 1 and transient; commonly occurring TRAEs included fatigue, dysuria and hematuria
- No participants experienced ≥ Grade 3 TRAEs, related SAEs or TRAEs leading to withdrawal

DISCLOSURES

This study was funded by Protara Therapeutics, Inc.

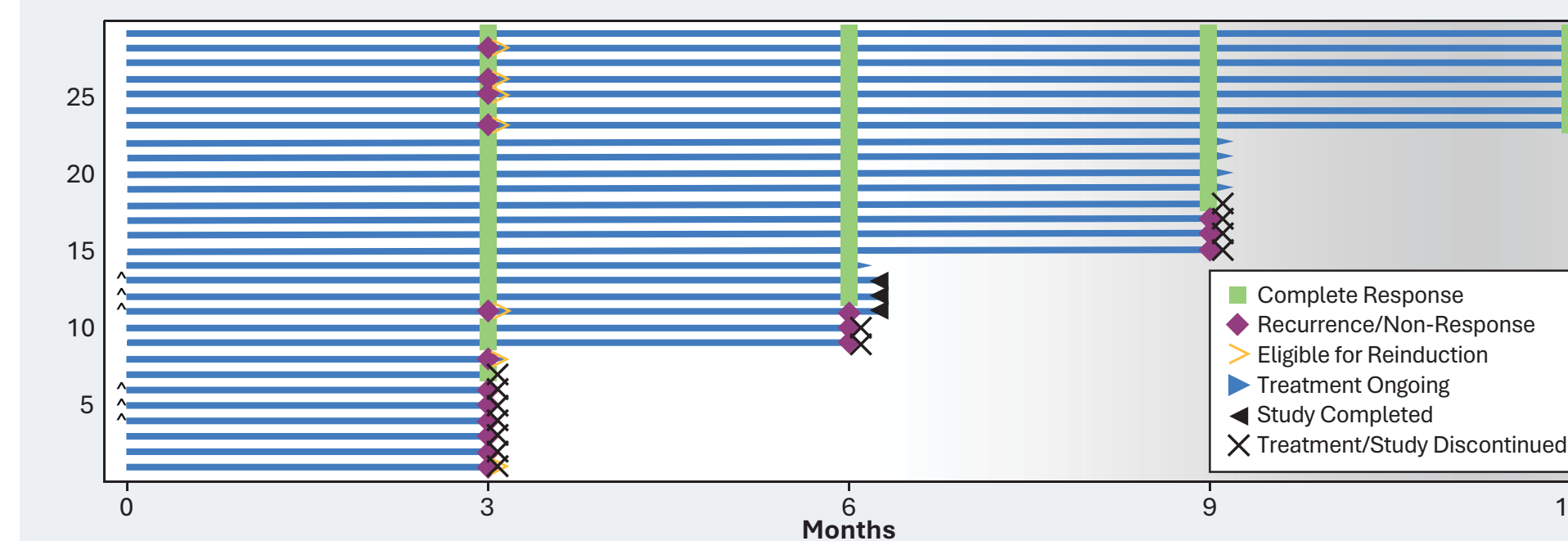
ACKNOWLEDGEMENTS

Digital and print editorial services powered by Princeton Biomedical Comm., LLC.



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TARA-002 MONOTHERAPY DEMONSTRATES 50% HIGH-GRADE COMPLETE RESPONSE AT 12 MONTHS 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 SHOWS A FAVORABLE SAFETY PROFILE WITH NO TRAEs ≥ GRADE 3, NO RELATED SAEs OR TRAEs LEADING TO WITHDRAWAL IN BCG-NAÏVE PARTICIPANTS

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	1 (3)	4 (13)	0
Related SAEs, n (%)	0	0	0	0	0
TRAEs leading to Study Drug Withdrawal, n (%)	0	0	0	0	0

Abbreviations: SAE = serious adverse event; TRAE = treatment related adverse event
 Note: Severity of adverse event is based on NCI-CTCAE Version 5.0 or after.

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 1 year
- Re-induction therapy successfully salvaged most initial non-responders, resulting in high conversion rates and durable responses
- TARA-002 was well tolerated; common urinary TEAEs reflect urinary tract instrumentation effects and systemic TEAEs were mild and easily managed
- These findings support continued investigation of TARA-002 in BCG-naïve HG-NMIBC