



## TARA-002 Demonstrates 68% Complete Response Rate at Six Months in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

February 23, 2026

*Favorable safety and tolerability profile with no Grade 3 or greater treatment-related adverse events*

*Company expects to complete enrollment of the BCG-Unresponsive cohort of the ADVANCED-2 trial in 2H 2026*

*Company to host conference call and webcast tomorrow at 8:00 a.m. ET*

NEW YORK, Feb. 23, 2026 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today announced updated interim results from its ongoing Phase 2 open-label ADVANCED-2 trial assessing intravesical TARA-002, the Company's investigational cell-based therapy, in patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) with carcinoma in situ or CIS ( $\pm$  Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive or BCG-Naïve. These results will be featured on Friday, February 27, 2026 during poster sessions at the American Society of Clinical Oncology Genitourinary Cancers Symposium in San Francisco.

"These interim data are highly encouraging with respect to TARA-002's efficacy and safety," said Raj Satkunasivam, MD, MS, FRCSC, Urologic Oncologist, Associate Professor at Houston Methodist Hospital and ADVANCED-2 study investigator. "The results in the BCG-Unresponsive cohort demonstrate compelling six-month response rates with maturing 12-month data showing promising signals of durability. These clinically meaningful response rates and favorable tolerability profile make TARA-002 a potentially promising treatment option."

"TARA-002 continues to demonstrate impressive and durable response rates with excellent safety and tolerability," said Neal Shore, MD, FACS, Medical Director of the START Carolinas/Carolina Urologic Research Center. "These results, coupled with a clean safety profile and a simple, streamlined administration for both physicians and patients, make TARA-002 a potentially innovative new therapy for urologists, particularly those in busy community practices."

### Updated Interim Results

#### *BCG-Unresponsive Cohort*

The interim analysis of the BCG-Unresponsive cohort includes 35 evaluable participants, of whom, 22 were evaluable at six months and 15 were evaluable at 12 months as of a January 28, 2026 data cutoff.

- The CR rate at any time was 65.7% (23 of 35)
- The CR rate was 68.2% (15 of 22) at six months and 33.3% (5 of 15) at 12 months
- Among responders:
  - The Kaplan-Meier (KM) estimated probability of maintaining a CR for six months was 71.1% (95% CI: 46.7, 95.5)
  - 100% (5 of 5) maintained their CR from nine to 12 months
- 61.5% (8 of 13) of re-induced patients converted to a CR at six months

#### *BCG-Naïve Cohort*

The interim analysis of the BCG-Naïve cohort includes 29 evaluable participants, 27 of whom, were evaluable at six months and 19 were evaluable at 12 months as of a January 28, 2026 data cutoff.

- The CR rate at any time was 72.4% (21 of 29)
- The CR rate was 66.7% (18 of 27) at six months and 57.9% (11 of 19) at 12 months
- Among responders:
  - The KM estimated probability of maintaining a CR for six months was 73.1% (95% CI: 52.9, 93.4)
  - 100% (11 of 11) maintained their CR from nine to 12 months
- 66.7% (4 of 6) of re-induced patients converted to a CR at six months

#### *Safety and Tolerability*

The majority of treatment-related adverse events (TRAEs) were Grade 1 and transient with no Grade 3 or greater TRAEs and no related serious adverse events as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most common TRAEs were dysuria, bladder spasm, fatigue and micturition urgency. Most bladder irritations resolved shortly after administration or within a few hours to a few days.

"The data generated to date in these high-risk NMIBC patient populations highlight TARA-002's potential as a meaningful addition to the treatment landscape," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "In addition to demonstrating impressive efficacy and safety, TARA-002 overcomes the limitations of existing NMIBC treatments that burden patients as well as urologists and their practices. We look forward to continuing to advance TARA-002's clinical development as we work to bring this treatment to patients."

## Next Steps

Protara expects to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial in the second half of 2026. Enrollment is complete in the BCG-Naïve cohort of the ADVANCED-2 trial with 31 patients, and the Company remains on track to initiate the ADVANCED-3 registrational trial in BCG-Naïve patients in the second half of 2026.

## Conference Call and Webcast

Protara will host a conference call and webcast tomorrow at 8:00 a.m. ET to review the data reported this evening. Neal Shore, MD, FACS, Medical Director of the Carolina Urologic Research Center will join management for the discussion. The live event and accompanying slides can be accessed by visiting <https://protara-therapeutics-asco-gu-update-call.open-exchange.net/>, or via the Events and Presentations section of the Company's website: <https://ir.protaratx.com>. A replay of the webcast will be archived for a limited time following the event.

## About ADVANCED-2

ADVANCED-2 (NCT05951179) is a Phase 2 open-label trial assessing intravesical TARA-002 in NMIBC patients with carcinoma in situ or CIS ( $\pm$  Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive (Cohort B N=75-100) or BCG-Naïve (Cohort A N=31). Trial subjects receive an induction course, with or without a reinduction, of six weekly intravesical instillations of TARA-002, followed by a maintenance course of three weekly instillations every three months.

## About TARA-002

TARA-002 is an investigational cell therapy in development for the treatment of NMIBC and of LMs, for which it has been granted Rare Pediatric Disease, Breakthrough and Fast Track Designations by the U.S. Food and Drug Administration. 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. When TARA-002 is administered, it is hypothesized that innate and adaptive immune cells within the cyst or tumor are activated and produce a pro-inflammatory response with release of cytokines such as tumor necrosis factor (TNF)-alpha, interferon (IFN)-gamma, IL-6, IL-10 and IL-12. TARA-002 also directly kills tumor cells and triggers a host immune response by inducing immunogenic cell death, which further enhances the antitumor immune response.

TARA-002 was developed from the same master cell bank of genetically distinct group A *Streptococcus pyogenes* as OK-432, a broad immunopotentiator marketed as Picibanil® in Japan by Chugai Pharmaceutical Co., Ltd. Protara has successfully shown manufacturing comparability between TARA-002 and OK-432.

## About Non-Muscle Invasive Bladder Cancer (NMIBC)

Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses, representing approximately 65,000 patients in the U.S. each year. NMIBC is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle.

## About Protara Therapeutics, Inc.

Protara is a clinical-stage biotechnology company committed to advancing transformative therapies for people with cancer and rare diseases. Protara's portfolio includes its lead candidate, TARA-002, an investigational cell-based therapy in development for the treatment of non-muscle invasive bladder cancer (NMIBC) and lymphatic malformations (LMs). The Company is evaluating TARA-002 in an ongoing Phase 2 trial in NMIBC patients with carcinoma in situ (CIS) who are unresponsive or naïve to treatment with Bacillus Calmette-Guérin, as well as a Phase 2 trial in pediatric patients with LMs. Additionally, Protara is developing IV Choline Chloride, an investigational phospholipid substrate replacement for patients on parenteral nutrition who are otherwise unable to meet their choline needs via oral or enteral routes. For more information, visit [www.protaratx.com](http://www.protaratx.com).

## Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Protara may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "designed," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include but are not limited to, statements regarding Protara's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: Protara's business strategy, including its development plans for its product candidates and plans regarding the timing or outcome of existing or future clinical trials (including the timing of any particular phases of such trials and the timing of the announcement of any data produced during such trials or phases thereof); statements related to expectations regarding interactions with the U.S. Food and Drug Administration (FDA); Protara's financial position; statements regarding the anticipated safety or efficacy of Protara's product candidates; and Protara's outlook for the remainder of the year and future periods. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that contribute to the uncertain nature of the forward-looking statements include: risks that Protara's financial guidance may not be as expected, as well as risks and uncertainties associated with: Protara's development programs, including the initiation and completion of non-clinical studies and clinical trials and the timing of required filings with the FDA and other regulatory agencies; general market conditions; changes in the competitive landscape; changes in Protara's strategic and commercial plans; Protara's ability to obtain sufficient financing to fund its strategic plans and commercialization efforts; having to use cash in ways or on timing other than expected; the impact of market volatility on cash reserves; failure to attract and retain management and key personnel; the impact of general U.S. and foreign, economic, industry, market, regulatory, political or public health conditions; and the risks and uncertainties associated with Protara's business and financial condition in general, including the risks and uncertainties described more fully under the caption "Risk Factors" and elsewhere in Protara's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Protara undertakes no obligation to update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as required by law.

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