Protara Therapeutics Announces Positive Updated 12-Month Data Demonstrating Durable Responses in the Fully Enrolled BCG-Naïve Cohort of the Ongoing Phase 2 ADVANCED-2 Trial of TARA-002 in NMIBC

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TARA-002 demonstrates 72% complete response rate at any time, 67% complete response rate at the 6-month landmark and 55% complete response rate at the 12-month landmark in BCG-Naïve patients

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

Company remains on track to initiate the ADVANCED-3 registrational trial in BCG-Naïve patients in 2H 2026

NEW YORK, May 15, 2026 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage biotechnology company developing transformative therapies for the treatment of cancer and rare diseases, today announced positive updated 12-month data from Cohort A of the ongoing Phase 2 open-label ADVANCED-2 trial of TARA-002 in patients with carcinoma in situ or CIS (± Ta/T1) non-muscle invasive bladder cancer (NMIBC). These results in Bacillus Calmette-Guérin (BCG)-Naïve NMIBC patients will be featured today during a poster session at the American Urological Association (AUA) 2026 Annual Meeting in Washington, D.C.

“Today’s presentation demonstrates TARA-002’s impressive 12-month durability data and excellent safety profile for patients with BCG-Naïve NMIBC,” said Mark Tyson, M.D., Professor of Urology, Mayo Clinic Phoenix, and ADVANCED-2 study investigator. “The NMIBC patient community faces a critical unmet need for safe, effective and bladder-sparing treatment options for this devastating disease. These compelling data, coupled with a simple, streamlined administration for both physicians and patients, make TARA-002 a potentially important new treatment option for BCG-Naïve high risk NMIBC patients.”

“These data continue to support our conviction that TARA-002 has the potential to make a meaningful difference in the lives of patients with BCG-Naïve NMIBC,” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “Notably, the durable 12-month complete response (CR) rate observed in the BCG-Naïve cohort continues to perform competitively among approved treatments and investigational therapies in development. We look forward to completing enrollment in the registrational BCG-Unresponsive cohort of ADVANCED-2 and initiating ADVANCED-3, a registrational trial of TARA-002 compared to intravesical chemotherapy in BCG-Naïve and potentially BCG-Exposed patients in the second half of 2026.”

Updated Data Results in BCG-Naïve Patients

Efficacy

The BCG-Naïve dataset includes a total of 31 patients of whom 29 were evaluable for efficacy, with 27 patients evaluable at six months and 20 patients evaluable at 12 months, as of an April 5, 2026 data cutoff.

- The CR rate at any time in BCG-Naïve patients was 72.4% (21 of 29).
- The CR rate in BCG-Naïve patients was 66.7% (18 of 27) at six months and 55.0% (11 of 20) at 12 months.
- Among responders:
  - The Kaplan-Meier 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 nine to 12 months.
- 66.7% (4 of 6) of re-induced patients converted to a CR at six months.

Safety

The majority of treatment-related adverse events (TRAEs) were Grade 1 and transient, with no Grade 3 or greater TRAEs reported, as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most commonly reported TRAEs were dysuria, fatigue, and hematuria.

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 (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive or BCG-Naïve. Trial subjects received 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. Protara has completed enrollment of the BCG-Naïve cohort and expects to complete enrollment of the BCG-Unresponsive cohort in the second half of 2026.

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, Orphan Drug, Breakthrough Therapy and Fast Track designations by the FDA. 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. 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 the 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.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

Bladder cancer is the sixth most common cancer in the United States, with non-muscle invasive bladder cancer (NMIBC) representing approximately 80% of bladder cancer diagnoses, or 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 support who are otherwise unable to meet their choline needs via oral or enteral routes. For more information, visit 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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