Protara Therapeutics to Present Updated Interim Data from Phase 2 ADVANCED-2 Trial of TARA-002 in BCG-Unresponsive NMIBC Patients at the ASCO Genitourinary Cancers Symposium

January 22, 2026

NEW YORK, Jan. 22, 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 that updated interim data from the cohort of BCG-Unresponsive non-muscle invasive bladder cancer (NMIBC) patients in the ongoing Phase 2 ADVANCED-2 trial of TARA-002 will be featured at the upcoming American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place from February 26, 2026 to February 28, 2026 in San Francisco.

The poster presentation will include updated safety and efficacy data from approximately 25 six-month evaluable BCG-Unresponsive NMIBC patients in the ongoing Phase 2 ADVANCED-2 trial.

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 (Cohort B N=75-100) or BCG-Naïve (Cohort A N=31). 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.

Details of the poster presentations are as follows:

Title: ADVANCED-2: Interim efficacy and safety data in BCG-Unresponsive participants with high-grade non-muscle invasive bladder cancer

Poster Number: F15

Poster Track: Urothelial Carcinoma

Session Title: Poster Session B: Prostate Cancer and Urothelial Carcinoma

Session Date and Time: Friday, February 27, 2026

In addition, interim safety and tolerability data from both BCG-Naïve and BCG-Unresponsive patients enrolled in ADVANCED-2 will also be presented.

Title: Interim safety and tolerability of TARA-002 in patients with BCG-Naïve and Unresponsive high-grade non-muscle invasive bladder cancer in ADVANCED-2

Poster Number: H8

Poster Track: Urothelial Carcinoma

Session Title: Poster Session B: Prostate Cancer and Urothelial Carcinoma

Session Date: Friday, February 27, 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 Designation by the U.S. Food and Drug Administration. 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.

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 release of cytokines such as tumor necrosis factor (TNF)-alpha, interferon (IFN)-gamma IL-6, IL-10, 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.

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. Approximately 65,000 patients are diagnosed with NMIBC in the United States 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.

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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