Protara Therapeutics Highlights Recent Updates and Anticipated 2026 Milestones

January 12, 2026

On track to report interim results from approximately 25 six-month evaluable BCG-Unresponsive patients in ADVANCED-2 trial in Q1 2026

Received Breakthrough Therapy and Fast Track designations for TARA-002 in LMs; regulatory update expected in 1H 2026

Dosed first patient in THRIVE-3 registrational trial of IV Choline Chloride in patients dependent on long-term parenteral support and expect to report interim results in 2H 2026

Recently completed approximately $86 million public offering extending cash runway into 2028

NEW YORK, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today highlighted recent updates and anticipated 2026 milestones.

“On the heels of a remarkable year marked by meaningful progress across the entirety of our pipeline, we are entering 2026 with unwavering resolve to continue to execute on our mission to deliver transformative therapies to patients with cancer and rare diseases,” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “For our non-muscle invasive bladder cancer (NMIBC) program, our growing body of clinical data continue to support that TARA-002 could serve as a differentiated, easy to administer treatment option across the NMIBC treatment landscape. Following our recent ADVANCED-2 update in which TARA-002 demonstrated meaningful and durable activity in BCG-Naïve NMIBC patients, we look forward to providing an interim update on the registrational BCG-Unresponsive trial later this quarter.”

Mr. Shefferman added, “We have also made important progress in our rare disease programs. Following positive results from the ongoing Phase 2 STARBORN-1 trial of TARA-002 in lymphatic malformations (LMs), we were pleased that the FDA granted this program both Breakthrough Therapy and Fast Track designations and we expect to provide a regulatory update defining the path to registration in the first half of this year. Additionally, we were pleased to announce that the first patient has been dosed in our registrational THRIVE-3 trial of IV Choline Chloride in patients on long-term parenteral support (PS) and expect to provide an interim analysis in the second half of 2026. We believe we are well positioned for continued success with several key milestones anticipated in the year ahead.”

Recent Company Updates and Planned 2026 Milestones

TARA-002 in NMIBC

- Protara remains on track to report in the first quarter of 2026 interim results in approximately 25 six-month evaluable patients from its ongoing Phase 2 open-label ADVANCED-2 trial in NMIBC patients with carcinoma in situ or CIS (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive.

- In December 2025, the Company reported positive interim results from its ongoing Phase 2 open-label ADVANCED-2 trial in NMIBC patients with CIS (± Ta/T1) who are BCG-Naïve at the 26th Annual Meeting of the Society of Urologic Oncology (SUO) in which TARA-002 demonstrated meaningful response rates at six and 12 months and a favorable safety and tolerability profile. Based on feedback from the U.S. Food and Drug Administration (FDA), the Company plans to commence a registrational trial of TARA-002 compared to intravesical chemotherapy in BCG-naïve patients in the second half of 2026.

- Protara continues to evaluate subcutaneous dosing through priming and maintenance combined with intravesical dosing, as well as exploring combination treatments with TARA-002 in NMIBC patients with CIS.

TARA-002 in LMs

- Protara recently announced that the FDA granted TARA-002 both Fast Track and Breakthrough Therapy designations for the treatment of pediatric patients with macrocystic and mixed cystic LMs. TARA-002 previously was granted Rare Pediatric Disease designation for the treatment of LMs.

- The Company plans to share a regulatory update on the path forward for registration for TARA-002 in LMs in the first half of 2026.

TARA-002 Manufacturing Update

- Protara recently announced that TARA-002 has been selected to participate in this year's FDA Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program. The FDA created the CDRP Program to facilitate CMC development for therapies with compressed clinical development timeframes based on the anticipated clinical benefits of earlier patient access to the therapy. The initiative is designed to promote earlier and more structured engagement between sponsors and FDA on CMC development strategies, and since its inception, has led to increased collaboration with the FDA so sponsors can confidently scale up manufacturing capacity while clinical development is ongoing.

IV Choline Chloride for Patients on PS

- The Company recently announced that the first patient has been dosed in THRIVE-3 (NCT06910943), a seamless Phase 2b/3 trial designed to assess the efficacy and safety of low and high dose IV Choline Chloride in adolescent and adult patients receiving long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated. Following an 8-week Phase 2b open-label, dose-confirmation trial in 24 patients, approximately 105 additional patients will be enrolled in a 24-week Phase 3 double-blinded, randomized, placebo-controlled trial. The primary endpoint of the trial is the change in plasma choline concentration from baseline compared to placebo. The Company expects to report interim results in the second half of 2026.

Corporate Update

- In December 2025, the Company announced that it closed an underwritten public equity offering of approximately $86 million before deducting underwriting discounts and commissions and offering expenses payable by Protara. The proceeds from the offering are expected to extend the Company's cash runway into 2028.

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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Source: Protara Therapeutics