



Protara Therapeutics Completes Enrollment of the Phase 2b Open-Label Dose Confirmation Phase of the THRIVE-3 Registrational Trial of IV Choline Chloride in Patients on Parenteral Support

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Company remains on track to report interim results from Phase 2b cohort in 4Q 2026

NEW YORK, Oct. 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 that it has completed enrollment of the Phase 2b, open-label dose confirmation phase of the THRIVE-3 clinical trial evaluating IV Choline Chloride in patients with intestinal failure who are dependent on parenteral support (PS). The dose confirmation phase of the trial includes 24 patients.

"We are excited about our progress in the registrational THRIVE-3 trial, which brings us one step closer to a solution for patients on parenteral support," said Jesse Shefferman, Chief Executive Officer at Protara Therapeutics. "Choline plays a critical role in liver function, yet there are currently no approved PS formulations containing choline, leaving approximately 80 percent of the roughly 30,000 PS-dependent adult patients in the U.S. with choline deficiency. The majority of these patients suffer from some degree of liver damage. We believe IV Choline Chloride has the potential to become the first FDA-approved IV Choline formulation for PS patients. We look forward to reporting interim results from the Phase 2b dosing cohort of THRIVE-3 in the fourth quarter of this year."

THRIVE-3 ([NCT06910943](#)) is a registrational, seamless Phase 2b/3 clinical trial evaluating the efficacy and safety of IV Choline Chloride in adolescent and adult patients with intestinal failure who are dependent on PS and have choline deficiency. The Phase 2b portion of the study is an open-label dose confirmation trial of 24 patients, designed to evaluate the safety and pharmacokinetics of IV Choline Chloride across multiple doses and to select dose(s) for continued evaluation. The Phase 3 trial is a randomized, double-blind, placebo-controlled phase of approximately 100 patients, designed to evaluate the efficacy of IV Choline Chloride in elevating plasma choline levels, as well as its safety. The primary endpoint is the change in plasma choline concentration from baseline to week 8 and the secondary endpoints include steatosis and liver function tests.

About IV Choline Chloride for Patients on Parenteral Support

IV Choline Chloride is an investigational, intravenous phospholipid substrate replacement therapy in development for patients receiving parenteral support (PS). Choline is an important substrate for phospholipids that are critical for healthy liver function and play an important role in modulating gene expression, cell membrane signaling, brain development and neurotransmission, muscle function and bone health. There are currently no available PS formulations containing choline. Every year in the U.S. there are approximately 90,000 people who require PS at home and of those approximately 30,000 are on long-term PS. IV Choline Chloride has the potential to become the first FDA approved IV choline formulation for PS patients. It has been granted Orphan Drug designation by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term parenteral nutrition and has been granted Fast Track designation as a source of choline when oral or enteral nutrition is not possible, insufficient or contraindicated.

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 ongoing clinical trials in NMIBC patients with carcinoma in situ (CIS) who are unresponsive or naïve to treatment with Bacillus Calmette-Guérin, as well as a pivotal 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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