Protara Therapeutics Announces Dosing of First Patient in Phase 3 Registrational THRIVE-3 Trial of IV Choline Chloride in Patients on Long-Term Parenteral Support

January 7, 2026

NEW YORK, Jan. 07, 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 patient dosing is now underway in its Phase 3 registrational THRIVE-3 clinical trial evaluating intravenous (IV) Choline Chloride in patients receiving long-term parenteral support (PS). IV Choline Chloride, the Company's investigational phospholipid substrate replacement therapy, was previously granted Fast Track designation by the U.S. Food and Drug Administration.

"Choline deficiency, which can lead to serious hepatic injury, neuropsychological impairment, muscle damage, and thrombotic abnormalities, has been shown to impact 78% of patients dependent on PS, yet there are currently no approved IV choline products globally to address this pressing need," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "We believe that IV Choline Chloride has the potential to make a meaningful impact in this highly underserved population and could ultimately become the first FDA-approved IV choline therapy for patients dependent on PS. We look forward to advancing this important study and expect to provide an interim analysis from the trial in the second half of 2026."

THRIVE-3 (NCT06910943) is 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. In addition, patients will be eligible to advance to an open-label extension period following completion of each phase of the study.

Choline is an essential quaternary amine that is naturally available in some foods and is widely utilized throughout the human body as an important contributor to many steps of metabolism. It serves as a key methyl donor in multiple metabolic pathways and is abundantly stored as a phospholipid throughout the human body. Patients on PS are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. IV choline is recommended for patients receiving PS by the American Society for Parenteral and Enteral Nutrition (ASPEN) in its Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi–Trace Element Products, as well as by the European Society for Clinical Nutrition and Metabolism (ESPEN) in its Guideline on Home Parenteral Nutrition.

About IV Choline Chloride

IV Choline Chloride is an investigational, intravenous phospholipid substrate replacement therapy in development for patients receiving PS. Choline is a known important substrate for phospholipids that are critical for healthy liver function that also play an important role in modulating gene expression, cell membrane signaling, brain development and neurotransmission, muscle function, and bone health. PS patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. Seventy-eight percent of patients dependent on PS are choline-deficient and 63% of those have some degree of liver dysfunction, which can lead to hepatic failure. 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 U.S. Food and Drug Administration (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 PN and has been granted Fast Track Designation as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated. The U.S. Patent and Trademark Office has issued Protara a U.S. patent claiming a choline composition and a U.S. patent claiming a method for treating choline deficiency with a choline composition, each with a term expiring in 2041.

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.

Company Contact:

Justine O'Malley
Protara Therapeutics
Justine.OMalley@protaratx.com
646-817-2836

Source: Protara Therapeutics