Protara Therapeutics Announces Trials in Progress Poster Presentation for the ADVANCED-1 Trial in NMIBC at the 23rd Annual Meeting of the Society of Urologic Oncology

December 1, 2022

NEW YORK, Dec. 01, 2022 (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 it will present a Trials in Progress poster related to its ADVANCED-1 Phase 1 trial at the Annual Meeting of the Society of Urologic Oncology being held in San Diego, California from November 30, 2022 through December 2, 2022. The ADVANCED-1 study is evaluating TARA-002, an investigational cell-based immunopotentiator, for the treatment of non-muscle invasive bladder cancer (NMIBC).

“This large addressable patient population is underserved by current treatment options which drives significant unmet need in NMIBC, and leaves room for creative therapeutic approaches such as TARA-002,” said Jathin Bandari, M.D., Chief Medical Officer of Protara Therapeutics. “Based on TARA-002’s immune-potentiating mechanism of action and supportive clinical data from its predecessor compound OK-432 in multiple solid tumors, we are excited to continue our ongoing ADVANCED-1 trial exploring TARA-002 in NMIBC and look forward to expanding our clinical development program.”

Details of the poster presentation are as follows:

Title: Phase 1a/b Safety Study of Intravesical Instillation of TARA-002 in Adults with High-grade Non-muscle Invasive Bladder Cancer (ADVANCED-1)
Poster Number: 191
Poster Category: Bladder 4 (Bladder Cancer > Non-Muscle Invasive Bladder Cancer)
Session Title: E-Poster Displays
Session Date and Time: Friday, December 2 at 9:00 a.m. - 10:00 a.m.
Location: Sapphire ABEFIJMN, Hilton San Diego Bayfront, San Diego, California

ADVANCED-1 is a Phase 1 dose-finding, open-label trial (NCT05085977 and NCT05085990) evaluating TARA-002 in treatment-naïve and treatment-experienced NMIBC patients with high-grade carcinoma in situ (CIS) and high-grade papillary tumors (Ta). In the initial dose escalation phase of the trial, patients will receive six weekly intravesical doses of TARA-002. The primary objective of the trial is to evaluate the safety, tolerability and preliminary signs of anti-tumor activity of TARA-002, with the goal of establishing a recommended dose for a planned Phase 2 clinical trial.

About TARA-002

TARA-002 is an investigational cell therapy in development for the treatment of NMIBC and 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 and Taiwan by Chugai Pharmaceutical Co., Ltd.

When TARA-002 is administered, it is hypothesized that innate and adaptive immune cells within the cyst or tumor are activated and produce a strong immune cascade. Neutrophils, monocytes and lymphocytes infiltrate the abnormal cells and various cytokines, including interleukins (IL)-2, IL-6, IL-8, IL-10, IL-12, interferon (IFN)-gamma, tumor necrosis factor (TNF)-alpha, granulocyte colony-stimulating factor, and granulocyte-macrophage colony-stimulating factor, are secreted by immune cells to induce a strong local inflammatory reaction and destroy the abnormal cells.

About Non-Muscle Invasive Bladder Cancer

Bladder cancer is the 6th 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 committed to identifying and advancing transformative therapies for people with cancer and rare diseases with limited treatment options. Protara’s portfolio includes its lead program, TARA-002, an investigational cell-based therapy being developed for the treatment of non-muscle invasive bladder cancer and lymphatic malformations, and IV Choline Chloride, an investigational phospholipid substrate replacement therapy for the treatment of intestinal failure-associated liver disease. 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; statements related to expectations regarding interactions with the FDA, including potential alignment with the FDA on, and finalization of, clinical trial design for TARA-002 in pediatric LM patients; Protara’s financial footing; statements regarding the anticipated safety or efficacy of Protara’s product candidates; and Protara’s outlook for the remainder of the year.

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; the impact of the COVID-19 pandemic on Protara's business and the global economy as well as the impact on Protara's contract research organizations, study sites or other clinical partners; 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; the loss of key members of management; the impact of general U.S. and foreign, economic, industry, market, regulatory or political 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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