# Protara Therapeutics to Present Interim Analysis from the Phase 2 ADVANCED-2 Trial of TARA-002 in Patients with NMIBC at the American Urological Association Annual Meeting

April 10, 2025

NEW YORK, April 10, 2025 (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 two presentations and a panel discussion highlighting the ongoing Phase 2 open-label ADVANCED-2 trial of TARA-002 in patients with non-muscle invasive bladder cancer (NMIBC) will be featured at the upcoming American Urological Association (AUA) 2025 Annual Meeting taking place from April 26, 2025 to April 29, 2025 in Las Vegas.

A copy of the abstract for the ADVANCED-2 interim analysis is now available on the AUA website. Updated safety and efficacy data, including data from patients who have reached the 12-month evaluation timepoint, will be featured during an interactive poster session on Saturday, April 26, 2025.

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 (n≈100) and BCG-Naïve (n=30). The BCG-Unresponsive cohort has been designed to be registrational in alignment with the U.S. Food and Drug Administration's 2024 BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment, Draft Guidance for Industry.

**Presentation Details:**

- **Title:** Preliminary Anti-Tumor Activity and Safety Results from ADVANCED-2: A Phase 2 Open-Label Study of Intravesical TARA-002 in Adults with High-Grade Non-Muscle Invasive Bladder Cancer
- **Session:** Bladder Cancer: Non-Invasive I
- **Presenter:** Gautam Jayram, M.D., Director, Advanced Therapeutics Center, Urology Associates P.C., Nashville, TN
- **Session Date and Time:** Saturday, April 26, 2025, 7:00 a.m. – 9:00 a.m. PT
- **Location**: Marco Polo 701

- **Title:** ADVANCED-2: A Phase 2 Open-Label Study to Evaluate the Safety and Efficacy of Intravesical Instillation of TARA-002 in Adults with High-Grade Non-Muscle Invasive Bladder Cancer
- **Session:** Clinical Trials in Progress: Bladder Cancer
- **Presenter:** Brian Mazzarella, M.D., Vice President of Research at Urology America, Austin, TX
- **Session Date and Time:** Monday, April 28, 2025, 9:16 a.m. – 9:24 a.m. PT
- **Location:** Hall C, The Square, Learning Lab

**AUA Learning Lab Featured Trials Panel Discussion Details:**

- **Title:** ADVANCED-2: A Phase 2 Open-Label Study to Evaluate the Safety and Efficacy of Intravesical Instillation of TARA-002 in Adults with High-Grade Non-Muscle Invasive Bladder Cancer
- **Moderator:** Jacqueline Zummo, Ph.D., Co-Founder, Senior Vice President, Chief Scientific Operations Officer, Protara Therapeutics
- **Speakers:**
  - Timothy D. Lyon, M.D., Associate Professor of Urology and Urology Residency Program Director at Mayo Clinic, Jacksonville, FL
  - Brian Mazzarella, M.D., Vice President of Research at Urology America, Austin, TX
  - Alex Sankin, M.D., MS, Director of Clinical Trials Program, Associate Program Director of Urology Residency, Associate Professor and Attending Physician at Montefiore Medical Center, Bronx, NY
- **Date and Time:** Monday, April 28, 2025, 11:00 a.m. – 11:30 a.m. PT

**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 and also approved in Taiwan. Protara has successfully shown manufacturing comparability between TARA-002 and OK-432.

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 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 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 (BCG), 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.

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