Protara Therapeutics Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 8, 2023

- Data from Phase 1a Portion of ADVANCED-1 Trial of TARA-002 for the Treatment of Non-Muscle Invasive Bladder Cancer Expected in 2Q23 –

- Start up Activities for Phase 2 Trial of TARA-002 in Lymphatic Malformations Underway; Trial Initiation Expected 2H23 -

- Cash, Cash Equivalents and Investments of $102.3M as of December 31, 2022 Expected to Fund Operations and Data Milestones into 2025 -

NEW YORK, March 08, 2023 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today announced financial results for the full year and fourth quarter ended December 31, 2022, and provided a business update.

"With key data and milestones expected from our clinical programs for TARA-002, including data from the Phase 1a portion of the ADVANCED-1 trial in non-muscle invasive bladder cancer (NMIBC) in the second quarter of 2023, we believe this year will be a particularly exciting time for Protara," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "We look forward to leveraging data from the ADVANCED-1 trial to inform the design of further clinical studies in our NIMBC program. For our program in lymphatic malformations (LMs), a highly underserved pediatric population for which we believe TARA-002 could serve as a meaningful intervention, we have begun Phase 2 clinical trial start up activities and anticipate initiating the trial in the second half of this year. We believe we are well positioned to successfully execute on our pipeline programs and look forward to providing updates in due course."

Recent Highlights

TARA-002 in NMIBC

- In December 2022, the Company's Phase 1 ADVANCED-1 clinical trial of TARA-002, Protara's investigational cell-based immunopotentiator for the treatment of NMIBC, was featured in a Trials in Progress poster at the Annual Meeting of the Society of Urologic Oncology.
- The Company expects to report data from the Phase 1a portion of the trial in the second quarter of 2023 and move rapidly into the Phase 1b expansion portion of the trial, which will evaluate safety and efficacy in patients with carcinoma in situ (CIS).

TARA-002 in LMs

- The Company has initiated study start up activities for a Phase 2 clinical trial of TARA-002 in pediatric patients with macrocystic and mixed-cystic LMs.

IV Choline Chloride in Intestinal Failure Associated Liver Disease (IFALD)

- Protara's prospective study to enhance understanding of the incidence of IFALD in patients dependent on parenteral nutrition is ongoing with results expected in the third quarter of 2023.
- The Company plans to leverage results from the prospective study, as well as its completed retrospective study, to inform next steps for the IV Choline Chloride development program.

Corporate Updates

- In January 2023, Protara announced the appointment of Patrick Fabbio as Chief Financial Officer. Mr. Fabbio brings to Protara more than 30 years of experience at various life science and pharmaceutical companies and most recently served as President and Chief Financial Officer at NYSE-listed Rafael Holdings, Inc.

Fourth Quarter and Full Year 2022 Financial Results

- As of December 31, 2022, cash, cash equivalents and marketable debt securities totaled $102.3 million. The Company expects its cash, cash equivalents, and marketable debt securities will be sufficient to fund its planned operations and data milestones into 2025.

- Research and development expenses for the fourth quarter of 2022 increased to $5.0 million from $4.1 million for the prior year period, and for the full year decreased to $16.8 million compared to $21.1 million for 2021. The fourth quarter increase was primarily due to an increase in non-clinical studies performed in the quarter versus the comparable period. The full year decrease was primarily due to a reduction in clinical manufacturing expenses.

- General and administrative expenses for the fourth quarter of 2022 decreased to $5.0 million from $6.2 million for the prior year period, and for the full year decreased to $20.7 million compared to $26.4 million for 2021. The fourth quarter and full year decreases were primarily due to a reduction in stock based compensation expense and market development activities.

- For the fourth quarter of 2022, Protara reported a net loss of $39.0 million, or $3.46 per share, compared with a net loss of $10.2 million, or $0.91 per share, for the same period in 2021. Net loss in the fourth quarter of 2022 included a non-cash goodwill impairment charge of $29.5 million associated with the accounting for the reverse merger transaction in January of 2020. Net loss for the year ended December 31, 2022 was $66.0 million, or $5.86 per share, compared with a net loss of $47.3 million, or $4.21 per share, for the year ended December 31, 2021. Net loss for the fourth quarter included approximately $1.4 million of stock-based compensation expenses. Net loss for the year ended December 31, 2022 included approximately $6.7 million of stock-based compensation expenses.

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. Protara has successfully demonstrated 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 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 (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 Lymphatic Malformations (LMs)

LMs are rare, congenital malformations of lymphatic vessels resulting in the failure of these structures to connect or drain into the venous system. Most LMs are present in the head and neck region and are diagnosed in early childhood during the period of active lymphatic growth, with more than 50% detected at birth and 90% diagnosed before the age of 3 years. The most common morbidities and serious manifestations of the disease include compression of the upper aerodigestive tract, including airway obstruction requiring intubation and possible tracheostomy dependence; intralesional bleeding; impingement on critical structures, including nerves, vessels, lymphatics; recurrent infection, and cosmetic and other functional disabilities.

About IV Choline Chloride and Intestinal Failure-associated Liver Disease (IFALD)

IV Choline Chloride is an investigational, intravenous (IV) phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition (PN) who have IFALD. Choline is a known important substrate for phospholipids that are critical for healthy liver function. Because PN patients cannot sufficiently absorb adequate levels of choline and no available PN formulations contain sufficient amounts of choline to correct this deficiency, PN patients often experience a prolonged progression to hepatic failure and death, with the only known intervention being a dual small bowel/liver transplant. If approved, IV Choline Chloride would be the first approved therapy for IFALD. It has been granted Orphan Drug Designations (ODDs) by the FDA for the treatment of IFALD and the prevention of choline deficiency in PN patients.

About Protara Therapeutics, Inc.

Protara is committed to advancing transformative therapies for people with cancer and rare diseases. 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; 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. 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

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; 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.

Protara Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 24,127	$ 35,724
Marketable debt securities	60,243	55,505
Prepaid expenses and other current assets	1,776	1,883
Total current assets	86,146	93,112
Restricted cash, non-current	745	745
Marketable debt securities, non-current	17,886	39,467
Property and equipment, net	1,592	1,719
Operating lease right-of-use asset	6,277	7,171
Goodwill	-	29,517
Other assets	644	865
Total assets	$ 113,290	$ 172,596
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,586	$ 954
Accrued expenses	3,237	2,489
Operating lease liability	917	855
Total current liabilities	5,740	4,298
Operating lease liability, non-current	5,467	6,384
Total liabilities	11,207	10,682
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value, authorized 10,000,000 shares:		
Series 1 convertible preferred stock, 8,028 shares authorized at December 31, 2022 and 2021, respectively 8,027 shares issued and outstanding as of December 31, 2022 and 2021, respectively.	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares:		
Common stock, 11,267,389 and 11,235,731 shares issued and outstanding as of December 31, 2022 and 2021, respectively.	11	11
Additional paid in capital	262,724	256,126
Accumulated deficit	(159,964)	(94,012)
Accumulated other comprehensive income (loss)	(688)	(211)
Total stockholders' equity	102,083	161,914
Total liabilities and stockholders' equity	$ 113,290	$ 172,596

Protara Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	(Unaudited)		*(Audited)*	
	Three months ended		**Years Ended December 31,**	
	12/31/2022	**12/31/2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 4,989	$ 4,068	$ 16,808	$ 21,088
General and administrative	5,003	6,220	20,737	26,401
Loss on impairment of goodwill	29,517	-	29,517	-
Total operating expenses	39,509	10,288	67,062	47,489

Loss from operations	(39,509)	(10,288)	(67,062)	(47,489)
Interest and investment income	543	59	1,110	237
Net loss	38,966	(10,229)	(65,952)	(47,252)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.46)	$ (0.91)	$ (5.86)	$ (4.21)
Weighted average shares outstanding, basic and diluted	11,267,389	11,235,731	11,259,615	11,232,576
Other comprehensive income (loss):				
Net unrealized (loss) gain on marketable debt securities	442	(172)	(477)	(211)
Other comprehensive income (loss)	442	(172)	(477)	(211)
Comprehensive Loss	$ (38,524)	$ (10,401)	$ (66,429)	$ (47,463)

Company Contact:

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

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