TRACON Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 10, 2022

SAN DIEGO, Aug. 10, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals, Inc. (Nasdaq: TCON), a clinical stage biopharmaceutical company utilizing a cost-efficient, CRO-independent product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies, today announced financial results for the second quarter ended June 30, 2022. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We continue to have robust accrual in the ENVASARC pivotal trial as we have enrolled more than 36 patients and look forward to reporting the interim efficacy analysis on the initial 36 patients in the fourth quarter, after each patient has had two on-study scans." said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Additionally, we await the outcome of the binding arbitration relating to I-Mab's alleged breaches of the TJ4309 and bispecific antibody agreements, and anticipate completing the TJ4309 Phase 1 trial that permits I-Mab the opportunity to terminate the license for a $9M payment to TRACON. We expect both the arbitration decision and the termination of the TJ4309 license to occur this year."

Recent Corporate Highlights

- In June, we announced a registered direct financing of approximately $4.0 million in the aggregate with an accredited institutional healthcare-focused fund, which was completed at market price.
- In July, we announced the enrollment of the 36th patient in the ENVASARC Phase 2 pivotal trial at the 600 mg dose of envafolimab.
- In August, we announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the initiation of a Phase 1/2 clinical study of YH001 in combination with envafolimab and doxorubicin for the treatment of sarcoma patients, including patients who have not received prior therapy.
- In August, the Independent Data Monitoring Committee (IDMC) recommended the ENVASARC trial proceed as planned following the review of more than three weeks of safety data from more than 20 patients who received the 600 mg dose of envafolimab as a single agent or with Yervoy®.

Expected Key 2022 Milestones

- Report the interim safety analysis by the IDMC following the review of more than twelve weeks of safety data from more than 20 patients who received the 600 mg dose of envafolimab as a single agent or with Yervoy®.
- Report the interim efficacy analysis by the IDMC following the review of more than twelve weeks of efficacy data from 36 patients who received the 600 mg dose of envafolimab as a single agent or with Yervoy®.
- Initiate dosing in the Phase 1/2 clinical trial of envafolimab with our potential best in class CTLA-4 antibody YH001 as well as with doxorubicin chemotherapy.
- Report the International Chamber of Commerce (ICC) Arbitration Panel's (the Tribunal) binding decision in the ongoing arbitration involving the TJ4309 and bispecific antibody agreements with I-Mab Biopharma where we are seeking to recover over $200 million in damages.
- Complete the TJ4309 Phase 1 clinical trial permitting I-Mab the opportunity to terminate the TJ4309 license for a $9.0 million payment to TRACON.

Second Quarter 2022 Financial Results

- Cash and cash equivalents were $13.6 million at June 30, 2022, compared to $24.1 million at December 31, 2021 and is

expected to fund the company into 2023.

- Research and development expenses for the second quarter of 2022 were $2.9 million, compared to $3.1 million for the second quarter of 2021.

- General and administrative expenses for the second quarter of 2022 were $3.3 million, compared to $6.1 million for the second quarter of 2021. The decrease was primarily attributable to legal expenses incurred in the second quarter of 2021 due to the now stayed lawsuit filed by I-Mab in the Delaware Court of Chancery involving the TJ4309 agreement.

- Net loss for the second quarter of 2022 was $6.2 million, compared to $8.9 million for the second quarter of 2021.

Conference Call Details

To access the call by phone, please register using this link and you will be provided with dial in details.

A live webcast of the conference call will be available online from the Investor/Events and Presentation page of the Company's website at www.traconpharma.com.

After the live webcast, a replay will remain available on TRACON's website for 60 days.

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology, is the first approved subcutaneously injected PD-(L)1 inhibitor. Envafolimab was approved by the Chinese NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the pivotal ENVASARC Phase 2 trial in the United States sponsored by TRACON and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at 30 top cancer centers in the United States and the United Kingdom that began dosing in December 2020. TRACON expects the trial to enroll more than 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into a cohort of treatment with single agent envafolimab at 600 mg every three weeks and 80 patients enrolled into a cohort of treatment with envafolimab at 600 mg every three weeks with Yervoy®. The primary endpoint is objective response rate by central review with duration of response a key secondary endpoint.

About YH001

YH001 is an IgG1 antibody against CTLA-4 that has shown enhanced antibody dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) *in vitro*. In preclinical studies YH001 demonstrated superior T cell activation and superior tumor growth inhibition activity compared to ipilimumab. YH001 also demonstrated superior activity compared to ipilimumab in human transgenic mouse tumor models when combined with a PD-(L)1 antibody. In these models, single agent YH001 depleted regulatory T cells and increased CD8+ T cells in tumor tissue. YH001 is being dosed as a single agent in a Phase 1 trial in China (NCT04699929) and in combination with the PD-1 antibody toripalimab in a Phase 1 trial in Australia (NCT04357756).

About TRC102

TRC102 (methoxyamine) is a novel small molecule inhibitor of the DNA base excision repair pathway, which is a pathway that causes resistance to alkylating and antimetabolite chemotherapeutics. TRC102 is currently being studied in multiple Phase 1 and Phase 2 clinical trials sponsored by the National Cancer Institute through a Cooperative Research and Development Agreement (CRADA) and has orphan drug designation from the FDA in malignant glioma, including glioblastoma.

About TJ004309

TJ004309 is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to adenosine, which is highly immunosuppressive. TJ004309 is currently being studied in an ongoing Phase 1 trial to assess safety and preliminary efficacy as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors.

About TRACON

TRACON is a clinical-stage biopharmaceutical company utilizing a cost-efficient, CRO-independent, product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies. The Company's clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships through a profit-share or revenue-share partnership, or through franchising TRACON's product development platform. TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States or who wish to become CRO-independent. To learn more about TRACON and its product pipeline, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

Statements made 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the timing of the final binding decision from the Tribunal regarding the legal disputes involving the TJ004309 and bispecific antibody agreements with I-Mab Biopharma; whether TRACON will recover any of the $200 million in damages it is seeking in its arbitration with I-Mab; the timing for TRACON’s completion of the TJ4309 Phase 1 trial and whether I-Mab will terminate the related license and pay $9 million to TRACON; TRACON’s expectations regarding the funding of its operations through its current cash and cash equivalents into 2023; TRACON’s and its collaboration partners’ plans to further develop product candidates; expectations regarding the timing and scope of clinical trials and availability of clinical data; expected development, regulatory and commercial milestones and timing thereof; potential utility of product candidates; and TRACON’s business development strategy and goals to enter into additional collaborations. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: the inherent uncertainty regarding arbitrations and the risk that the Tribunal delays the date by which it will render its decision or decides that TRACON is not entitled to recover any or only a portion of the damages that it is seeking; risks associated with clinical development and regulatory approval of novel pharmaceutical product candidates; whether TRACON or others will be able to complete or initiate clinical trials on TRACON’s expected timelines, if at all, including due to risks associated with the COVID-19 pandemic and macroeconomic events, such as the ongoing military conflict between Ukraine and Russia and related sanctions, and whether I-Mab will pay TRACON $9 million upon completion of the TJ4309 Phase 1 trial to terminate the related license; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials or initiate additional trials of TRACON’s product candidates; the fact that TRACON’s collaboration agreements are subject to early termination; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; potential changes in regulatory requirements in the United States and foreign countries; TRACON’s reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON’s filings with the Securities and Exchange Commission under the heading “Risk Factors”. 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. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ —	$ 346	$ —	$ 346
Operating expenses:				
Research and development	2,923	3,068	5,916	5,352
General and administrative	3,316	6,126	9,769	8,797
Total operating expenses	6,239	9,194	15,685	14,149
Loss from operations	(6,239)	(8,848)	(15,685)	(13,803)
Total other income (expense)	9	(91)	(18)	(200)
Net loss	$ (6,230)	$ (8,939)	$ (15,703)	$ (14,003)
Net loss per share, basic and diluted	$ (0.31)	$ (0.58)	$ (0.79)	$ (0.90)
Weighted-average common shares outstanding, basic and diluted	20,268,220	15,497,315	19,940,424	15,488,359

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 13,580	$ 24,072
Prepaid and other assets	576	864
Total current assets	14,156	24,936
Property and equipment, net	50	50
Other assets	1,471	1,571
Total assets	$ 15,677	$ 26,557
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 11,002	$ 10,753
Accrued compensation and related expenses	1,061	1,532
Long-term debt, current portion	—	1,391

Total current liabilities	12,063	13,676
Other long-term liabilities	1,072	1,167
Commitments and contingencies		
Stockholders' equity:		
Common stock	21	19
Additional paid-in capital	226,000	219,471
Accumulated deficit	(223,479)	(207,776)
Total stockholders' equity	2,542	11,714
Total liabilities and stockholders' equity	$ 15,677	$ 26,557

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com

Source: TRACON Pharmaceuticals, Inc.