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

May 11, 2022

SAN DIEGO, May 11, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals, Inc. (Nasdaq:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with companies to develop and commercialize innovative products in the U.S., today announced financial results for the first quarter ended March 31, 2022. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We are pleased with the pace of enrollment under the amended ENVASARC protocol and remain on track to deliver interim efficacy data in the second half of this year," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Additionally, with the arbitration hearing now completed we look forward to the outcome of the binding arbitration for the TJ4309 and Bispecific Antibody agreements during the second half of this year. We also continue preparations to initiate dosing of the Phase 1/2 clinical trial of envafolimab with our potential best-in-class CTLA-4 antibody, YH001, as well as doxorubicin chemotherapy in the second half of 2022."

Recent Corporate Highlights

- In March, we announced the amended ENVASARC protocol using a higher dose of envafolimab was approved by the FDA.
- In April, we announced the amended ENVASARC protocol was approved by internal review boards or ethic committees at each of the 30 clinical sites in the U.S. and U.K. and that all sites were open for enrolment, with more than 10 patients enrolled.

Expected Key Upcoming Milestones

- Two interim safety reviews and the interim efficacy data review by the ENVASARC Independent Data Monitoring Committee (IDMC) in the second half of 2022.
- Initiate dosing of a Phase 1/2 clinical trial of envafolimab with our potential best in class CTLA-4 antibody YH001 as well as with doxorubicin chemotherapy in the second half of 2022.
- Report the International Chamber of Commerce (ICC) Arbitration Panel's binding decisions on the legal disputes involving the TJ4309 and bispecific antibody agreements with I-Mab this year.
- Complete the TJ4309 Phase 1 trial permitting I-Mab the opportunity to terminate the license for $9M this year.
- Initiate dosing of a randomized Phase 2 trial of TRC102 in locally advanced non-small cell lung cancer sponsored and funded by the National Cancer Institute this year.

First Quarter 2022 Financial Results

- Cash, cash equivalents and short-term investments were $16.6 million at March 31, 2022, compared to $24.1 million at December 31, 2021. The Company expects that its current cash and cash equivalents will fund operations into 2023.
- Research and development expenses for the first quarter of 2022 were $3.0 million, compared to $2.3 million for the first quarter of 2021.
- General and administrative expenses for the first quarter of 2022 were $6.5 million, compared to $2.7 million for the first quarter of 2021. The increase was primarily attributable to legal expenses incurred due to the arbitration hearing held in February 2022 with I-Mab related to the TJ4309 and bispecific antibody agreements, and the Company expects general and administrative expenses to decrease significantly for the remainder of the year.

- Net loss for the first quarter of 2022 was $9.5 million, compared to $5.1 million for the first quarter of 2021.

Conference Call Details

Wednesday, May 11, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**8178208**

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 develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. 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 whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States. 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 report from the International Chamber of Commerce Arbitration Panel's regarding the binding decisions on the legal disputes involving the TJ4309 and bispecific antibody agreements with I-Mab; 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: 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; 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$2,993	$2,284
General and administrative	6,453	2,671
Total operating expenses	9,446	4,955
Loss from operations	(9,446)	(4,955)
Total other expense	(27)	(109)
Net loss	$(9,473)	$(5,064)
Net loss per share, basic and diluted	$(0.48)	$(0.33)
Weighted-average common shares outstanding, basic and diluted	19,608,986	15,479,304

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

	March 31, 2022	**December 31, 2021**
Assets		
Current assets:		
Cash and cash equivalents	$16,640	$24,072
Prepaid and other assets	653	864
Total current assets	17,293	24,936
Property and equipment, net	49	50
Other assets	1,522	1,571
Total assets	$18,864	$26,557
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$13,439	$10,753
Accrued compensation and related expenses	816	1,532
Long-term debt, current portion	698	1,391
Total current liabilities	14,953	13,676
Other long-term liabilities	1,121	1,167
Commitments and contingencies		
Stockholders' equity:		
Common stock	20	19
Additional paid-in capital	220,019	219,471
Accumulated deficit	(217,249)	(207,776)
Total stockholders' equity	2,790	11,714
Total liabilities and stockholders' equity	$18,864	$26,557

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