TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Corporate Update

March 15, 2022

Announced FDA Approval of Amended ENVASARC Protocol, ENVASARC Interim Efficacy Data on Track for 2H22

Initiating combination trial of proprietary CTLA-4 with envafolimab in 2022

SAN DIEGO, March 15, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (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 ex-U.S. companies to develop and commercialize innovative products in the United States, today announced financial results for the fourth quarter and year ended December 31, 2021. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

“The ENVASARC trial remains our top priority in 2022, to address the significant unmet medical need in refractory sarcoma for the approval of safe and effective treatments. In December 2021, based on the compelling tolerability profile and significantly higher response rate observed in lower weight patients, the Independent Data Monitoring Committee recommended increasing the dose of envafolimab to 600 mg subcutaneously every three weeks, both as a single agent and in combination with Yervoy, in our pivotal ENVASARC trial. Based on prior clinical experience with envafolimab in more than 700 patients, we believe a doubling of the dose can be well-tolerated, result in higher exposures, and thereby potentially optimize efficacy for the greatest number of sarcoma patients,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “The amended protocol was approved by the FDA and we have begun treating patients at this higher dose level, and expect to report interim ENVASARC efficacy data in the second half of this year. We also look forward to initiating the first clinical trial of our proprietary CTLA-4 inhibitor, YH001, in combination with envafolimab in sarcoma patients later this year.”

Recent Corporate Highlights

- In February 2022, following review of the higher envafolimab dose level by the FDA, we began dosing ENVASARC patients at the higher dose of envafolimab of 600 mg subcutaneously every three weeks as a single agent or in combination with Yervoy.
- In February 2022, we announced that the National Cancer Institute initiated a randomized Phase 2 trial of TRC102 in advanced localized non-small cell lung cancer (NCT05198830: https://clinicaltrials.gov/ct2/show/NCT05198830?term=TRC102&draw=2&rank=3).
- In February 2022, we attended the arbitration hearing held by a tribunal of the International Chamber of Commerce on our disputes with I-Mab related to the TJ4309 and bispecific antibody agreements. We expect the ruling on the arbitration later this year.
- In November 2021, we announced that envafolimab was approved in China by our partners 3D Medicines and Alphamab Oncology for patients with microsatellite instability-high (MSI-H) or deficient MisMatch Repair (dMMR) advanced solid tumors, which represented the first regulatory approval of a subcutaneously administered checkpoint inhibitor.
- In October 2021, we announced a partnership with Eucure Biopharma for the development of YH001, a CTLA-4 antibody with enhanced effector functions that we plan to develop in combination with envafolimab in first-line sarcoma and in other tumor types as a single agent or with approved therapies.

Expected Key Upcoming Milestones

- Interim ENVASARC safety and efficacy data review by the Independent Data Monitoring Committee (IDMC) in the second half of 2022.
- Initiate dosing of a Phase 1/2 clinical trial of envafolimab with YH001 in the second half of 2022.

- Report the Arbitration Panel's binding decisions with respect to the outcome of the legal disputes with I-Mab.

- Complete the TJ4309 trial this year permitting I-Mab the opportunity to terminate the license for $9M.

Fourth Quarter 2021 Financial Results

- Cash, cash equivalents and short-term investments were $24.1 million at December 31, 2021, compared to $36.1 million at December 31, 2020.

- Research and development expenses for the fourth quarter of 2021 were $3.1 million, compared to $2.2 million for the fourth quarter of 2020. The increase relates to enrollment in the pivotal ENVASARC trial.

- General and administrative expenses for the fourth quarter of 2021 were $4.6 million, compared to $2.0 million for the fourth quarter of 2020. The increase was primarily attributable to legal expenses incurred due to the ongoing arbitration with I-Mab related to the TJ4309 and bispecific antibody agreements.

- Net loss for the fourth quarter of 2021 was $7.7 million, compared to $4.3 million for the fourth quarter of 2020.

Conference Call Details

Tuesday, March 15 at 4:30 PM Eastern Time / 1:30 PM Pacific Time	
Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**4073534**

A live webcast of the conference call will be available online from the Investor/Events and Presentations 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 subcutaneously injected PD-(L)1 inhibitor 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 approximately 25 top cancer centers in the United States 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 overall 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 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
License revenue	$ —	$ —	$ 346	$ —
Operating expenses:				
Research and development	3,064	2,197	11,146	8,198
General and administrative	4,599	1,980	17,547	8,025
Total operating expenses	7,663	4,177	28,693	16,223
Loss from operations	(7,663)	(4,177)	(28,347)	(16,223)
Total other expense	(49)	(134)	(320)	(552)
Net loss	$ (7,712)	$ (4,311)	$ (28,667)	$ (16,775)
Net loss per share, basic and diluted	$ (0.40)	$ (0.31)	$ (1.66)	$ (1.87)
Weighted-average shares outstanding, basic and diluted	19,442,526	13,800,711	17,252,637	8,984,148

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 24,072	$ 32,131
Short-term investments	—	3,999
Prepaid and other assets	864	784
Total current assets	24,936	36,914

Property and equipment, net	50	16
Other assets	1,571	508
Total assets	$ 26,557	$ 37,438
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,753	$ 6,235
Accrued compensation and related expenses	1,532	1,590
Long-term debt, current portion	1,391	2,718
Total current liabilities	13,676	10,543
Other long-term liabilities	1,167	432
Long-term debt, less current portion	—	1,391
Commitments and contingencies		
Stockholders' equity:		
Common stock	19	15
Additional paid-in capital	219,471	204,166
Accumulated deficit	(207,776)	(179,109)
Total stockholders' equity	11,714	25,072
Total liabilities and stockholders' equity	$ 26,557	$ 37,438

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