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

November 14, 2022

SAN DIEGO, Nov. 14, 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 third quarter ended September 30, 2022. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

“Enrollment in the ENVASARC Phase 2 pivotal trial continues to be ahead of schedule and we 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 have been notified by the ICC Tribunal that it is far along in its deliberations but invited additional information on two discrete issues and requested arbitration costs prior to determining the final award of the binding arbitration with I-Mab. We now expect to receive the decision in the first quarter of 2023.”

Recent Corporate Highlights

- In August, we announced that the U.S. Food and Drug Administration (FDA) approved our Investigational New Drug (IND) application for the initiation of a Phase 1/2 clinical trial of our CTLA-4 antibody YH001 in combination with envafolimab and doxorubicin for the treatment of sarcoma patients, including patients who have not received prior therapy.

- In September, we announced entry into a $35 million non-dilutive long-term debt facility with Runway Growth Finance Corp., with $10 million funded at closing which extended the Company’s runway to mid-2023.

- In September, we announced that we received fast track designation from the FDA for the development of envafolimab for patients with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) who have progressed on one or two prior lines of chemotherapy.

- In October, the Independent Data Monitoring Committee (IDMC) recommended the ENVASARC Phase 2 pivotal trial proceed as planned following the review of more than 12 weeks of safety data from more than 20 patients who received the 600 mg dose of envafolimab as a single agent or in combination with Yervoy® (ipilimumab).

Expected Upcoming Milestones

- Report the interim efficacy analysis by the IDMC following the review of more than 12 weeks of efficacy data from 36 patients who received the 600 mg dose of envafolimab as a single agent or in combination 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 binding decision of the International Chamber of Commerce (ICC) Arbitration Panel on 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, which we expect in the first quarter of 2023.

Third Quarter 2022 Financial Results

- Cash and cash equivalents were $17.0 million at September 30, 2022, compared to $24.1 million at December 31, 2021, and is expected to fund the company into mid-2023.

- Research and development expenses for the third quarter of 2022 were $4.1 million, compared to $2.7 million for the third quarter of 2021.

- General and administrative expenses for the third quarter of 2022 were $2.3 million, compared to $4.2 million for the third quarter of 2021. The decrease was primarily attributable to legal expenses incurred in the third quarter of 2021 due to the arbitration with I-Mab.

- Net loss for the third quarter of 2022 was $6.4 million, compared to $7.0 million for the third 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 as well as multiple Phase 1 and Phase 2 clinical trials 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 and complement dependent cytotoxicity *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 studied with envafolimab and doxorubicin in a Phase 1/2 clinical trial sponsored by TRACON (NCT05448820), and in multiple Phase 1 trials in China and Australia sponsored by TRACON's corporate partner Eucure, a division of Biocytogen.

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 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 1/2 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 TJ4309 license and pay $9 million to TRACON; the initiation of dosing in TRACON's Phase

1/2 clinical trial of envafolimab with YH001 and doxorubicin; TRACON's expectations regarding the funding of its operations through its current cash and cash equivalents into mid-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, including the timing and results of data from TRACON's ENVASARC Phase 2 pivotal trial and a report of the IDMC on its interim efficacy analysis for the initial 36 patients; 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 geopolitical and macroeconomic events, such as the COVID-19 pandemic, the ongoing military conflict between Ukraine and Russia and related sanctions, and whether I-Mab will pay TRACON $9 million to terminate the TJ4309 license in connection with completion of the TJ4309 Phase 1 trial; 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ —	$ —	$ —	$ 346
Operating expenses:				
Research and development	4,097	2,730	10,013	8,082
General and administrative	2,280	4,151	12,049	12,948
Total operating expenses	6,377	6,881	22,062	21,030
Loss from operations	(6,377)	(6,881)	(22,062)	(20,684)
Total other income (expense)	(58)	(71)	(76)	(271)
Net loss	$(6,435)	$(6,952)	$(22,138)	$(20,955)
Net loss per share, basic and diluted	$(0.30)	$(0.38)	$(1.08)	$(1.27)
Weighted-average common shares outstanding, basic and diluted	21,469,977	18,533,772	20,455,877	16,514,652

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$17,037	$24,072
Prepaid and other assets	983	864
Total current assets	18,020	24,936
Property and equipment, net	51	50
Restricted Cash	175	—
Other assets	1,420	1,571
Total assets	$19,666	$26,557
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$10,477	$10,753
Accrued compensation and related expenses	1,283	1,532
Long-term debt, current portion	—	1,391
Total current liabilities	11,760	13,676
Other long-term liabilities	1,446	1,167
Long-term debt, less current portion	9,095	—

Commitments and contingencies		
Stockholders' equity:		
Common stock	22	19
Additional paid-in capital	227,257	219,471
Accumulated deficit	(229,914)	(207,776)
Total stockholders' equity	(2,635)	11,714
Total liabilities and stockholders' equity	$19,666	$26,557

Company Contact:
Charles Theuer
Chief Executive Officer
(858) 550-0780
ctheuer@traconpharma.com

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

Source: TRACON Pharmaceuticals, Inc.