TRACON Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 10, 2023

SAN DIEGO, May 10, 2023 (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 first quarter ended March 31, 2023. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

"We were pleased with the arbitration award of approximately $23 million, which will extend our cash runway into early 2024, when collected," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Most importantly, in the third quarter we expect the second and final interim efficacy analysis in the ongoing ENVASARC pivotal trial that will review 46 patients in the cohort of single agent envafolimab and 46 patients in the cohort of envafolimab dosed with Yervoy (ipilimumab), after each patient has had two on-study scans. Accrual in ENVASARC remains ahead of projections and we expect to complete enrollment before year end, with final data anticipated in mid-2024 and potential commercial launch in 2025."

Recent Corporate Highlights

- In March, we announced a private placement of approximately $3.0 million with an accredited institutional healthcare-focused fund, which was completed at market price.
- In April, we announced we received an arbitration award of approximately $23.0 million from the arbitration with I-Mab Biopharma.
- In May, we entered into a Common Stock Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC"), in which LPC has committed to purchase up to $26.0 million of shares of our common stock from time to time at prices based on the market price calculated over a certain period of time and in accordance with terms set forth in the Common Stock Purchase Agreement. Additionally, LPC has committed to purchase upon our request up to $1.0 million of shares of our common stock when all conditions to commencement are met, including that a resale registration statement is filed and declared effective.

Expected Upcoming Milestones

- Report an ad hoc analysis from the ENVASARC pivotal trial by the independent data monitoring committee (IDMC) as required by the IDMC Charter that requires a review of available safety and efficacy data at a minimum of every six months, which we expect in the second quarter of 2023.
- Report the second and final interim efficacy analysis from the ENVASARC pivotal trial following the review of more than 12 weeks of efficacy data (including two on-study CT scans) by the IDMC from 46 patients who receive envafolimab as a single agent and 46 patients who receive envafolimab in combination with Yervoy®, which we expect in the third quarter of 2023 as the ENVASARC trial has enrolled more than 92 patients to date.
- Complete full accrual of the ENVASARC pivotal trial before the end of 2023.
- Report Phase 1 data from the Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin in patients with soft tissue sarcoma, which we expect in the second half of 2023.

First Quarter 2023 Financial Results

- Cash and cash equivalents were $6.6 million at March 31, 2023, compared to $17.4 million at December 31, 2022, which is expected to fund the Company into the third quarter of 2023, and with the amounts we expect to recover from I-Mab pursuant to the arbitration award, when received, into early 2024.
- Research and development expenses for the first quarter of 2023 were $5.0 million, compared to $3.0 million for the first quarter of 2022. The increase was primarily related to envafolimab drug product purchased in the first quarter of 2023.

- General and administrative expenses for the first quarter of 2023 were $2.3 million, compared to $6.5 million for the first quarter of 2022. The decrease was primarily attributable to legal expenses incurred in the first quarter of 2022 in connection with the arbitration hearing with I-Mab.

- Net loss for the first quarter of 2023 was $8.5 million, compared to $9.5 million for the first quarter of 2022.

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 and licensed by TRACON, 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. TRACON has received orphan drug designation from the U.S. Food and Drug Administration for envafolimab for patients with soft tissue sarcoma and fast track designation from the U.S. Food and Drug Administration for 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.

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 has been studied 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 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; and TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer. 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 recoverability and timing of recovery for the amounts awarded to TRACON in its arbitration with I-Mab; expectations regarding TRACON's cash runway, inclusive of the amounts the Company expects to recover pursuant to such award; the expected closing of the agreement with LPC and LPC's purchase of $1.0 million of shares of TRACON's common stock in connection therewith; TRACON's expectations regarding LPC's purchase of additional amounts of TRACON's common stock under TRACON's agreement with LPC; 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 accrual and data from TRACON's ENVASARC Phase 2 pivotal trial, a report of the IDMC on its second interim efficacy analysis and receipt

of the Phase 1 data from the Phase 1/2 clinical trial of YH001; expected results of the ad hoc safety review analysis from the ENVASARC pivotal trial and the timing of those results; 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 recovery of arbitration awards and the timing of such recovery; the risk that TRACON's cash runway will be less than currently anticipated; risks associated with closing the Purchas Agreement with LPC, including that relevant closing conditions are not timely completed; risks that LPC will not be able to purchase the fully committed amount under the agreement with LPC, including due to insufficient authorized shares and the value of TRACON's common stock; 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, ; 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 except as required by law.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 4,969	$ 2,993
General and administrative	2,344	6,453
Total operating expenses	7,313	9,446
Loss from operations	(7,313)	(9,446)
Total other expense	(1,191)	(27)
Net loss	$ (8,504)	$ (9,473)
Net loss per share, basic and diluted	$ (0.36)	$ (0.48)
Weighted-average common shares outstanding, basic and diluted	23,702,178	19,608,986

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

	March 31, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 6,610	$ 17,433
Prepaid and other assets	529	795
Total current assets	7,139	18,228
Property and equipment, net	47	51
Restricted Cash	67	67
Other assets	1,070	1,123
Total assets	$ 8,323	$ 19,469
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,342	$ 11,107
Accrued compensation and related expenses	1,840	1,457
Long-term debt, current portion	-	9,807
Total current liabilities	14,182	22,371
Other long-term liabilities	914	969
Arbitration financing payable	4,299	3,280
Commitments and contingencies		
Stockholders' deficit:		

Common stock	24	23
Additional paid-in capital	234,319	229,737
Accumulated deficit	(245,415)	(236,911)
Total stockholders' deficit	(11,072)	(7,151)
Total liabilities and stockholders' deficit	$ 8,323	$ 19,469

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