TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2019 Financial Results and Provides Corporate Update

February 27, 2020

SAN DIEGO, Feb. 27, 2020 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and utilizing a product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today announced financial results for the fourth quarter and year ended December 31, 2019.

Recent Corporate Highlights

- In December, TRACON entered into a collaborative partnership agreement with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab), for the North American development of envafolimab, a PD-L1 single-domain antibody administered by subcutaneous injection without an adjuvant, in soft tissue sarcoma. We expect to meet with the FDA to discuss a potential pivotal trial design and apply for orphan drug designation in the second quarter. In addition, we anticipate beginning patient enrollment in the study during the second half of this year.

- In December and January, TRACON sold shares through our ATM facility with JonesTrading for gross proceeds of $5.3 million that extends the Company's cash runway into 2021.

"We are pleased to have entered into this recent promising collaboration with 3D Medicines and Alphamab for the development and commercialization of envafolimab, a potentially best in class PD-L1 single domain antibody that may offer a much needed new treatment option for sarcoma patients," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Envafolimab has now become our lead asset. We are focused on beginning a pivotal trial as quickly as possible so we can address the high unmet medical need that exists for sarcoma patients, and have the opportunity to become a commercial company in the U.S. in approximately three years with envafolimab."

Expected Upcoming Milestones

- Meet with FDA to discuss potential pivotal trial design for envafolimab, followed by the submission of an application for orphan drug designation, in the first half of 2020.

- Enroll the first patient in a potentially pivotal trial of envafolimab in sarcoma during the second half of 2020.

- Top-line data from the fully enrolled randomized Phase 2 AVANTE trial of DE-122 in patients with wet AMD, including the primary endpoint of mean change in best corrected visual acuity at six months, are expected in the first half of 2020. In this trial, the combination of DE-122 with Lucentis is being compared with Lucentis single agent treatment.

- Phase 2 proof-of-concept data from the fully enrolled Phase 1/2 clinical trial of TRC253 in metastatic castrate resistant prostate cancer are expected in the first half of 2020. These clinical data will trigger Janssen's 90-day option to reacquire full rights to TRC253 for an opt-in payment of $45 million to TRACON and obligations to pay regulatory and commercialization milestones totaling up to $137.5 million upon the achievement of specified events, in addition to a low single-digit royalty on net sales. If Janssen does not opt in, TRACON can maintain ownership of TRC253 and would owe Janssen up to $45 million upon the achievement of specified events, in addition to a low single-digit royalty on net sales.

- Top-line data from the Phase 1 dose escalation study of TJ004309, a CD73 antibody, as a single agent and in combination with Tecentriq, a marketed PD-L1 antibody being supplied by Roche, are expected in the second half of 2020. We are developing TJ004309 in collaboration with our corporate partner I-Mab Biopharma.

- Nomination and IND filing of the initial bispecific antibody (BsAb) from the I-Mab pipeline is expected in the second half of 2020. The I-Mab BsAb pipeline includes PD-L1 x IL-7, PD-L1 x CD47, PD-L1 x CD73, PD-L1 x B7-H3, and PD-L1 x 4-1BB antibodies. In 2018, TRACON and I-Mab entered into a cost-sharing product development collaboration, whereby TRACON

will be responsible for the regulatory and clinical development of up to five of the BsAbs in North America and Europe, with the majority of the development effort expected to occur in the U.S. TRACON will bear the costs of early phase clinical trials and I-Mab will share the costs for more advanced development stages and commercialization. TRACON will share North American rights of any selected BsAbs with I-Mab for each collaborative program and TRACON retains an opt-in right to in-license ex-greater China rights to each of the selected BsAbs from I-Mab.

Fourth Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments were $16.4 million at December 31, 2019, compared to $39.1 million at December 31, 2018. We expect our current cash, cash equivalents and short-term investments to fund operations into 2021.

- Research and development expenses for the fourth quarter of 2019 were $1.9 million, compared to $5.9 million for the fourth quarter of 2018. The decrease was primarily attributable to lower manufacturing expenses and clinical trial expenses due to the discontinuation of the TRC105 program.

- General and administrative expenses for the fourth quarter of 2019 were $1.9 million, compared to $1.8 million for the fourth quarter of 2018.

- Net loss for the fourth quarter of 2019 was $3.9 million, compared to $7.8 million for the fourth quarter of 2018.

Investor Conference Call

The Company will hold a conference call today at 4:30 p.m. EDT / 1:30 p.m. PDT to provide an update on corporate activities and to discuss the financial results of its fourth quarter and full year of 2019. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 3228345. 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 is a novel, single-domain antibody against PD-L1 that is administered by subcutaneous injection without the need for an adjuvant. Envafolimab is currently dosing in Phase 1 trials in the U.S. and Japan and is being studied in China in a Phase 2 registration trial as a single agent in MSI-H tumor patients, and in combination with gemcitabine and oxaliplatin in a Phase 3 registration trial in biliary tract cancer. Subject to positive data from the MSI-H registrational trial, 3D Medicines plans to file a BLA in China for envafolimab in 2020 based on overall response rate in MSI-H patients. The filing would be based on the principle that the response rate required for approval in China is similar to the response rate for Keytruda and Opdivo in MSI-H patients from separate clinical trials per the product package inserts.

About DE-122 (carotuximab)

DE-122, an ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and designed to enhance the effect of approved VEGF inhibitors used to treat wet AMD. DE-122 is being investigated in the Phase 2 randomized AVANTE trial assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD.

About TRC253

TRC253 is a novel, orally bioavailable small molecule drug that is a potent, high affinity competitive inhibitor of the androgen receptor (AR) and AR mutations, including the F877L mutation. The AR F877L mutation results in an alteration in the AR ligand binding domain that confers resistance to therapies for prostate cancer. Therapies targeting the AR have demonstrated clinical efficacy by extending time to disease progression, and in some cases, the survival of patients with metastatic castration-resistant prostate cancer. However, resistance to these agents is often observed and several molecular mechanisms of resistance have been identified, including gene amplification, overexpression, alternative splicing, and point mutation of the AR. TRC253 is currently being studied in a Phase 1/2 clinical trial in prostate cancer.

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 a 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 and ophthalmic diseases. The Company's clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody to be developed for the treatment of sarcoma; DE-122, the ophthalmic formulation of carotuximab, an endoglin antibody that is being developed for patients with wet AMD through a license to Santen Pharmaceutical Company Ltd.; TRC102, a small molecule drug being developed for the treatment of lung cancer; TRC253, a small molecule drug being developed for the treatment of prostate cancer; and TJ004309, a CD73 antibody being developed for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads 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 U.S. To learn more about TRACON and its product candidates, 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 plans to further develop product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones and timing thereof, estimated cash runway, potential access to future capital, potential utility of product candidates, potential events under collaboration and license agreements, 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; whether TRACON or others will be able to complete or initiate clinical trials on TRACON’s expected timelines, if at all; 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; whether and when any bispecific antibodies are developed under TRACON’s collaboration with I-Mab; 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; the possibility of unexpected expenses or other uses of TRACON’s cash resources; 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,	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$ -	$ -	$ -	$ 3,000
Operating expenses:				
Research and development	1,913	5,931	14,530	30,460
General and administrative	1,899	1,800	7,766	7,280
Total operating expenses	3,812	7,731	22,296	37,740
Loss from operations	(3,812)	(7,731)	(22,296)	(34,740)
Total other income (expense)	(124)	(25)	(378)	(219)
Net loss	$ (3,936)	$ (7,756)	$ (22,674)	$ (34,959)
Net loss per share, basic and diluted	$ (1.25)	$ (2.60)	$ (7.47)	$ (12.97)
Weighted-average common shares outstanding, basic and diluted	3,159,740	2,986,454	3,034,299	2,694,624

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

	December 31, 2019	**December 31, 2018**
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 16,412	$ 25,136
Short-term investments	-	13,968
Prepaid and other assets	848	1,499
Total current assets	17,260	40,603
Property and equipment, net	23	45
Other assets	838	-
Total assets	$ 18,121	$ 40,648
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,875	$ 10,947
Accrued compensation and related expenses	1,355	1,464
Long-term debt, current portion	2,604	1,084
Total current liabilities	11,834	13,495
Other long-term liabilities	850	368

Long-term debt, less current portion	2,739	5,343
Commitments and contingencies		
Stockholders' equity:		
Common stock	4	3
Additional paid-in capital	165,028	161,099
Accumulated deficit	(162,334)	(139,660)
Total stockholders' equity	2,698	21,442
Total liabilities and stockholders' equity	$ 18,121	$ 40,648

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