TRACON Pharmaceuticals Reports Fourth Quarter and Year-End 2018 Financial Results and Provides Corporate Update

February 28, 2019

SAN DIEGO, Feb. 28, 2019 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, and through our license to Santen Pharmaceutical Co. Ltd., wet age-related macular degeneration, today announced financial results for the fourth quarter and year ended December 31, 2018.

Fourth Quarter 2018 and Recent Corporate Highlights

- In February, we began preparation of data tables for the interim analysis by the Independent Data Monitoring Committee (DMC), following enrollment of the 120th patient into the TAPPAS Phase 3 trial. We expect the DMC to meet and provide the final sample size of the trial in April. The sample size needed to complete the trial will be a total of 190 patients if the interim results lie in the favorable or unfavorable zone and will be a total of 340 patients if in the promising zone. If the interim results lie in the enrichment zone, the trial will enroll a total of 220 patients with cutaneous disease. In the unfavorable scenario, the DMC could elect to terminate the trial early for futility.

- In February, our partner Santen announced that they increased the sample size of the ongoing AVANTE Phase 2 randomized trial assessing the efficacy of DE-122, the ophthalmic formulation of TRC105, in combination with Lucentis® in patients with wet AMD. The primary endpoint of the trial is unchanged and measures best corrected visual acuity. Top-line data from the study is expected in the first half of 2020. Santen is responsible for global development of DE-122 in eye disease and TRACON is entitled to receive up to $145M in additional developmental, regulatory and commercial milestones, as well as royalties on net sales ranging from the high single digits to low teen double digits.

- In February, Dr. Francisco Robert of the University of Alabama, Birmingham updated positive top-line data reported in December 2018 from the Phase 1 trial of TRC105 and Opdivo® in patients with non-small cell lung cancer at the International Association for the Study of Lung Cancer Targeted Therapies for Lung Cancer conference. The combination of TRC105 and Opdivo was well-tolerated without the development of dose limiting toxicity in six patients who were treated as part of dose escalation. One of these six patients, whose archival tumor did not express PD-L1 and who had not received prior PD-1/PD-L1 checkpoint inhibitor treatment, developed a confirmed partial response by RECIST and remains on study for more than 12 months. Two of the other five patients, one of whom progressed following prior Opdivo treatment, remain on trial with stable disease. Patients are currently enrolling into two parallel 12 patient expansion cohorts, one that includes patients who have progressed following prior PD-1/PD-L1 checkpoint inhibitor treatment and one that includes patients who have not received prior PD-1/PD-L1 checkpoint inhibitor treatment. Top-line data from these cohorts is expected to be reported in late 2019.

- In February, we reacquired rights to develop TRC105 in Greater China from Ambrx. We had licensed rights to develop and commercialize TRC105 in Greater China to Ambrx for terms that included an upfront fee of $3.0M that was received in December 2017. Following discussions with Ambrx regarding their progress towards initiating a Phase 1 clinical trial of TRC105 in China, Ambrx notified us that it had elected to terminate the license agreement, resulting in all rights to TRC105 in Greater China reverting to TRACON. We now expect to engage a partner with substantial clinical development experience in China to lead TRC105 development, especially in hepatocellular cancer.

- In February, following completion of pre-clinical development of TRC694, we determined the compound did not warrant further development and returned all rights to Janssen. TRC694 was licensed from Janssen in 2016 as part of a two compound agreement, one that included the license of TRC253 and an equity investment from Johnson & Johnson Innovation – JJDC, Inc. We continue to develop TRC253, which is in Phase 2 testing.

- In January, we reported updated data from the ongoing Phase 1/2 trial of TRC105 and Nexavar® in patients with

hepatocellular carcinoma (HCC) at the Gastrointestinal Cancers Symposia of ASCO. Three of 15 evaluable patients had confirmed partial responses by RECIST (20%). Since that time, one additional patient achieved a partial response, such that four of seventeen evaluable patients (24%) have now achieved partial responses by RECIST to date. For comparison, in separate Phase 3 trials, the confirmed partial response rate by RECIST in HCC patients treated with single agent Nexavar was 2% and 3%.

- In December 2018, we submitted an IND for the CD73 antibody TJ4309 after executing a licensing agreement with I-Mab Biopharma (I-Mab) in November 2018. In January, the FDA cleared the IND and we expect to dose TJ4309 in a Phase 1 trial of cancer patients beginning in the first half of 2019.

- In December 2018, we reported the Phase 2 TRAXAR trial of TRC105 and Inlyta® in patients with advanced or metastatic renal cell carcinoma did not meet the primary endpoint of improving progression free survival when compared to single agent Inlyta. We expect to present data from this study at a scientific conference in the second half of 2019.

- In November 2018, we announced a strategic partnership for up to five immuno-oncology programs with I-Mab to be nominated over a five year period. TRACON and I-Mab entered into a cost-sharing product development and commercialization collaboration whereby TRACON will be responsible for the regulatory and clinical development of TJ4309 and up to five bispecific antibodies in North America, with the majority of development expected to occur in the US. TRACON will bear the costs of early phases of clinical trials and I-Mab will share the costs for more advanced development stages and commercialization. TRACON will also share the North America rights of any selected bispecific antibodies with I-Mab for each collaborative program, with opt-in rights to in-license the bispecific antibodies from I-Mab in certain territories.

- In November 2018, we reported top-line data from the Phase 2 trial of TRC102 and Temodar® in patients with recurrent glioblastoma at the Society for Neuro-Oncology annual meeting. The combination of TRC102 and Temodar was tolerable, but did not meet the primary efficacy endpoint of demonstrating objective responses by Response Assessment in Neuro-Oncology criteria in the initial 19 enrolled patients. Two patients (10.5%) demonstrated evidence of clinical benefit and met the secondary endpoint of progression free survival (PFS) beyond 6 months. Both patients who demonstrated PFS for more than 11 months expressed methyl purine glycosylase, a biomarker associated with TRC102 activity in preclinical models.

“We continue to be encouraged by the rate of accrual into the TAPPAS Phase 3 trial and are excited to complete the interim analysis and implement the DMC’s decision with respect to the final sample size of the trial.” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We expect the DMC decision in April, at which time we will provide further details in a conference call.”

Expected Upcoming Milestones

- Announcement of the results of the interim analysis to determine the final sample size of the Phase 3 pivotal TAPPAS trial of TRC105 in angiosarcoma is expected in April.

- Announcement of first in human dosing of TJ4309 is expected in the first half of 2019.

- Presentation of preclinical data by Leiden University researchers on the activity of TRC105 in combination with checkpoint inhibitors at the American Association for Cancer Research (AACR) annual meeting in Philadelphia, PA is expected in March.

- Presentation of expanded cohort data by the National Cancer Institute from the Phase 1 trial of TRC102 and Temodar in patients with colorectal, lung and ovarian cancer at the AACR annual meeting in Philadelphia, PA is expected in April.

- Presentation of TRC253 Phase 1 data in patients with metastatic castrate resistant prostate cancer is expected in the first half of 2019.

Fourth Quarter 2018 Financial Results

- Cash, cash equivalents and short-term investments were $39.1 million at December 31, 2018, compared to $34.5 million at December 31, 2017. We expect our current cash, cash equivalents and short-term investments to fund operations late into the first quarter of 2020.

- Research and development expenses for the fourth quarter of 2018 were $5.9 million compared to $4.6 million for the fourth quarter of 2017. The increase was primarily attributable to manufacturing expenses for TRC105 in the fourth quarter of 2018 as compared to the 2017 period.

- General and administrative expenses for the fourth quarter of 2018 were $1.8 million compared to $1.7 million for the fourth quarter of 2017.

- Net loss for the fourth quarter of 2018 was $7.8 million compared to a net loss of $6.6 million for the fourth quarter of 2017.

Investor Conference Call

The Company will hold a conference call today at 4:30 p.m. EST / 1:30 p.m. PST to provide an update on corporate activities and to discuss the financial results of its fourth quarter and full year of 2018. The dial-in numbers are (855) 779-9066 for domestic callers and (631) 485-4859 for international callers. Please use passcode 7886794. 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 TRC105 (carotuximab)

TRC105, the oncology formulation of carotuximab, is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in the pivotal Phase 3 TAPPAS trial in patients with angiosarcoma as well as multiple Phase 1 and Phase 2 clinical trials in other tumor types. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the US and EU. The ophthalmic formulation of TRC105, DE-122, is currently being studied in the randomized Phase 2 AVANTE trial in patients with wet AMD. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

About DE-122 (carotuximab)

DE-122, a novel ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and expected 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 TRC102

TRC102 (methoxyamine) is a novel, clinical-stage 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 or Case Comprehensive Cancer Center. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

About TRC253

TRC253 is a novel, orally bioavailable small molecule 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. For more information about the clinical trial, please visit TRACON's website at www.traconpharma.com/clinical_trials.php

About TJ4309

TJ4309 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. TJ4309 is expected to begin clinical testing in the U.S. in the first half of 2019 in a trial to assess safety and preliminary efficacy as a single agent and when combined with a PD-1/PD-L1 checkpoint inhibitor in patients with advanced solid tumors.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company's clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule being developed for the treatment of prostate cancer. TRACON is actively seeking additional corporate partnerships whereby it shares in the cost and risk of clinical development and commercialization of new product candidates. 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 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 its product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, estimated cash runway, potential utility of TRACON's product candidates, potential events under collaboration and license agreements, and TRACON's business development strategy. 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; 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,	
	2018	**2017**	**2018**	**2017**
Collaboration revenue	$-	$-	$3,000	$8,755
Operating expenses:				
Research and development	5,931	4,623	30,460	19,355
General and administrative	1,800	1,731	7,280	7,610
Total operating expenses	7,731	6,354	37,740	26,965
Loss from operations	(7,731)	(6,354)	(34,740)	(18,210)
Total other expense	(25)	(206)	(219)	(893)
Net loss	$(7,756)	$(6,560)	$(34,959)	$(19,103)
Net loss per share, basic and diluted	$(0.26)	$(0.37)	$(1.30)	$(1.14)
Weighted-average common shares outstanding, basic and diluted	29,864,038	17,563,861	26,945,705	16,806,094

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

	December 31, 2018 (Unaudited)	**December 31, 2017**
Assets		
Current assets:		
Cash and cash equivalents	$25,136	$29,467
Short-term investments	13,968	4,999
Prepaid and other assets	1,499	1,591
Total current assets	40,603	36,057
Property and equipment, net	45	73
Total assets	$40,648	$36,130
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$10,947	$6,800
Accrued compensation and related expenses	1,464	1,494
Current portion of deferred revenue	-	667
Long-term debt, current portion	1,084	2,837
Total current liabilities	13,495	11,798
Other long-term liabilities	368	409
Deferred revenue	-	2,333
Long-term debt, less current portion	5,343	4,603
Commitments and contingencies		
Stockholders' equity:		
Common stock	30	18
Additional paid-in capital	161,072	121,670
Accumulated deficit	(139,660)	(104,701)
Total stockholders' equity	21,442	16,987
Total liabilities and stockholders' equity	$40,648	$36,130

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