TRACON Pharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Corporate Update

August 5, 2020

SAN DIEGO, Aug. 05, 2020 (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 U.S., today announced financial results for the second quarter ended June 30, 2020. The Company will host a conference call and webcast today at 4:30 PM Eastern Time / 1:30 PM Pacific Time.

Recent Corporate Highlights

- In July, TRACON filed the ENVASARC pivotal trial protocol with the U.S. Food and Drug Administration (FDA) as part of an Investigational New Drug (IND) application. Following the 30 day FDA review period, TRACON expects to enroll the first patient in the ENVASARC trial evaluating the PD-L1 single domain antibody envafolimab in the soft tissue sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) in the fourth quarter of 2020. Key elements of the ENVASARC pivotal trial include:
    - Multi-center, open-label, randomized, non-comparative, parallel cohort study.
    - Eligible patients will have undifferentiated pleomorphic sarcoma (UPS) or myxofibrosarcoma (MFS) and will have received one or two prior lines of cancer therapy, and no prior immune checkpoint inhibitor therapy.
    - Planned total enrollment of 160 patients, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled in cohort B of treatment with envafolimab and Yervoy.
    - Primary endpoint of objective response rate (ORR) with duration of response a key secondary endpoint. Nine of 80 objective responses (11.25% ORR) are required to demonstrate an ORR that is statistically higher than the 4% ORR reported for Votrient, the only approved therapy for refractory UPS/MFS, in its package insert.
    - Open-label format with blinded independent central review of efficacy endpoint data.

- In May, TRACON announced positive results for envafolimab at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program from the Company's corporate partners, 3D Medicines and Alphamab Oncology, that showed single agent envafolimab demonstrated a 30.0% confirmed ORR in 50 patients with MSI-H/dMMR colorectal cancer (CRC) who failed a fluoropyrimidine, oxaliplatin and irinotecan (n=39) or those with advanced gastric cancer who failed at least one prior systemic treatment (n=11), with at least two on-study tumor assessments. The confirmed ORR in MSI-H/dMMR CRC patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 28.2%, which was nearly identical to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 27.9% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of KEYNOTE-164.

- In May, TRACON highlighted data at the 2020 ASCO Virtual Scientific Program from the Alliance for Clinical Trials in Oncology that showed a 29% confirmed ORR in patients (n=14) with highly refractory UPS who received dual checkpoint inhibition with Opdivo in combination with Yervoy. For reference, cohort B of the ENVASARC pivotal trial will enroll UPS/MFS patients who will receive dual checkpoint inhibition with envafolimab with Yervoy.

- In May, positive data were presented from multiple TRC102 clinical trials at the 2020 ASCO Virtual Scientific Program. In a Phase 2 trial, two of 14 mesothelioma patients who progressed previously on Alimta had objective responses following treatment with Alimta and TRC102. In a Phase 1 trial, TRC102 in combination with chemo-radiation resulted in an objective response in all 15 patients with locally advanced non-squamous non-small cell lung cancer, including three patients who demonstrated a complete response to treatment. The 100% ORR indicates a significant improvement as compared to historical data of chemoradiation without TRC102 in advanced lung cancer.

"We were excited by the ASCO data presented by our corporate partners showing that envafolimab activity was comparable to the activity of the approved products Opdivo and Keytruda in separate trials of MSI-H/dMMR CRC. Moreover, we were encouraged by additional data presented at ASCO from the Alliance group which showed an impressive response rate for dual checkpoint inhibition with Opdivo and Yervoy in UPS. Importantly, these data provide the rationale for testing dual checkpoint inhibition using envafolimab and Yervoy in the ENVASARC trial," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "Achieving a 29% response rate in ENVASARC would represent a marked improvement in the treatment of patients with refractory UPS/MFS, where the only approved therapy demonstrated a 4% response rate. We look forward to enrolling the first patient in ENVASARC later this year and plan to provide interim data in 2021, final data in 2022, and assuming positive clinical data and regulatory approval, potentially commercialize envafolimab in 2023."

Expected Upcoming Milestones

- Completion of the 30 day FDA review period for the ENVASARC protocol, a pivotal trial in the sarcoma subtypes of UPS and MFS, that was submitted to the FDA on July 16, 2020.
- Enroll the first patient in ENVASARC during the fourth quarter of 2020.
- Submission of the envafolimab BLA with the National Medical Products Association in China (NMPA) by our partners, 3D Medicines and Alphamab Oncology.
- Report top-line data from the Phase 1 dose escalation study of TJ4309, a CD73 antibody, as a single agent and in combination with Tecentriq (a PD-L1 antibody being supplied by Roche), in the second half of 2020.

Second Quarter 2020 Financial Results

- Cash and cash equivalents were $14.5 million at June 30, 2020, compared to $16.4 million at December 31, 2019. We expect our current cash and cash equivalents to fund operations into the second quarter of 2021. If the remaining $11.7 million available under the Aspire Capital agreement as of June 30, 2020 were fully utilized, cash runway would extend late into the third quarter of 2021.
- Research and development expenses for the second quarter of 2020 were $2.2 million, compared to $4.3 million for the second quarter of 2019. The decrease was primarily attributable to lower manufacturing expenses and clinical trial expenses due to the discontinuation of the Phase 3 TRC105 program.
- General and administrative expenses for the second quarter of 2020 were $2.1 million, compared to $1.9 million for the second quarter of 2019.
- Net loss for the second quarter of 2020 was $4.5 million, compared to $6.3 million for the second quarter of 2019.

Conference Call Details

Wednesday, August 5, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Domestic:	**855-779-9066**
International:	**631-485-4859**
Conference ID:	**9281324**

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 novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in registrational trials. Envafolimab is currently dosing in a Phase 2 registration trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 registration trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China. 3D Medicines and Alphamab Oncology, TRACON's corporate partners for this program, plan to submit a BLA to the NMPA in China for envafolimab in 2020 based on the ORR in MSI-H/dMMR advanced solid tumor patients. The confirmed ORR in MSI-H/dMMR colorectal cancer patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan reported at ASCO 2020 was 28.2%, which was nearly identical to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR colorectal cancer patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 27.9% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of KEYNOTE-164.

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 or Case Comprehensive Cancer Center.

About TRC253

TRC253 is a Phase 3 ready 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 recently completed a Phase 1/2 clinical trial in prostate cancer conducted by TRACON. TRACON believes TRC253 can be developed and commercialized successfully in China and is actively seeking a strategic collaboration.

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 utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a subcutaneous PD-L1 single-domain antibody being developed for the treatment of sarcoma with the goal of initiating a registrational trial in the U.S. in the fourth quarter of 2020; TRC253, a small molecule drug candidate for the treatment of prostate cancer; TRC102, a Phase 2 small molecule drug candidate being developed 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 U.S. 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 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, estimated cash runway, potential access to future capital, potential utility of product candidates, potential events, payments and actions 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 and regulatory approval of novel pharmaceutical products; 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, including being able to meet the conditions for sales of common stock under TRACON’s agreement with Aspire Capital; 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$2,218	$4,347	$4,216	$9,561
General and administrative	2,096	1,893	3,982	3,842
Total operating expenses	4,314	6,240	8,198	13,403
Loss from operations	(4,314)	(6,240)	(8,198)	(13,403)
Total other income (expense)	(137)	(86)	(274)	(136)
Net loss	$(4,451)	$(6,326)	$(8,472)	$(13,539)
Net loss per share, basic and diluted	$(0.70)	$(2.11)	$(1.47)	$(4.53)
Weighted-average common shares outstanding, basic and diluted	6,385,562	2,992,936	5,778,456	2,991,079

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

	June 30,	**December 31,**

	2020	2019
Assets	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$14,453	$16,412
Prepaid and other assets	503	848
Total current assets	14,956	17,260
Property and equipment, net	16	23
Other assets	678	838
Total assets	$15,650	$18,121
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$6,583	$7,875
Accrued compensation and related expenses	906	1,355
Long-term debt, current portion	1,746	2,604
Total current liabilities	9,235	11,834
Other long-term liabilities	651	850
Long-term debt, less current portion	2,761	2,739
Commitments and contingencies		
Stockholders' equity:		
Common stock	8	4
Additional paid-in capital	173,801	165,028
Accumulated deficit	(170,806)	(162,334)
Total stockholders' equity	3,003	2,698
Total liabilities and stockholders' equity	$15,650	$18,121

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Andrew McDonald
LifeSci Advisors LLC
646-597-6987
Andrew@lifesciadvisors.com

Source: TRACON Pharmaceuticals, Inc.