UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 20, 2019**

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36818**	**34-2037594**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4350 La Jolla Village Drive, Suite 800 San Diego, California	**92122**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 550-0780

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 1.01 Entry into a Material Definitive Agreement.

On December 20, 2019, TRACON Pharmaceuticals, Inc. (the "Company"), 3D Medicines Co., Ltd. ("3D Medicines"), and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("Alphamab") entered into a collaboration and clinical trial agreement (the "Collaboration Agreement") for the development of envafolimab, which is also known as KN035, an investigational PD-L1 single domain antibody administered by subcutaneous injection, for the treatment of soft tissue sarcoma in North America.

Pursuant to the Collaboration Agreement, the Company was granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. The Company is responsible for conducting, and will bear the costs of, any Phase 1, Phase 2, Phase 3, or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of soft tissue sarcoma. 3D Medicines and Alphamab are responsible for conducting, and will bear the costs of, IND-enabling studies (other than those specific to the sarcoma indication) and the preparation of CMC activities sections of an investigational new drug (IND) application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to the Company at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than soft tissue sarcoma.

The Company will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than soft tissue sarcoma and launched in North America, or (b) envafolimab is first approved in North America for soft tissue sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for soft tissue sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Collaboration Agreement, the Company has the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace the Company as the party responsible for commercialization, and the Company elects and 3D Medicines and Alphamab agree for the Company to not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate the Company for its costs associated with preparing for and conducting commercial activities.

If the Company has responsibility for commercialization under the Collaboration Agreement, it will owe 3D Medicines and Alphamab escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Collaboration Agreement, the Company will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if the Company has chosen to not to co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if the Company has chosen to co-market envafolimab in sarcoma. Payment obligations under the Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without the written consent of the Company and the parties must negotiate in good faith and agree to fair compensation to be paid to the Company for the value of and opportunity represented by the required rights.

Each party agreed that during the term of the Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1.

The term of the Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event

the Company elects, or a joint steering committee determines, to cease further development or commercialization of envafolimab, or if the Company fails to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and does not cure such failure within a specified time period, then the Company's rights and obligations under the Collaboration Agreement will revert to 3D Medicines and Alphamab.

The description of the Collaboration Agreement above is qualified in its entirety by reference to the text of the agreement, a copy of which will be filed as an exhibit to the Company's annual report on Form 10-K for the year ending December 31, 2019.

On December 20, 2019, the Company issued a press release with respect to entering into the Collaboration Agreement described under Item 1.01 of this current report. A copy of the press release is attached hereto as Exhibit 99.1.

Item 8.01 Other Events

Envafolimab is an investigational single-domain antibody ("sdAb") with affinity to PD-L1 administered by subcutaneous injection without an adjuvant. Envafolimab is being developed by 3D Medicines for the treatment of various cancer indications.

Single-domain antibodies are a novel class of therapeutic protein that contain the unique structural and functional properties of naturally-occurring heavy chains and lack light chains. On February 6, 2019, the FDA approved the first single-domain antibody, Cablivi® (caplacizumab), for adults with acquired thrombotic thrombocytopenic purpura.

PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, and is utilized by tumor cells as an immune escape mechanism. Numerous preclinical and clinical studies of PD-1/PD-L1 products have demonstrated that antibodies that block the interaction of PD-1 with its ligands, PD-L1 and PD-L2, or those that block only the interaction of PD-L1 with PD-1 can augment anti-tumor T-cell responses and lead to complete and lasting tumor eradication in a certain proportion of patients. Potent therapeutic anti-tumor responses due to blocking of PD-1/PD-L1 interaction has been demonstrated by these approved products in patients with various solid tumors including, but not limited to, non-small cell lung cancer ("NSCLC"), melanoma, renal cell carcinoma ("RCC"), head and neck cancer, cutaneous squamous cell carcinoma ("cSCC") and urothelial carcinoma.

Envafolimab is a camelid IgG4 single domain antibody with single digit nanomolar affinity to PD-L1. Benefitting from the single domain antibody format, envafolimab has half the molecular weight as compared to a full antibody with better stability and high solubility, which enables the development of high concentration formulation injections suitable for subcutaneous injection. In addition, the effector functions are muted in envafolimab to help limit its exposure to the immune system and avoid unwanted adverse immune responses. As a result, compared with approved PD-(L)1 inhibitors, envafolimab potentially has the following advantages:

- *Better patient compliance with increased convenience*. Subcutaneous formulation enables quicker administration and self-injection, which is more convenient for patients in long-term care and enables better patient compliance with the treatment regimen;

- *Wider patient coverage*. Envafolimab has the potential to be used in patients who are not eligible for intravenous administration, such as elderly patients who are heavily treated with chemotherapy resulting in loss of venous access, and

- *Relatively stable plasma-drug concentration*. The plasma-drug concentration of envafolimab is relatively stable without significant fluctuations due to the nature of subcutaneous administration. Its different PK profile compared with intravenous formulations may result in lower risks to patients.

Clinical Development of envafolimab

As of October 11, 2019, Envafolimab had been dosed in more than 650 patients in a total of 6 ongoing clinical trials in the United States, China or Japan, including a pivotal Phase 2 trial in microsatellite instability-high (MSI-H) cancer patients in China, a Phase 2 trial of KN035 plus chemotherapy in gastric cancer, a Phase 3 randomized trial of KN035 plus chemotherapy versus chemotherapy in biliary tract cancer in China, a Phase 1 dose escalation and dose exploration trial in the United States, a Phase 1 dose escalation and dose exploration trial in China, and a Phase 1 dose escalation and dose exploration trial in Japan.

Phase I Dose Escalation Clinical Trial in China

An open-label, single-arm phase I dose escalation and exploration clinical trial of envafolimab has completed enrollment in China. The safety and efficacy data from this trial were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019. Based on the data presented in the ASCO Annual Meeting ("ASCO Presentation"), 17 subjects were enrolled in the dose escalation phase in this trial as of May 1, 2019. A total of 287 subjects were enrolled in this phase 1 study.

Study purpose. The primary objectives of the phase I dose escalation were to assess the safety and tolerability profile and maximum tolerated dose ("MTD") of single agent envafolimab administered subcutaneously in subjects with advanced solid tumors. The secondary objectives were to evaluate the PK profile, immunogenicity and anti-tumor activity.

Study design of the dose escalation phase. This trial adopted a modified "3+3" design with a dose limiting toxicity ("DLT") evaluation period of 28 days. Subjects received envafolimab in six cohorts at 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 2.5 mg/kg, 5.0 mg/kg and 10.0 mg/kg once every week ("QW") subcutaneously. One patient was planned for the 0.1 and 0.3 mg/kg cohorts in absence of treatment-related grade 2 AE. Starting from the 1.0 mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring treatment emergent adverse events ("TEAEs"). Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The majority of the subjects received two or more prior systemic oncology treatments. According to the ASCO Presentation, 16 of the subjects had discontinued treatment due to disease progression (n=15) or consent withdrawal (n=1). All of the enrolled subjects experienced TEAEs. 13 (76.5%) experienced treatment-related TEAEs. Three (17.6%) subjects experienced serious TEAEs, although none were determined to be treatment-related. TEAE led to treatment discontinuation in one subject but was also determined to be not treatment-related. No DLT was reported and the MTD was not reached. Details of the TEAEs observed from the 17 subjects enrolled in the phase I dose escalation study are summarized in the following table.

TEAE categories[1]	n (%) (N=17)
AE	17 (100%)
Any TEAE	17 (100%)
TEAE, Grade ≥ 3	7 (41.2%)
Treatment-related TEAE[2]	13 (76.5%)
Treatment-related TEAE, Grade ≥ 3[3]	1 (5.9%)
SAEs	3 (17.6%)
Treatment-related SAEs	0
IrAEs	1 (5.9%)
IrAEs, Grade ≥ 3[3]	1 (5.9%)
TEAE leading to permanent treatment discontinuation	1 (5.9%)
Treatment-related TEAE leading to permanent treatment discontinuation	0
TEAE leading to death	0
Treatment-related TEAE leading to death	0

(1) Reported under National Cancer Institute Common Terminology Criteria for Adverse Events v. 4.03.
(2) The most frequent treatment-related TEAEs (all grades ≥ 10%) included increased alanine aminotransferase (n=6, 35.3%), increased aspartate aminotransferase (n=6, 35.3%), dermatitis/rash (n=3, 17.6%), blood bilirubin increased (n=3, 17.6%), injection site reaction (n=2, 11.8%).
(3) An immune-related dermatitis that occurred in the 0.3 mg/kg cohort. The subject recovered completely after the study drug was withheld.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, Abstract No. 2608, Poster No. 252, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

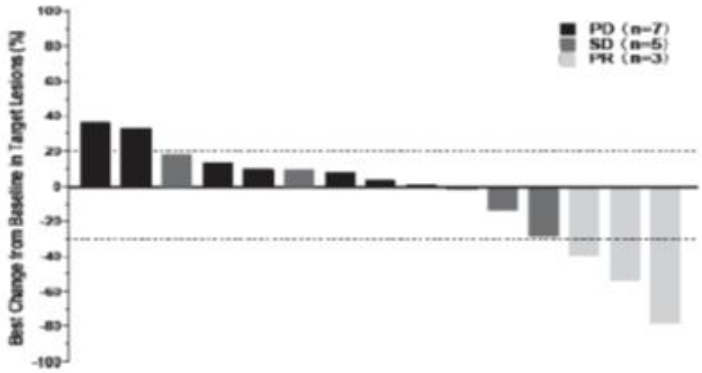
Efficacy. According to the ASCO Presentation, 15 out of 17 subjects were evaluable for the efficacy analysis. Three subjects had confirmed partial response ("PR"), including one RCC subject in the 2.5 mg/kg cohort, one intrahepatic cholangiocarcinoma subject from the 5.0 mg/kg cohort and one biliary tract cancer ("BTC") subject from the 10.0 mg/kg cohort. In addition, five subjects achieved stable disease ("SD"). All 15 subjects completed at least one post-baseline tumor assessment, according to the ASCO Presentation. Two enrolled subjects who had not reached the first post-baseline tumor assessment were excluded. The table below summarizes the best overall response in the efficacy analysis of this trial, according to the ASCO Presentation.

Response	0.1 mg/kg (N=1)	0.3 mg/kg (N=2)	1.0 mg/kg (N=3)	2.5 mg/kg (N=3)	5.0 mg/kg (N=3)	10.0 mg/kg (N=3)	Total (N=15)
				n (%)			
CR	0	0	0	0	0	0	0
PR	0	0	0	1	1	1	3 (20.0%)
SD	0	0	2	2	1	0	5 (33.3%)
PD	1	2	1	0	1	2	7 (46.7%)
CR+PR	0	0	0	1	1	1	3 (20.0%)
DCR (CR+PR+SD)	0	0	2	3	2	1	8 (53.3%)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, DCR=disease control rate.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

The following waterfall plot shows the best overall response of the 15 evaluable subjects receiving envafolimab as measured by percentage of change of target lesions from baseline.



Abbreviations: PD=progressive disease, SD=stable disease, PR=partial response.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

Conclusion. According to the ASCO Presentation, envafolimab exhibited a tolerable safety profile and preliminary efficacy in patients with advanced malignancies.

Phase I Dose Escalation Clinical Trial in the United States

The dose escalation phase of an open-label, single-arm phase I dose escalation and dose exploration clinical trial of envafolimab was completed in the United States. The safety and efficacy data from the dose escalation phase of this trial was presented at the 2018 Annual Congress of the European Society for Medical Oncology (ESMO) in October 2018. Based on the data presented in the ESMO (the “ESMO Presentation”), 18 subjects were enrolled in the dose escalation phase of this trial as of July 5, 2018.

Study purpose of the dose escalation phase. The primary objectives of the phase I dose escalation clinical trial were to evaluate and characterize the tolerability and safety profile of single agent envafolimab in subjects with locally advanced or metastatic solid tumors. The secondary objectives were to characterize the PK profile, determine MTD and to evaluate anti-tumor activity.

Study design of the dose escalation phase. This trial adopted a modified "3+3" design with a DLT evaluation period of 28 days. Subjects received envafolimab across eight cohorts at 0.01 mg/kg, 0.03 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 2.5 mg/kg, 5.0 mg/kg and 10.0 mg/kg QW subcutaneously. One patient was planned for the 0.01, 0.03 and 0.1 mg/kg cohorts in absence of treatment-related grade 2 AE. Starting from the 0.3 mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring TEAEs. Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The median duration of exposure to envafolimab was 9 weeks with a range of 6 to 32 weeks. As of July 5, 2018, two of the subjects (11.1%) remained in the study, 11 subjects had discontinued treatment due to disease progression, three subjects had discontinued treatment due to TEAEs, and two subjects had discontinued treatment due to the opinion of the investigator that no more clinical benefit could be obtained or other reasons. All of the 18 enrolled subjects experienced TEAEs. Treatment-related TEAEs at grade 3 or above included increased aspartate aminotransferase (10.5%), increased alanine aminotransferase (10.5%) and lymphopenia (10.5%). No DLT was observed and the planned maximum dose of 10.0 mg/kg was reached.

Efficacy of dose escalation phase. According to the ESMO Presentation, 17 out of 18 subjects were evaluable for the efficacy analysis. Two subjects had confirmed PR, including one NSCLC subject from the 0.3 mg/kg QW cohort (response duration of 9 months) and one MSI-H prostate cancer subject from the 2.5 mg/kg QW cohort (ongoing duration of 10 months). In addition, five subjects had achieved SD. All 17 evaluable subjects had completed at least one post-baseline tumor assessment according to the ESMO Presentation. One enrolled subject who had not reached the first post-baseline tumor assessment was excluded. The table below summarizes the best overall response in the efficacy analysis of this trial according to the ESMO Presentation.

	0.01 mg/kg weekly (N=1)	0.03 mg/kg weekly (N=1)	0.1 mg/kg weekly (N=1)	0.3 mg/kg weekly (N=3)	1.0 mg/kg weekly (N=3)	2.5 mg/kg weekly (N=3)	5.0 mg/kg weekly (N=3)	10.0 mg/kg weekly (N=3)	Total (N=18)
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
CR	0	0	0	0	0	0	0	0	0
PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
SD	0	1 (100)	0	1 (33.3)	1 (33.3)	0	1 (33.3)	1 (33.3)	5 (27.8)
PD	1 (100)	0	1 (100)	0	2 (66.7)	2 (66.7)	2 (66.7)	1 (33.3)	9 (50.0)
NE	0	0	0	0	0	0	0	1 (33.3)	1 (5.6)
CR+PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
DCR: (CR+PR+SD)	0	1 (100)	0	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	7 (38.9)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, NE=not evaluable, DCR=disease control rate.

Source: *Phase I Study of KN035, A Novel Fusion Anti-PD-L1 Antibody Administered Subcutaneously in Patients with Advanced Solid Tumors in the USA, 2018 Annual Congress of the European Society for Medical Oncology (ESMO)*

PK profile of dose escalation phase. This study showed that the exposure to envafolimab was dose-dependent and increased proportionally across all eight dose levels. Average half-life of envafolimab was approximately 200 hours.

Conclusion. According to the ESMO Presentation, envafolimab exhibited a favorable safety profile in subjects with advanced solid tumors and preliminary efficacy results demonstrated encouraging anti-tumor activity.

Phase I Clinical Trial in Japan

An open-label phase I dose escalation and dose exploration clinical trial of envafolimab is being conducted in Japan. The safety, efficacy and PK data of this trial as of May 5, 2019 was presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019. Based on the data presented in the ASCO Annual Meeting (the "Japan Trial ASCO Presentation"), 26 subjects were enrolled in this trial as of May 5, 2019.

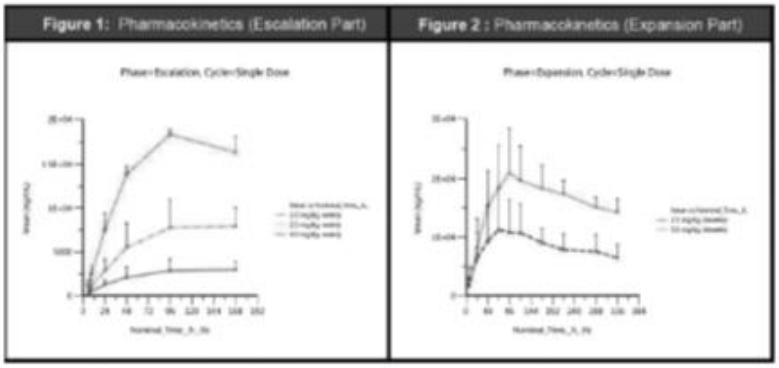
Study purpose. The primary objectives of the phase I clinical trial are to assess the safety and tolerability profile of single agent envafolimab in Japanese subjects with previously treated advanced solid tumors. The secondary objectives are to characterize the PK profile, determine MTD and evaluate the anti-tumor activity.

Study design. This phase I trial consists of a multi-dose escalation phase followed by a dose exploration phase. Subjects will receive envafolimab across five cohorts at 1.0 mg/kg, 2.5 mg/kg and 5.0 mg/kg QW subcutaneously, and 2.5 mg/kg and 5.0 mg/kg Q2W subcutaneously. The QW schedule adopted a traditional "3+3" design. For the Q2W schedule, six patients were planned for each cohort. Safety and tolerability are being assessed by monitoring TEAEs under common terminology criteria for adverse events ("CTCAE") version 4.0. Tumor assessments are being performed based on RECIST version 1.1. Full PK sampling is performed after the first dose of cycle 1 (28 days) and sparse PK samples are collected at pre-dose and around Cmax during the subsequent cycles.

Safety. According to the Japan Trial ASCO Presentation, as of May 5, 2019, no MTD had been reached. As of the same date, three subjects had remained in the study. 21 subjects had discontinued treatment due to disease progression and two subjects had discontinued treatment due to TEAE. All of the enrolled subjects experienced TEAEs, 17 subjects (65.4%) experienced treatment-related TEAEs, and only one grade 3 treatment-related TEAE (cerebral infraction) was reported. There were no grade 4/5 treatment-related TEAEs. There were a total of four SAEs, two of which were treatment-related. No DLT was reported.

Efficacy. According to the Japan Trial ASCO Presentation, nine out of 26 subjects were evaluable patients for the efficacy analysis as of May 5, 2019. Two subjects had confirmed PR and two subjects had unconfirmed PR. The other five evaluable subjects had achieved SD. 17 enrolled subjects who did not reach the first post-baseline tumor assessment were excluded.

PK profile. In the dose escalation phase, the exposure to envafolimab was dose-dependent and increased proportionally. Tmax varied from 96 to 168 hours after a single dose as shown in Figure 1 below. In the dose exploration phase, the exposure to envafolimab was dose-dependent and increased proportionally. Preliminary PK suggested a prolonged half-life that may support a less frequent dosing schedule than once every 2 weeks.



Source: Phase I Study and Pharmacokinetic Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Japanese Patients with Advanced Solid Tumors, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

Conclusion. Envafolimab exhibited a favorable safety profile in patients with advanced malignancies and preliminary efficacy results demonstrated promising anti-tumor activity.

Other Ongoing Clinical Trials

A pivotal clinical trial of envafolimab dosed as a single agent for the treatment of MSI-H tumors was initiated in August 2018. The trial is a non-randomized trial enrolling approximately 110 patients in China, including colorectal cancer patients who are required to have been previously treated with standard therapies, which must include fluoropyrimidine, oxaliplatin, or irinotecan, and other solid tumor patients, who are required to have been previously treated with at least one line of systemic standard of care therapy. Patients will receive 150mg of envafolimab subcutaneously dosed weekly. Top-line data from the trial are expected in 2020 with ORR as the primary endpoint defined by RECIST version 1.1. 3D Medicines is planning to file a BLA in China for envafolimab in 2020 provided there is positive overall response rate data from the trial in patients with MSI-H tumors. The filing is based on the principle that the response rate required for approval in China should be similar to the response rate for products approved in the US for in MSI-H cancer patients.

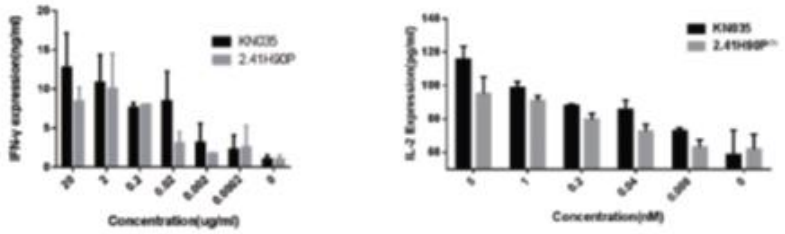
A Phase 3 randomized clinical trial in biliary tract cancer was initiated in April 2018. This trial is an open-label study to assess the safety and efficacy of envafolimab plus standard of care gemcitabine-based chemotherapy compared to gemcitabine-based chemotherapy with overall survival ("OS") as the primary endpoint. In the envafolimab arm, envafolimab will be dosed at 2.5 mg/kg subcutaneously weekly, along with gemcitabine and oxaliplatin at recommended doses. The trial is expected to enroll over 390 patients in China and data are expected in 2022.

A phase 2 study of envafolimab in combination with chemotherapy (FOLFOX) in first line treatment of advanced gastric cancer was fully enrolled (n=15) as of January 15, 2019.

Preclinical Studies

In pre-clinical studies in human cell and humanized mouse model, envafolimab was compared with durvalumab, the only approved PD-L1 inhibitor at the time, and envafolimab showed the following potential advantages:

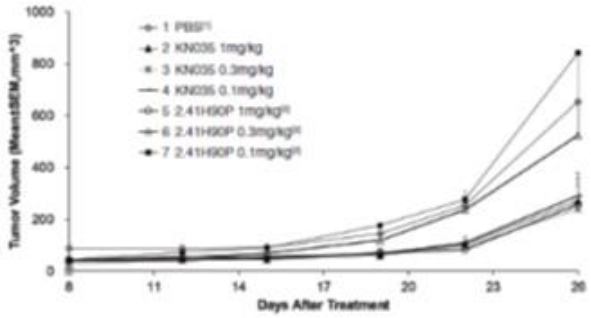
- *Stronger T-cell activation effect.* The level of T-cell activation can be measured by the secretion levels of IFN- and IL-2. Higher secretion levels are generally associated with stronger T-cell activation. In pre-clinical studies, envafolimab had a slightly better stimulatory effect on IFN- and IL-2 secretion compared to durvalumab. The following graphs illustrate the secretion levels of IFN- and IL-2 stimulated by envafolimab and durvalumab.



(1) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *Higher anti-tumor efficacy*. Each of envafolimab and durvalumab was injected intraperitoneally in mice at 0.1 mg/kg, 0.3 mg/kg and 1.0 mg/kg dose levels. As illustrated in the following graph, envafolimab showed stronger tumor growth inhibition effects than that of durvalumab at 0.3 mg/kg and 0.1 mg/kg.



(1) The control group was given PBS alone.

(2) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *Faster tumor penetration.* After injection of envafolimab and durvalumab in tumor bearing nude mice, the tumor radioactivity signal was consistently higher in the envafolimab group than the durvalumab group up to 52 hours post injection. The tumor radioactivity signal in the envafolimab group between 1 hour to 2.5 hours was statistically significantly higher than that of durvalumab, which suggests potentially better biological distribution of envafolimab.

Clinical Development in UPS

The Company intends to file an IND, apply for orphan drug status, and initiate a registration enabling study of envafolimab in the sarcoma subtype of undifferentiated pleomorphic sarcoma ("UPS") in 2020. Subject to input from the FDA, the Company is expecting that the trial will enroll approximately 100 patients and will be a single-arm non-randomized trial with ORR as the primary endpoint, which could be the basis for accelerated BLA approval. No enrichment strategy will be proposed for the registration enabling trial, however an adaptive design may be proposed with an interim analysis for futility in PD-L1 negative patients that would also reassess the sample size. Additionally, provided positive data from the initial UPS trial, the Company plans to initiate a biomarker directed randomized trial for multiple soft tissue sarcoma subtypes, which could expand the target patient population. The Company estimates having an interim response assessment which would include correlation with PD-L1 expression in mid-2021, final response assessment in early 2022, and, assuming positive data, filing for BLA accelerated approval by the end of 2022.

UPS has an incidence of 0.8 to 1.0 cases per 100,000 patients in the western world and accounts for 10% of new cases of soft tissue sarcoma in the United States. The Company estimates that refractory UPS represents a potential market of $200 million without considering a price premium to the reference PD-1 inhibitors Opdivo® (nivolumab) or Keytruda® (pembrolizumab) that are administered intravenously.

Manufacturing

Envafolimab is manufactured by AlphaMab in China and fill finish is performed by a contract manufacturer in the United States.

Competition

There is no PD-1 or PD-L1 therapy approved by the FDA for the treatment of soft tissue sarcoma. If envafolimab is approved, it may nevertheless compete with currently marketed PD-1 and PD-L1 inhibitors, including Opdivo (marketed by Bristol-Meyers Squibb), Keytruda (marketed by Merck), Imfinzi (marketed by AstraZeneca), and Tecentriq (marketed by Roche) which are approved by the FDA in multiple indications other than soft tissue sarcoma. PD-1 and PD-L1 inhibitors collectively sold over $14 billion in 2018.

Intellectual Property

Alphamab has filed patents on the composition of matter and methods of use of envafolimab in China, the European Union and the United States, including application US2019/0352404 that was published November 21, 2019.

Forward-Looking Statements

Statements made in report 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 Company’s, 3D Medicines’ and Alphamab’s plans to further develop envafolimab, potential benefits of the Collaboration Agreement, expectations regarding the timing of regulatory submissions and clinical trials, potential payments and activities under the Collaboration Agreement, expected development milestones and potential utility of envafolimab. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether the Company or others will be able to complete or initiate clinical trials on 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 the Collaboration Agreement is subject to early termination; potential changes in regulatory requirements in the United States and foreign countries; the Company’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 the Company will be able to obtain additional financing; and other risks described in the Company’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. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release issued by TRACON Pharmaceuticals, Inc. on December 20, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TRACON Pharmaceuticals, Inc.

Dated: December 20, 2019

By: /s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 99.1

TRACON Pharmaceuticals, 3D Medicines and Jiangsu Alphamab Announce Partnership for Development of Subcutaneous PD-L1 Single-Domain Antibody in Soft Tissue Sarcoma

Company to Host Investor Conference Call Today at 8:30 a.m. ET / 5:30 a.m. PT

Envafolimab represents a potential best-in-class PD-L1 inhibitor that is injectable subcutaneously without the need for an adjuvant

Envafolimab has been dosed in more than 650 patients in the U.S., China and Japan, and is currently being evaluated in registrational trials in China in patients with high microsatellite instability ("MSI-H") cancer and biliary tract cancer

Immune checkpoint inhibitors targeting the PD-1 or PD-L1 pathway have demonstrated activity in multiple soft tissue sarcoma subtypes, including undifferentiated pleomorphic sarcoma (UPS)

TRACON intends to initiate a registration enabling study of envafolimab in the sarcoma subtype of UPS in 2020

San Diego, CA – December 20, 2019 – TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, announced today that it has signed a collaborative partnership agreement with 3D Medicines (Beijing) Co., Ltd., a China-based biopharmaceutical company focused on cancer precision medical treatment, and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., a wholly-owned subsidiary of Alphamab Oncology (HKEX: 9966) and a China-based clinical stage biopharmaceutical company primarily engaging in research and development, manufacturing and commercialization of biologics of oncology, for the development of envafolimab, also known as KN035, a PD-L1 single-domain antibody administered by subcutaneous injection, for development in soft tissue sarcoma in North America.

TRACON and 3D Medicines and Jiangsu Alphamab entered into a product development collaboration whereby TRACON will be responsible for the clinical development and commercialization of envafolimab in soft tissue sarcoma in North America, with the majority of the development activities expected to occur in the U.S. TRACON will bear the costs of clinical trials and 3D Medicines and Jiangsu Alphamab will supply envafolimab at pre-negotiated prices.

TRACON will be responsible for commercializing envafolimab for sarcoma in North America, except in certain circumstances involving the approval of envafolimab for other indications in North America, in which case TRACON has the option to co-market envafolimab for sarcoma in North America.

If TRACON has responsibility for commercialization under the Collaboration Agreement, it will owe 3D Medicines and Jiangsu Alphamab escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits, which amounts shall be split between 3D Medicines and Jiangsu Alphamab as negotiated. If 3D Medicines and Jiangsu Alphamab have responsibility for commercialization under

the Collaboration Agreement, TRACON will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if TRACON has chosen to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if TRACON has chosen to co-market envafolimab in sarcoma.

At the American Society of Clinical Oncology 2019 meeting, data were presented from the SARC 028 clinical study demonstrating that the PD-1 inhibitor Keytruda® (pembrolizumab) achieved a 23% response rate in 40 patients with UPS, irrespective of PD-L1 expression in the tumor specimen. Additional data published subsequently indicate that Keytruda achieved more than a 50% objective response rate in cutaneous angiosarcoma. In a separate study, the PD-L1 inhibitor Tecentriq® (atezolizumab) achieved a more than 40% objective response rate in alveolar soft part sarcoma.

“Given the activity of other PD-1 and PD-L1 inhibitors in sarcoma, we believe a registration enabling study of envafolimab in the sarcoma subtype of UPS will be meaningful to patients and providers, and is strategically aligned with TRACON’s mission to rapidly develop and commercialize drugs targeting unmet need indications in the U.S.,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “We expect to discuss our plan of initiating a pivotal trial of envafolimab in UPS with the U.S. FDA in early 2020. Our ultimate goal is to enable a biomarker directed approach for treatment with envafolimab in patients with multiple types of soft tissue sarcoma.”

UPS accounts for 10% of new cases of soft tissue sarcoma in the United States and TRACON estimates that it represents a potential market of $200M without considering a price premium to the reference PD-1 inhibitors Opdivo® (nivolumb) and Keytruda® (pembrolizumab). Approval in soft tissue sarcoma subtypes other than UPS could increase the market opportunity significantly.

“We believe that collaboration with TRACON will give cancer patients an option for a subcutaneous injection in the United States. In earlier clinical trials, the safety and efficacy profiles of envafolimab are comparable to other PD-1/PD-L1 antibodies in the market.” said John Gong, CEO of 3D Medicines.

Dr. Ting Xu, Chairman and CEO of Alphamab Oncology, added “The collaboration is an important part of envafolimab’s global development strategy. As the most advanced single domain antibody in IO with the advantage of a subcutaneous dosage, we are confident it will bring a valuable option for cancer patients.”

Investor Conference Call

The Company will hold a conference call today at 8:30 a.m. ET / 5:30 a.m. PT to provide further details on the agreement and envafolimab. The dial-in numbers are (877) 407-0784 for domestic callers and (201) 689-8560 for international callers. Please use passcode 13697590. A live webcast of the conference call will be available at http://public.viavid.com/index.php?id=137389.

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 at a dose of 300 mg on a every 2 week schedule, and PK suggest a prolonged half-life that would support a less frequent dosing schedule. Envafolimab is currently dosing in Phase 1 trials in the US 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 in China that the response rate is required to be similar to the response rate for Keytruda and Opdivo in MSI-H patients from separate clinical trials per the product package inserts.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company’s clinical-stage pipeline includes: 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.

About 3D Medicines

3D Medicines is a clinical-stage biopharmaceutical company focused on the development of differentiated next-generation immuno-oncology drugs for cancer patients. The world's first subcutaneous injection PD-L1 antibody Envafolimab (KN035), is currently under clinical development in the United States, China and Japan. We are building our pipeline targeting major indications through combination strategy, either with in-house assets or in collaboration with partners around the world. With a professional team in the China and US, 3D Medicines is capable of conducting global clinical development and registration.

About Jiangsu Alphamab

Jiangsu Alphamab is a wholly-owned principal operating subsidiary of Alphamab Oncology, a company incorporated in the Cayman Islands with limited liability and listed on the main board of the Hong Kong Stock Exchange (stock code: 09966). Alphamab Oncology is a leading clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific and protein engineering. Its differentiated in-house pipeline consists of eight oncology drug candidates, including four in the phase I-III clinical trial development stage. Alphamab Oncology has developed various technologies and platforms of antibody-based therapies for oncology treatment and expertise in this regard. Benefitting from its proprietary

protein engineering platforms and structure-guided molecular modeling expertise, Alphamab Oncology is able to create a new generation of multi-functional bio-macromolecule new drugs that benefit patients globally.

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, 3D Medicines’ and Jiangsu Alphamab’s plans to further develop envafolimab, potential benefits of the collaboration between TRACON, 3D Medicines and Jiangsu Alphamab, expectations regarding the timing of regulatory submissions and clinical trials, potential payments and activities under the collaboration with 3D Medicines and Jiangsu Alphamab, expected development milestones, TRACON’s plans to leverage its product development platform and potential benefits derived from the platform, and potential utility of TRACON’s product candidates. 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’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; 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 Company Contact:
Mark Wiggins
Chief Business Officer
(858) 550-0780 ext. 236
mwiggins@traconpharma.com

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

3D Medicines Investor Contact:
Fang Xia
Assistant of CEO
+86 13811076622
fang.xia@3dmedcare.com

Jiangsu Alphamab Investor Contact:
Investor Relationship
+86-512 6285 0800
ir@alphamabonc.com