

TRACON Pharmaceuticals

08:30 06 Aug 2020

TRACON posts 2Q results showing it has ample funds for ENVASARC trial to study envafolimab as a sarcoma treatment

TRACON Pharmaceuticals Inc (NASDAQ:TCON) reported second-quarter financial results after the market closed on Wednesday that showed it has enough funds to carry out a pivotal trial of single-domain antibody envafolimab as a treatment for sarcoma cancers.

In July, TRACON filed the ENVASARC pivotal trial protocol with the US Food and Drug Administration (FDA) as part of an Investigational New Drug (IND) application.

San Deigo-based TRACON said it expects to initiate enrollment in the ENVASARC trial evaluating envafolimab in the fourth quarter. It will weigh envafolimab's effectiveness in treating undifferentiated pleomorphic sarcoma (UPS), a rare type of cancer that begins in the soft tissues, and myxofibrosarcoma (MFS), a cancer that appears as a painless lump on legs or arms.

The company said it had cash and equivalents of \$14.5 million as of June 30, 2020.

READ: TRACON Pharmaceuticals files ENVASARC protocol with FDA to study envafolimab as sarcoma treatment

"We expect our current cash and cash equivalents to fund operations into the second quarter of 2021," the company said in its earnings statement.

During the quarter, TRACON shared positive results at the 2020 American Society of Clinical Oncology (ASCO) virtual program from the company's partners — 3D Medicines and Alphamab Oncology — that showed envafolimab demonstrated a 30% confirmed ORR in 50 patients with MSI-H/dMMR colorectal cancer (CRC) who failed a fluoropyrimidine, oxaliplatin and irinotecan, or those with advanced gastric cancer who failed at least one systemic treatment, with at least two on-study tumor assessments.

"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 colorectal cancer," TRACON CEO Charles Theuer said in the update.

"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," he added.

The TRACON boss noted that 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.

Price: 9.1

Market Cap: \$124.53 m

1 Year Share Price Graph



November 2019 May 2020 November 20

Share Information

Code: TCON

Listing: NASDAQ

52 week	High	Low
	10.1	0.95

Sector: Pharma & Biotech

Website: www.traconpharma.com

Company Synopsis:

TRACON (NASDAQ:TCON) is a U. S. biotech with a product development platform that offers corporate partners CRO-independent clinical development and U. S. commercialization expertise. TRACON has in-licensed N.

action@proactiveinvestors.com

"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," Theuer concluded.

For its second quarter ended June 30, 2020, TRACON reported a net loss of \$4.5 million, compared to \$6.3 million for the second quarter of 2019. The company chalked up the decrease to R&D expenses which dropped to \$2.2 million, compared to \$4.3 million for the second quarter of 2019. The decrease was also due to lower clinical trial expenses from the discontinuation of the Phase 3 TRC105 program.

Contact the author Uttara Choudhury at uttara@proactiveinvestors.com

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