TRACON Pharmaceuticals Announces Positive Results Based on Double-Digit Objective Response Rate in Each Cohort from the Ongoing ENVASARC Phase 2 Pivotal Trial

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Objective Response Rate (ORR) by Central Review Achieved in Each Cohort at Interim Efficacy Analysis that Exceeded the Futility Threshold

Enrollment Continues Ahead of Schedule; Next Interim Analysis Expected in mid-2023 with Full Accrual Now Expected Before the End of 2023

Arbitration Decision Expected in 1Q 2023 has Potential to Increase Cash Runway

SAN DIEGO, Dec. 14, 2022 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company utilizing a cost-efficient, CRO-independent product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies, today announced the IDMC for the ongoing ENVASARC Phase 2 pivotal trial recommended continued accrual as planned in both cohorts: single agent envafolimab and envafolimab in combination with Yervoy (ipilimumab).

The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The double-digit ORR assessed by blinded independent central review in each cohort more than satisfied the prespecified futility rule. Envafolimab monotherapy and in combination with Yervoy was well tolerated, with only a single related serious adverse event reported in 36 patients. Responses were noted in patients regardless of weight at the 600 mg dose of envafolimab that was instituted following the previous IDMC review of interim safety and efficacy data from patients in the ENVASARC trial treated at the 300 mg dose of envafolimab.

“We are pleased with the activity of the 600 mg dose of envafolimab that has demonstrated a double-digit objective response rate both as a single agent and in combination with Yervoy, even at this early 12-week time point,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “We are also encouraged with the safety data showing that envafolimab monotherapy and in combination with Yervoy are well tolerated. This interim analysis is a positive milestone and we look forward to the next interim analysis which will be conducted after the 46th patient in each cohort has completed a minimum of 12 weeks of efficacy evaluations. Importantly, accrual in ENVASARC remains ahead of projections and we are excited by the emerging data and for envafolimab’s potential to become a differentiated treatment for sarcoma patients.”

“Achieving a double-digit ORR with a well tolerated safety profile, as both monotherapy and in combination, positions envafolimab to become a potential treatment option for patients with refractory UPS and MFS,” said Charles Theuer, M.D., Ph.D., TRACON’s Chief Executive Officer. “The sole approved treatment for these patients is Votrient, which achieved a 4% ORR and carries a black box warning for fatal liver toxicity.”

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology and licensed by TRACON, is the first approved subcutaneously injected PD-(L)1 inhibitor. Envafolimab was approved by the Chinese NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the United States sponsored by TRACON and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON’s corporate partners, Alphamab Oncology and 3D Medicines. In September 2022, TRACON received fast track designation from the U.S. Food and Drug Administration for envafolimab (KN035) for patients with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS) who have progressed on one or two prior lines of chemotherapy.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at 30 top cancer centers in the United States and the United Kingdom that began dosing in December 2020. TRACON expects the trial to enroll more than 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into a cohort of treatment with single agent envafolimab at 600 mg every three weeks and 80 patients enrolled into a cohort of treatment with envafolimab at 600 mg every three weeks with Yervoy®. The primary endpoint is objective response rate by central review with duration of response a key secondary endpoint.

About TRACON

TRACON is a clinical-stage biopharmaceutical company utilizing a cost-efficient, CRO-independent, product development platform to advance its pipeline of novel targeted cancer therapeutics and to partner with other life science companies. The Company’s clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; TRC102, a Phase 2 small molecule drug candidate 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 through a profit-share or revenue-share partnership, or through franchising TRACON's product development platform. TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States or who wish to become CRO-independent. 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 expectations for the timing and scope of its clinical trials, the availability and expected results of clinical data and the timing of future reviews of data by the Independent Data Monitoring Committee, continued accrual in the ENVASARC Phase 2 pivotal trial and the potential for envafolimab to become a treatment option. 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 pharmaceutical product candidates; whether other therapies are developed and compete with TRACON's product candidates; 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 or other geopolitical events; the fact that future clinical results may not be consistent with preliminary results or results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval 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; expectations on the timing and results of the arbitration with I-Mab and its effects on TRACON's cash runway; 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 on favorable terms or at all; 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 except as required by law.

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