TRACON Pharmaceuticals Provides Update on Phase 1/2 Trial of TRC253 in Patients with Metastatic Castrate Resistant Prostate Cancer

July 2, 2019

Phase 1 Data Published in ASCO Proceedings Determined the Recommended Phase 2 Dose

Additional Cohort of Patients with a Specific Androgen Receptor Point Mutation Added to Ongoing Phase 2 Study

Phase 2 Data Expected in 2nd half 2020; Potential for $45 Million Opt-in Payment from Janssen

SAN DIEGO, July 02, 2019 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration through our license to Santen Pharmaceutical Co. Ltd., and utilizing our product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., today provided an update on its TRC253 program for the treatment of metastatic castrate resistant prostate cancer, which was licensed from Janssen Pharmaceutica N.V. in 2016.

Phase 1 data from the ongoing Phase 1/2 clinical trial published in the 2019 ASCO Proceedings

- 21 patients with metastatic castrate resistant prostate cancer who had progressed on prior Xtandi® (enzalutamide) or Erleada™ (apalutamide) treatment were enrolled into one of six cohorts of escalating doses of TRC253.
- Target PK exposures were achieved consistently with the 280 mg daily oral dose, which was selected as the recommended Phase 2 dose.
- The single patient with a F877L androgen receptor (AR) point mutation at baseline remained on treatment for 49 weeks with a partial response by RECIST.
- The remaining 20 patients did not have a F877L AR point mutation at baseline, and 48% (10) remained on study for at least 6 months and one patient had a greater than 50% decrease in prostate specific antigen (PSA).
- TRC253 was well-tolerated and no drug-related serious adverse events were reported. Drug-related adverse events included QTcF prolongation, elevated lipase, fatigue, arthralgia, diarrhea, and platelet count decrease.
- Additional data are available on the ASCO website: https://abstracts.asco.org/239/AbstView_239_270075.html

Phase 2 portion of the ongoing Phase 1/2 trial amended to add an additional cohort of patients

- Based on evidence of potential efficacy in the data from the completed Phase 1 portion of the study, an additional cohort of patients was added to the ongoing Phase 2 study. This cohort will test the hypothesis of whether TRC253 has efficacy in mCRPC patients with a defined point mutation other than F877L AR.
- Enrollment is ongoing in the new cohort with a defined point mutation, as well as the two existing cohorts, the first including patients with a F877L AR mutation and the second consisting of patients with another basis for resistance to Xtandi or Erleada.

“We are pleased to have successfully completed the Phase 1 portion of the first-in-human study of TRC253 and look forward to the availability of Phase 2 data, which we expect in the second half of 2020,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Following delivery of the Phase 2 data, Janssen will have the right to reacquire the TRC253 program in return for an opt-in fee of $45 million and further success-based milestone and royalty payments.”

About TRC253 (formerly JNJ-63576253)

TRC253 is a novel, orally bioavailable small molecule discovered and developed by Janssen that is a potent, high affinity competitive inhibitor of the AR. TRC253 is also a pan-inhibitor of multiple AR mutations, including the F877L mutation, and is under development for the treatment of men with

prostate cancer in a Phase 1/2 clinical trial (NCT02987829). The AR F877L mutation results in an alteration in the ligand binding domain that confers resistance to current AR inhibitors.

Activation of the AR is crucial for the growth of prostate cancer at all stages of the disease. 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 amplification, overexpression or mutation of the AR.

TRC253 is intended to address resistance mechanisms to current AR inhibitors by specifically targeting mutations in the AR ligand binding domain. TRC253 also potently inhibits signalling through the wild type AR. These susceptible AR mutations have been identified using circulating tumor DNA assays, potentially allowing for selected patient biomarker-directed therapy.

Following completion of the initial Phase 1/2 clinical trial, Janssen will have an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45 million to TRACON, and obligations to pay regulatory and commercialization milestones totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, TRACON would then retain worldwide development and commercialization rights to the program and would be obligated to pay Janssen a total of up to $45 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

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 being developed in wet AMD through a license to Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; TRC253, a small molecule 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 shares in the cost and risk of clinical development and commercialization of innovative 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 product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, potential utility of product candidates, potential events and payments 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'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.

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