TransCode Therapeutics Reports Third Quarter 2023 Results; Provides Business Update

November 14, 2023

BOSTON, Nov. 14, 2023 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today reported financial results for the third quarter ended September 30, 2023, and recent business progress.

“In the third quarter of 2023, we successfully completed a follow-on public offering in a very difficult biotech market as we continue our clinical study with our lead therapeutic candidate, an RNA targeted therapeutic candidate for treating metastatic disease,” said Michael Dudley, co-founder, president and Chief Executive Officer of TransCode. “We were excited to dose our first patient in our Phase 0 clinical trial with TTX-MC138 in cancer patients with advanced solid tumors for which further enrollment is underway.

TransCode co-founder and Chief Technology Officer, Dr. Zdravka Medarova, commented, “We also announced encouraging preclinical data in glioblastoma multiforme (GBM) with our lead candidate. In addition, we published results of a preclinical study showing that inhibition of microRNA-10b, the therapeutic target of TTX-MC138, in breast cancer cells impaired the capacity of cancer stem cells to create new tumors and become metastatic. We believe these findings are important because cancer stem cells have long been known to play a critical role in cancer initiation, metastasis, recurrence, and resistance to therapy. Therefore, we believe that inhibiting the tumor-creating capacity of these cells using TTX-MC138 has the potential to improve outcomes in patients with breast cancer that is recurrent and resistant to treatment.”

Recent Business Highlights

- In July, the company announced the results of a pre-clinical study of its lead therapeutic candidate, TTX-MC138, in non-human primates, effectively engaging its target and showing favorable pharmacokinetics and tissue distribution. In the study, non-human primates (n = 4) were injected with a microdose of radiolabeled TTX-MC138 and imaged by positron emission tomography-magnetic resonance imaging (PET-MRI) to determine the pharmacokinetics and tissue distribution of the therapeutic candidate. In addition, the pharmacodynamic activity of radiolabeled TTX-MC138 following a microdose injection was determined by measuring inhibition of its target, miRNA-10b, using qRT-PCR. TTX-MC138 demonstrated a long circulation half-life and tissue distribution consistent with hepatic clearance. Importantly, even at a microdose, the therapeutic candidate showed lasting activity and significantly inhibited miRNA-10b, known to be a driver of metastatic progression in a number of cancers.
- In August, the company dosed the first patient in its First-in-Human Phase 0 clinical study. The Phase 0 trial is an open-label, single-center, microdose study intended to demonstrate delivery of the radiolabeled version of TTX-MC138 to radiographically-confirmed metastases in subjects with advanced solid tumors. Preliminary data showed that radioactivity consistent with accumulation of TTX-MC138 was detected by noninvasive imaging in the regions of the metastatic lesions previously identified by fluorodeoxyglucose (FDG)/positron emission tomography (PET) (FDG/PET). In addition, radiolabeled TTX-MC138 had pharmacokinetic behavior consistent with that expected based on non-clinical IND-enabling studies. The patient tolerated the dosing with no reported adverse reactions. Metabolite analysis indicated circulation of intact radiolabeled TTX-MC138 for more than 20 hours, equivalent to that predicted by Drug Metabolism and Pharmacokinetics (DMPK) modelling, and that the drug candidate analyzed in the blood was identical to that of the manufactured drug candidate, demonstrating *in vivo* stability. Complete analysis of data from this first patient is in process and will be included in the final report for all patients enrolled in the study.
- In September, the company announced the results of a pre-clinical study of TTX-MC138 in murine models bearing human glioblastoma multiforme (GBM) tumors. In this study, the therapeutic candidate was delivered to brain tumors where it effectively engaged its target. In the study reported by TransCode, mice implanted with tumors derived from human GBM patients were treated with TTX-MC138 and imaged by magnetic resonance imaging (MRI) to determine delivery of the therapeutic candidate to the tumors. In addition, the pharmacodynamic activity of TTX-MC138 was determined by measuring inhibition of miRNA-10b using qRT-PCR. TTX-MC138 was injected intravenously and accumulated efficiently in the tumors. Importantly, the therapeutic candidate showed lasting activity and significantly inhibited miRNA-10b, known to be a driver of tumor progression in glioblastoma.
- Also, in September, the company closed an underwritten public offering of an aggregate of 16,863,000 shares of its common stock (or pre-funded warrants in lieu thereof), including the partial exercise of the underwriter’s over-allotment option. Each share of common stock (or pre-funded warrant) was sold at a public offering price of $0.51 per share (inclusive of the pre-funded warrant exercise price of $0.01 per share). All of the shares and pre-funded warrants in the offering were sold by the company. Gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses, were approximately $8.5 million.

Planned Milestones

TransCode's goals to continue to advance its portfolio include:

- TTX-MC138
  - Enroll additional patients in First-in-Human Phase 0 clinical trial intended to demonstrate quantifiable evidence of delivery of radiolabeled TTX-MC138 to metastatic lesions in advanced solid tumors; measure pharmacokinetics and biodistribution in vital organs and other tissues; potentially inform therapeutic dose levels for future trials based on Phase 0 microdose results; and potentially validate delivery for the TTX pipeline more broadly, which could open-up additional relevant RNA targets that have been previously undruggable due to challenges with RNA delivery.
  - Submission to FDA of an Investigational New Drug (IND) application for a Phase I clinical trial with TTX-MC138.
- Publication of preclinical *in vivo* studies supporting therapeutic candidates, TTX-RIGA and TTX-siPDL1, as well as TTX-MC138 in pancreatic adenocarcinoma.
- Continuation of discussions with potential strategic partners regarding partnerships in multiple therapeutic areas including CRISPR and intracellular delivery of proteins using TransCode's TTX delivery platform.
- Filing for orphan drug designation for TTX-MC138 in additional tumor indications.

Third Quarter 2023 Financial Highlights

- Cash was approximately $7.5 million at September 30, 2023, compared to approximately $5.0 million at December 31, 2022.
- Research and development expense was approximately $3.3 million in the third quarter of 2023, compared to approximately $3.0 million in the third quarter of 2022.
- General and administrative expense was approximately $2.0 million in the third quarter of 2023, compared to approximately $1.9 million in the third quarter of 2022.
- Operating loss for the three months ended September 30, 2023, was approximately $5.3 million, compared to an operating loss of approximately $4.3 million in the prior year period.

Financial Guidance

TransCode expects that its cash of approximately $7.5 million as of September 30, 2023, is sufficient to fund planned operations into January 2024 but not for a full 12 months from the date of its financial statements.

About TransCode Therapeutics

TransCode is an RNA oncology company created on the belief that cancer can be more effectively treated using RNA therapeutics. Using its iron oxide nanoparticle delivery platform, the company has created a portfolio of drug candidates designed to target a variety of tumor types with the objective of significantly improving patient outcomes. The company's lead therapeutic candidate, TTX-MC138, is focused on treating metastatic cancer, which is believed to cause approximately 90% of all cancer deaths totaling over nine million per year worldwide. Another of the company's drug candidates, TTX-siPDL1, focuses on treating tumors by targeting a protein called Programmed death-ligand 1 (PD-L1). TransCode also has three cancer-agnostic programs: TTX-RIGA, an RNA–based agonist of the retinoic acid-inducible gene I designed to drive an immune response in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9–based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and TTX-mRNA, an mRNA-based platform for the development of cancer vaccines designed to activate cytotoxic immune responses against tumor cells.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning financial position and financial guidance, including cash runway guidance, statements concerning expected clinical results of TransCode's therapeutic candidates, statements concerning the results of RNA research, statements concerning the potential for treating cancer with RNA therapeutics, statements concerning the timing and outcome of expected regulatory filings and clinical trials, including the Phase 0, First-in-Human study of TTX-MC138, statements regarding planned milestones and goals to continue to advance TransCode's portfolio, including the timing of regulatory filings and submissions and publications, statements regarding discussions with potential strategic partners and statements concerning TransCode's development programs and TTX technology platform generally. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with TransCode's financial condition and its need to obtain additional funding to support its business activities, including TransCode's ability to continue as a going concern; the risk associated with drug discovery and development; the risk that the results of our planned clinical trials will not be consistent with our pre-clinical studies or expectations; risks associated with the timing and outcome of TransCode's planned regulatory submissions; risks associated with TransCode's planned clinical trials for its product candidates; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with TransCode's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risks associated with TransCode's dependence on third parties; and risks associated with global economic and political developments. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause TransCode's actual results to differ from those contained in or implied by the forward-looking statements, see the section entitled "Risk Factors" in TransCode's Annual Report on Form 10-K for the year ended December 31, 2022, as well as discussions of potential risks, uncertainties and other important factors in any subsequent TransCode filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release; TransCode undertakes no duty to update this information

unless required by law.

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