TransCode Therapeutics Reports First Quarter 2022 Results; Provides Business Update

May 16, 2022

BOSTON, May 16, 2022 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to defeating cancer using RNA therapeutics, today reported financial results for the first quarter ended March 31, 2022, and recent business progress.

TransCode co-founder and Chief Technology Officer, Dr. Zdravka Medarova, indicated, "We believe we remain on track to submit an exploratory Investigational New Drug Application (eIND) this year to test our lead therapeutic candidate, TTX-MC138, in a Phase 0 study in cancer patients with advanced solid tumors. We believe this study has the potential to establish proof-of-mechanism for our platform which ultimately could help us build a broad and diverse pipeline of therapeutics and diagnostics that have the potential to reach previously undruggable genetic targets."

"Additionally, we believe we achieved the first milestone related to our Small Business Innovation Research (SBIR) grant during the first quarter and anticipate receiving the next tranche of award funding during the second quarter," said Michael Dudley, co-founder, president and CEO of TransCode. "This non-dilutive funding, combined with capital from our 2021 IPO, provide the resources to drive continued progress across the organization, including key additions to our team who bring valuable expertise, and continued advancement of our lead therapeutic candidate and preclinical development of our other therapeutic candidates. As we move toward the Phase 0 proof-of-mechanism clinical trial, we continue to focus on using the power and versatility of our TTX platform to solve the challenges of RNA delivery in oncology."

Other First Quarter 2022 Highlights

- Expanded global RNA oncology patent portfolio with filing of an International PCT Application (PCT/US21/65580) entitled TEMPLATE DIRECTED IMMUNOMODULATION FOR CANCER THERAPY (the '580 application). The '580 application, expected to be published in June 2022, represents an extension of TransCode's use of its patented RNA therapeutic platform to include using pattern recognition receptors (PRR) to target tumor cells by activating the RIG-I signaling pathway. Once inside a cell, the selected PRR-activating oligonucleotide encounters a microRNA specific to that tumor where it is expected to activate a type I interferon-driven immune response, leading to programmed tumor cell death.
- Published article in the journal "Cancers" titled, *Clinical Applications of Short Non-Coding RNA-Based Therapies in the Era of Precision Medicine*, in collaboration with teams from Massachusetts General Hospital (MGH), Michigan State University, and Northeastern University. The article describes the development, challenges, and clinical successes of short non-coding RNA-based drugs and details several examples of how these RNA drugs are designed, chemically modified, and delivered to treat cancer, cardiovascular disease, and rare genetic disorders. In addition, the article highlights key similarities and differences between various short non-coding RNA platforms and discusses considerations to maximize treatment efficacy of RNA-based therapeutics. TransCode Co-Founder and scientific advisor, Dr. Anna Moore, was a contributing author to the article. The article was published on March 21, 2022.

Planned Milestones

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

- TTX-MC138
  - Submission to FDA of an eIND application for its First-in-Human (FIH) clinical trial.
  - Completion of a FIH Phase 0 clinical study 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 based on microdose results; and validate delivery for the TTX pipeline more broadly, potentially opening-up additional relevant RNA targets that have been previously undruggable due to challenges with RNA delivery.
  - Concurrent completion of IND-enabling studies to support filing an IND application for a Phase I clinical trial of TTX-MC138.
- Publication of preclinical results supporting the lead therapeutic candidate, TTX-MC138, in pancreatic cancer and glioblastoma multiforme.
- Publication of preclinical results supporting therapeutic candidate, TTX-RIGA.
- Continuation of preclinical studies for therapeutic candidates TTX-RIGA, TTX-siPDL1, and TTX-siLIN28B.
- Continuation of discussions regarding potential partnerships.

- File for Orphan Drug Designation for its lead therapeutic candidate in additional tumor indications.

First Quarter 2022 Financial Highlights

- Cash and cash equivalents were $16.9 million at March 31, 2022, compared to $20.8 million at December 31, 2021.
- Research and development expense was $1.9 million in the first quarter of 2022, compared to $0.3 million in the first quarter of 2021.
- General and administrative expense was $1.6 million in the first quarter of 2022, compared to $0.2 million in the first quarter of 2021.
- Operating loss for the three months ended March 31, 2022, was $3.5 million, compared to an operating loss of $0.4 million in the prior year period.

Financial Guidance

TransCode expects that its cash of $16.9 million as of March 31, 2022, together with additional funding expected from the April 2021 SBIR award, are sufficient to fund planned operations into the first quarter 2023 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 defeated using RNA therapeutics. The Company has created a platform 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. The Company believes that TTX-MC138 has the potential to produce regression without recurrence in a range of cancers, including breast, pancreatic, ovarian and colon cancer, glioblastomas and others. Two of the Company's other drug candidates, TTX-siPDL1 and TTX-siLIN28B, focus on treating tumors by targeting PD-L1 and LIN28B, respectively. TransCode also has three cancer-agnostic programs: TTX-RIGA, an RNA–based agonist of the retinoic acid-inducible gene I, or RIG-I, approach 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 the timing and outcome of expected regulatory filings and clinical trials, including the filing of an eIND for the planned first-in-human study of TTX-MC138, statements concerning the expected timing and outcome of this trial, including whether this trial will demonstrate proof-of-mechanism, statements concerning financial results, financial condition, and financial expectations including regarding a Small Business Innovation Research grant, achievement of related milestones and award of funds thereunder, statements concerning patent applications and the use of related technologies, and statements concerning TransCode's development programs and its 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: 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 financial condition and its need to obtain additional funding to support its business activities, including TransCode's ability to continue as a going concern; risks associated with TransCode's dependence on third parties; and risks associated with the COVID-19 coronavirus. 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 period ended December 31, 2021, 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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