TransCode Therapeutics Reports Second Quarter 2022 Results; Provides Business Update

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BOSTON, Aug. 15, 2022 (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 second quarter ended June 30, 2022, and recent business progress.

“We continued to advance our therapeutic programs during the second quarter,” said Michael Dudley, co-founder, president and CEO of TransCode. “We remain on track to submit an exploratory Investigational New Drug Application (eIND) this year for our planned Phase 0 clinical trial with TTX-MC138 in cancer patients with advanced solid tumors. In addition, we were granted orphan drug designation by the US Food and Drug Administration (FDA) for TTX-siPDL1 for pancreatic cancer, and we continued preclinical studies with our other therapeutic candidates in a variety of tumor indications. In May, we were awarded the second tranche of additional non-dilutive funding from our NIH grant. We believe that these funds, along with our existing cash, provide sufficient runway to carry us into the first quarter of 2023.”

“Subsequent to the quarter end, we announced a strategic alliance with MD Anderson Cancer Center to further advance our pipeline of RNA-targeted oncology therapeutic and diagnostic candidates. Under the alliance, scientists from both organizations will collaborate on preclinical studies and clinical trials seeking to further validate our pipeline candidates and expand the reach of our TTX discovery engine,” added Dudley.

TransCode co-founder and Chief Technology Officer, Dr. Zdravka Medarova, commented, “We believe our unique RNA delivery platform, TTX, has the potential to enable the development of a wide array of safe and effective RNA therapeutics for cancer by addressing the challenge of delivery to tumor cells anywhere in the body. We seek to demonstrate TTX’s ability to reach metastatic lesions in cancer patients in our planned Phase 0 clinical trial. We believe the trial has the potential to establish proof of delivery for our TTX platform, which ultimately could help enable us to build a broad and diverse pipeline of therapeutics and diagnostics to reach previously undruggable genetic targets.”

Recent Business Highlights

- In June 2022, the FDA granted our request for orphan drug designation (ODD) for TTX-siPDL1 for the treatment of pancreatic cancer. ODD status for TTX-siPDL1 provides several potential benefits including seven years of marketing exclusivity if the designated candidate receives FDA marketing approval, tax credits for qualified R&D expenses, and an exemption from payment of the Prescription Drug User Fee Amendment (PDUFA) filing fee, a savings estimated to be more than $3 million.
- In May 2022, received notice of the availability of the second tranche of funding from a Fast-Track Small Business Innovation Research (SBIR) grant we were awarded by the National Cancer Institute of the NIH (Award Number R44CA257093). The SBIR award, totaling $2.3 million, supports the continued clinical evaluation of TTX-MC138. The Company achieved the first milestone related to the SBIR grant during the first quarter of 2022.
- In May 2022, acquired an option giving TransCode the right to negotiate an exclusive, worldwide, royalty-bearing license related to a radiotheranostic technology disclosed in patent application PCT/US2021/057912 entitled THERAPEUTIC, RADIOLABLED NANOPARTICLES AND METHODS OF USE THEREOF. Invented by Dr. Medarova and colleagues at Massachusetts General Hospital, the technology represents another potential advancement in the diagnosis and treatment of cancer. The use of radioisotopes is expected to enable further advancement of our pipeline of RNA therapeutics by expanding their scope to include theranostic applications.

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 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 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.
  - Further progress toward completion of IND-enabling studies to support filing an IND application for a Phase I clinical trial of TTX-MC138.
- Completion of preclinical *in vivo* studies supporting the lead therapeutic candidate, TTX-MC138, in pancreatic cancer and glioblastoma multiforme.
- Completion of preclinical *in vivo* studies supporting therapeutic candidates, TTX-RIGA, TTX-siPDL1 and TTX-siLIN28B.
- Continuation of discussions regarding potential partnerships.

- File for orphan drug designation for TTX-MC138 in additional tumor indications.

Second Quarter 2022 Financial Highlights

- Cash was $13.4 million at June 30, 2022, compared to $20.8 million at December 31, 2021.
- Research and development expense was $2.6 million in the second quarter of 2022, compared to $0.2 million in the second quarter of 2021.
- General and administrative expense was $2.1 million in the second quarter of 2022, compared to $0.1 million in the second quarter of 2021.
- Operating loss for the three months ended June 30, 2022, was $4.7 million, compared to an operating loss of $0.4 million in the prior year period.

Financial Guidance

TransCode expects that its cash of $13.4 million as of June 30, 2022, is 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 more effectively treated 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 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 orphan drug designation and the possible benefits therefrom, statements concerning preclinical studies and the outcomes of those studies, statements concerning our financial condition, financial results, and financial expectations including regarding a Small Business Innovation Research grant, achievement of related milestones and the award of funds thereunder, statements concerning the strategic alliance with MD Anderson Cancer Center and the results that may arise therefrom, statements concerning TransCode's development programs and its TTX technology platform generally, and statements concerning patents and patent applications and the use of related technologies. 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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