TransCode Therapeutics Announces First Patients Treated in Phase 1 Clinical Trial with First-in-Class Lead Therapeutic Candidate

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- Two patients dosed; several additional patients screened for enrollment
- Trial to evaluate safety and tolerability of TTX-MC138 in patients with metastatic cancer
- TTX-MC138 is an antisense oligonucleotide conjugated to TransCode's proprietary TTX delivery system designed to inhibit microRNA-10b, a known driver of metastasis in multiple cancers
- Phase 1 clinical trial follows evidence of delivery and pharmacodynamic activity in prior first-in-human Phase 0 clinical trial with radiolabeled TTX-MC138

BOSTON, Sept. 17, 2024 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today announced dosing of the first two patients in its Phase 1 clinical trial with its lead candidate, TTX-MC138. Several additional patients have been screened for enrollment in the trial, a multicenter, open-label, dose-escalation and dose-expansion study of TTX-MC138.

"We are thrilled to announce the first two patients were administered TTX-MC138 in our Phase 1 clinical trial. This is a significant milestone for the TTX-MC138 clinical development program with our novel approach to treating metastatic cancers," commented Sue Duggan, Senior Vice President of Operations, at TransCode. Duggan added, "TTX-MC138 is a first-in-class therapeutic candidate that showed evidence of delivery to metastatic lesions in our Phase 0 clinical trial."

TransCode believes that TTX-MC138 is the first therapeutic candidate in clinical development designed to specifically target a molecule responsible for metastatic disease across multiple indications and irrespective of the site of metastasis. It has the potential to positively affect patient outcomes in a range of cancers, including breast, pancreatic, ovarian, colon, lung and others. Successful clinical development of TTX-MC138 could represent a breakthrough approach to effectively treating patients with metastatic cancer.

About the Trial
The Phase 1 clinical trial is a multicenter, open-label, dose-escalation and dose-expansion study, designed to generate critical data to support evaluation of the safety and tolerability of TTX-MC138 in patients with a variety of metastatic solid cancers. While not an endpoint, the trial may provide early evidence of clinical activity of TTX-MC138. The trial comprises an initial dose-escalation phase followed by a dose-expansion phase. The primary objective of the dose-escalation phase is to evaluate the safety and tolerability of escalating dose levels of TTX-MC138. In the dose-expansion phase, the safety, tolerability and anti-tumor activity of TTX-MC138 will be further evaluated in certain tumor types selected based on preliminary results from the dose-escalation phase.

Further information is available at www.clinicaltrials.gov NCT Identifier: (NCT06260774).

About TransCode Therapeutics
TransCode is a clinical-stage oncology company focused on treating metastatic disease. The company is committed to defeating cancer through the intelligent design and effective delivery of RNA therapeutics based on its proprietary TTX nanoparticle platform. The company's lead therapeutic candidate, TTX-MC138, is focused on treating metastatic tumors which overexpress microRNA-10b, a unique, well-documented biomarker of metastasis. In addition, TransCode is developing a portfolio of other first-in-class RNA therapeutic candidates designed to overcome the challenges of RNA delivery and thus unlock therapeutic access to a variety of novel genetic targets that could be relevant to treating a variety of cancers.

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 therapeutic potential of TransCode's TTX-MC138 and the timing, conduct and results of the planned Phase 1 clinical trial. 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 clinical trials will not be consistent with TransCode's pre-clinical studies or expectations or with results from previous clinical trials; risks associated with the conduct of clinical trials; risks associated with the timing and outcome of TransCode's planned regulatory submissions; 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; risks 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 geopolitical events and pandemics, including 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 year ended December 31, 2023, 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 this release; TransCode undertakes no duty to update this information unless required by law.

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