TRANSCODE

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TransCode Therapeutics Announces Phase 1 Clinical Trial Initiation

August 15, 2024

- Two clinical trial sites activated
- Patient enrollment expected this quarter
- Trial designed to evaluate the safety and preliminary anti-tumor activity of TTX-MC138

BOSTON, Aug. 15, 2024 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today announced initiation of its Phase 1 multicenter, open-label, clinical study of its lead therapeutic candidate, TTX-MC138.

Two clinical trial sites have been activated with patient enrollment expected to begin during the current quarter. TransCode may activate a total of up to five clinical trial sites, all of which are expected to be activated this quarter.

The Phase 1 clinical trial is designed to generate critical data to support evaluation of the safety of TTX-MC138 in patients with a variety of metastatic solid cancer. It may provide early evidence of TTX-MC138 clinical activity. 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.

"We are thrilled to have garnered such high interest in TTX-MC138 from eminent oncologists working in some of the most respected clinical trial sites in the country," commented Sue Duggan, Senior Vice President, Operations, at TransCode. "Advancing breakthrough RNA therapeutics science in the clinic is our primary goal as a biotechnology company at the cusp of innovative technology," added Duggan.

Active and recruiting sites can be found at: https://clinicaltrials.gov/study/NCT06260774?spons=transcode&rank=1

About TransCode Therapeutics

TransCode Therapeutics 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 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 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 our clinical trials will not be consistent with our pre-clinical studies or expectations or with previous clinical trials; risks associated with the timing and outcome of TransCode's planned regulatory submissions; risks associated with TransCode's conduct of clinical trials; 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 the release; TransCode undertakes no duty to update this information unless required by law.

For more information, please contact:

TransCode Therapeutics, Inc. Tania Montgomery-Hammon, VP of Business Development tania.montgomery@transcodetherapeutics.com