TransCode Therapeutics Announces FDA Clearance To Initiate Phase 1/2 Clinical Trial with TTX-MC138 in Patients with Advanced Solid Tumors

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Clinical trial expected to commence in mid-2024 to evaluate the safety and preliminary anti-tumor activity of TTX-MC138

BOSTON, April 15, 2024 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has completed its review of the company's Investigational New Drug (IND) application and concluded that the company may proceed with its Phase 1/2 multicenter, open-label, dose-escalation and dose-expansion study of its lead therapeutic candidate, TTX-MC138, in patients with advanced solid tumors.

"We are thrilled to have obtained FDA authorization to advance TTX-MC138 into the clinic. FDA's clearance of our IND application represents a significant milestone for our company," commented Sue Duggan, Senior Vice President, Operations, at TransCode. "Activation of the IND opens the door for continued development of TTX-MC138 in the clinical setting. The Phase 1/2 clinical trial is designed to generate critical data to support evaluation of the safety of TTX-MC138 and may provide early evidence of its clinical activity in patients with metastatic disease."

The Phase 1/2 clinical trial includes an initial dose-escalation phase followed by a dose-expansion phase. The dose-escalation portion of the trial is designed to include patients with a variety of metastatic solid cancers. The primary objective of this phase is to evaluate the safety and tolerability of escalating dose levels of TTX-MC138. In the dose-expansion phase, certain tumor types will be evaluated based on preliminary results from the dose-escalation phase. The primary objective of the dose-expansion phase is to further evaluate safety as well as tolerability and anti-tumor activity of TTX-MC138 in cancer patients.

The company believes that TTX-MC138 has the potential to positively affect patient outcomes in a range of cancers, including breast, pancreatic, ovarian, colon, glioblastomas and others. In multiple animal models of cancer, treatment with TTX-MC138 led to statistically significant reductions of metastatic burden and longer animal survival relative to animals given control treatments. Successful clinical development of TTX-MC138 potentially represents a novel solution for patients with metastatic cancer.

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 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 1/2 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.

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