BridgeBio Oncology Therapeutics (BBOT) Granted U.S. FDA Fast Track Designation for BBO-8520 for KRASG12C-Mutated Metastatic Non-Small Cell Lung Cancer

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The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BBO-8520 for the treatment of adult patients with previously treated, KRAS^{G12C}-mutated metastatic non-small cell lung cancer (NSCLC)

BBO-8520 is currently being evaluated in the ONKORAS-101 trial, a Phase 1 study for patients with KRAS^{G12C} mutant NSCLC

SOUTH SAN FRANCISCO, Calif. January 9, 2024 –(BUSINESS WIRE)-TheRas, Inc. d/b/a BridgeBio Oncology Therapeutics ("BBOT" or the "Company"), a clinical-stage biopharmaceutical company focused on RAS-pathway malignancies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BBO-8520, an investigational oral therapy for the treatment of adult patients with previously treated, KRAS^{G12C}-mutated metastatic non-small cell lung cancer (NSCLC).

BBO-8520 is designed to inhibit the "ON and OFF" state to provide optimal target coverage and to address KRAS^{G12C} amplification and receptor tyrosine kinase activation – the two key mechanisms of adaptive resistance to current "OFF" state inhibitors. It drives substantial tumor growth inhibition in multiple preclinical models, even after emergence of resistance to sotorasib, an FDA approved "OFF" state inhibitor of KRAS ^{G12C}.[i] The discovery of BBO-8520 was the result of a collaboration between the National Cancer Institute RAS Initiative at Frederick National Laboratory for Cancer Research, Lawrence Livermore National Laboratory, and BBOT.

"Receiving Fast Track designation for BBO-8520 is a significant milestone in our efforts to overcome the limitations of existing therapies for KRAS^{G12C}-mutant cancers," said Yong Ben, MD, Chief Medical and Development Officer of BBOT. "BBO-8520 represents a first-in-class approach with potential to address high unmet medical needs and shift the paradigm for cancer treatment. We will continue to work closely with the FDA to expedite the development of BBO-8520, which is currently being evaluated in a Phase 1 study (NCT06343402) of KRAS^{G12C} NSCLC patients pre-treated with first generation KRAS^{G12C} "OFF" inhibitors or with no prior KRAS^{G12C} targeted therapy experience."

Fast Track designation is intended to help rapidly advance the development and review process for promising therapeutic candidates for serious conditions that may fill an unmet medical need.

About TheRas, Inc. d/b/a BridgeBio Oncology Therapeutics (BBOT)

BridgeBio Oncology Therapeutics (BBOT) is a clinical-stage biopharmaceutical company advancing a next generation pipeline of novel small molecule therapeutics targeting RAS and PI3K malignancies. Initially formed as a subsidiary of BridgeBio, BBOT completed a $200M private financing with external investors in 2024 with the goal of improving outcomes for patients with cancers driven by the two most prevalent oncogenes in human tumors. For more information visit bbotx.com.

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[i] Maciag et al., Cancer Discovery. 2024