BBOT Granted U.S. FDA Fast Track Designation for BBO-11818 for the Treatment of Adult Patients with Advanced KRAS-Mutant Pancreatic Ductal Adenocarcinoma

April 20, 2026

BBO-11818 is currently being evaluated in the Phase 1 KONQUER-101 trial in subjects with locally advanced unresectable or metastatic KRAS-mutant solid tumors

Updated Phase 1 clinical data are expected in the second half of 2026

SOUTH SAN FRANCISCO, Calif., April 20, 2026 (GLOBE NEWSWIRE) -- BridgeBio Oncology Therapeutics, Inc. (“BBOT”) (Nasdaq: BBOT), 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-11818 for the treatment of adult patients with advanced KRAS-mutant pancreatic ductal adenocarcinoma.

"Receiving Fast Track designation from the FDA for BBO-11818 in KRAS-mutant pancreatic ductal adenocarcinoma reflects the importance and urgency of accelerating the development of our pan-KRAS inhibitor in this serious disease," said Yong Ben, MD, Chief Medical and Development Officer of BBOT. "Pancreatic cancer remains one of the most difficult-to-treat malignancies. KRAS mutations are present in the vast majority of cases, yet patients have had few targeted options. This designation will help us collaborate closely with the FDA to advance BBO-11818 as efficiently as possible for patients who need new options."

This designation follows preliminary data, first released in January 2026, in which BBO-11818 monotherapy demonstrated a confirmed partial response in pancreatic cancer. In addition, anti-tumor activity was observed across dose levels and tumor types with tumor reductions at higher dose levels with a generally favorable, differentiated safety profile in dose escalation.

While $KRAS^{G12C}$ inhibitors have demonstrated promising clinical efficacy, there remains a clear unmet medical need for therapies targeting cancers that carry other KRAS mutations, such as $KRAS^{G12D}$ and $KRAS^{G12V}$. BBO-11818 was developed to address this gap and is specifically designed as a potent pan-KRAS inhibitor with strong binding affinity for KRAS, high selectivity over HRAS and NRAS, and the ability to achieve high levels of KRAS inhibition in both the ON and OFF states. BBO-11818 is being evaluated as monotherapy, in combination with standard-of-care therapies, or alongside BBOT’s RAS:PI3Kα breaker, BBO-10203.

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 BBO-11818
BBO-11818 is a selective, orally bioavailable non-covalent inhibitor that targets KRAS in both the ON and OFF states, has high selectivity over HRAS and NRAS, and displays strong activity in KRAS-mutant preclinical models, including $KRAS^{G12D}$ and $KRAS^{G12V}$. In addition, it potently suppresses MAPK signaling and inhibits cell proliferation in KRAS-mutant cell lines. BBO-11818 is currently being evaluated in the Phase 1 KONQUER-101 trial in subjects with locally advanced unresectable or metastatic KRAS-mutant solid tumors.

About BBOT
BBOT is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small molecule therapeutics targeting RAS and PI3Kα malignancies. BBOT has the goal of improving outcomes for patients with cancers driven by the two most prevalent oncogenes in human tumors. For more information, please visit www.bbotx.com and follow us on LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements in this press release that are not historical facts may be deemed forward-looking statements, which generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends. These statements are based on various assumptions, whether or not identified in this press release, and are the current expectations of BBOT’s management and are not predictions of actual performance. Many actual events and circumstances are beyond the control of BBOT. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to the timing of expected regulatory and business milestones, including interactions with regulatory authorities, the progress of enrollment in clinical trials and availability of data from ongoing and planned clinical trials; and those factors discussed in documents BBOT has filed or will file with the U.S. Securities and Exchange Commission.

In addition, forward-looking statements reflect BBOT's expectations, plans, or forecasts of future events and views as of the date of this press release and are qualified in their entirety by reference to the cautionary statements herein. BBOT anticipates that subsequent events and developments will cause BBOT's assessments to change. These forward-looking statements should not be relied upon as any guarantee, assurance, prediction or definitive statement of fact or probability or as representing BBOT's assessments as of any date subsequent to the date of this press release. Neither BBOT, nor any of its affiliates undertake any obligation to update these forward-looking statements, except as required by law.

BBOT Contacts:

Investor Contact:
Heather Armstrong, Head of Investor Relations
BBOT
Investors@BBOTx.com

Media Contact:
Jake Robison
Inizio Evoke Comms
Jake.robison@inizioevoke.com