BBOT Announces New BBO-8520 Data; Highlights Strategic Focus on 2L+ NSCLC BBO-8520 Combination as Well as BBO-11818 and BBO-10203 Combinations in KRAS-Mutant Cancers

September 8, 2026

- *BBO-8520 plus pembrolizumab demonstrated a 75% ORR at 500 mg QD and 53% ORR across dose levels in 2L+ KRAS^{G12C} inhibitor-experienced NSCLC patients*
- *BBO-8520 monotherapy continues to show highly competitive ORR in the 2L+ KRAS^{G12C} inhibitor-naïve NSCLC with ORR of 63% (26/41), disease control rate (DCR) of 100% (41/41) and no grade 3 liver enzyme elevations*
- *BBO-11818 and BBO-10203 combination cohorts enrolling in KRAS-mutant CRC and PDAC*
- *$344.1 million in cash, cash equivalents and marketable securities as of June 30, 2026, provides runway into 2028*

SOUTH SAN FRANCISCO, Calif., Sept. 08, 2026 (GLOBE NEWSWIRE) -- BridgeBio Oncology Therapeutics, Inc. (“BBOT”) (Nasdaq: BBOT), a clinical-stage biopharmaceutical company focused on RAS-pathway malignancies, today announced new clinical data for KRAS^{G12C} inhibitor BBO-8520 and the strategic prioritization of (i) BBO-8520 in combination with checkpoint inhibitor in 2L+ KRAS^{G12C} inhibitor-experienced non-small cell lung cancer (NSCLC) patients and (ii) BBO-11818 and BBO-10203 combinations in KRAS-mutant cancers.

“Across our portfolio, all three programs have now generated encouraging clinical data supporting further development, enabling us to focus our capital on the opportunities with the highest probability of success, clearest development paths, and greatest potential patient benefit,” said Pedro J. Beltran, Ph.D., Chief Executive Officer of BBOT. “With a strong balance sheet and multiple data catalysts through mid-2027, we believe BBOT is well positioned to advance differentiated therapies for patients with KRAS-driven cancers.”

BBO-8520 (Direct KRAS^{G12C} ON/OFF Inhibitor) Key Findings:

BBO-8520 is an oral, direct KRAS^{G12C}(ON/OFF) inhibitor. By directly inhibiting both the ON and OFF states of KRAS^{G12C}, BBO-8520 is designed to achieve potent pathway inhibition at lower free-drug exposures and enable combination with checkpoint inhibition. In the ongoing ONKORAS-101 (**NCT06343402**) Phase 1 study (data cutoff: June 1, 2026):

BBO-8520 in combination with pembrolizumab in NSCLC KRAS^{G12C} inhibitor-experienced patients showed:

- Objective response rate (ORR): 75% at the 500 mg once-daily (QD) dose level and 53% across all dose levels (N=17).
- Generally tolerable and manageable safety profile. Adverse events were primarily gastrointestinal (GI)-related, and a favorable liver safety profile was observed.

BBO-8520 monotherapy in 2L+ NSCLC KRAS^{G12C} inhibitor-naïve patients showed:

- ORR: 63% (26/41), with a disease control rate (DCR) of 100% (41/41).
- Among 28 patients eligible for a six-month follow-up, 75% (21/28) remained on treatment beyond six months.
- Tolerable and manageable safety profile with no grade 3 liver enzyme elevations.

“The encouraging efficacy and safety profile with BBO-8520 plus pembrolizumab supports development in patients with KRAS^{G12C}-mutant NSCLC who have progressed on a prior G12C inhibitor, a growing population with significant unmet need,” said Yong (Ben) Ben, M.D., Chief Medical and Development Officer of BBOT.

Approximately 21,000 patients are expected to be diagnosed with NSCLC harboring KRAS ^{G12C} mutations in the United States in 2026. As G12C OFF-state inhibitors potentially move into the first-line setting, BBOT expects a growing population of patients who progress following treatment with a G12C inhibitor and for whom there is currently no approved targeted therapy.

Strategic Prioritization:

BBOT is focusing its capital and resources on opportunities that offer the highest probability of success and greatest potential benefit for patients:

- BBO-8520 in combination with pembrolizumab in 2L+, $KRAS^{G12C}$ inhibitor-experienced NSCLC patients.
- BBO-11818 and BBO-10203 internal combination and independent combinations with standard of care agents in KRAS-mutant cancers.

Financial Position and Upcoming Milestones

As of June 30, 2026, BBOT had approximately $344.1 million in cash, cash equivalents and marketable securities which BBOT projects will fund operations into 2028. BBOT expects the following data catalysts over the next 12 months:

- BBO-11818 and BBO-10203 monotherapy data update in the fourth quarter of 2026.
- Expanded BBO-8520 plus pembrolizumab dataset in 2L+ $KRAS^{G12C}$ inhibitor-experienced NSCLC expected in mid-2027.
- Data from BBO-11818 and BBO-10203 internal and standard-of-care combination cohorts in colorectal cancer (CRC) and pancreatic ductal adenocarcinoma (PDAC) expected in mid-2027.

About BBOT

BBOT is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of RAS-targeting small molecules. BBOT has the goal of employing novel therapeutic approaches to improve outcomes for patients with KRAS-driven cancers. For more information, please visit http://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 forward-looking statements include, without limitation, statements regarding the clinical and therapeutic potential and safety profile of BBOT’s product candidates, including BBO-8520, BBO-10203 and BBO-11818, as monotherapy or in combination with other therapeutics, the design and conduct of clinical trials with BBOT’s product candidates, including expected timelines for clinical data readouts, ongoing and planned regulatory interactions, BBOT’s plans to continue and expand its clinical trials, including its planned internal combination studies, the market opportunities and competitive landscape for BBOT’s product candidates, and BBOT's beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, including statements regarding anticipated operating expenses, BBOT’s projected cash runway and sufficiency of its cash, cash equivalents and marketable securities to fund its operations.

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 initial and interim data from BBOT’s clinical trials not being indicative or final data; the design, success and timing of ongoing and planned clinical trials; adverse events that may be encountered in BBOT’s clinical trials; risks relating to the uncertainty of the projected financial information with respect to BBOT; risks related to the regulatory review and potential approval of BBOT’s product candidates and the timing of expected regulatory and business milestones, including the progress of enrollment in clinical trials and availability of data from ongoing and planned clinical trials; the impact of competitive product candidates and commercial products; ability to obtain sufficient supply of materials; BBOT’s ability to maintain its existing agreements with third parties and to negotiate and enter into new definitive agreements on favorable terms, if at all; intellectual property-related claims; global economic and political conditions; changes in domestic and foreign business, market, financial, political, and legal conditions; and those other risks and uncertainties factors are described more fully in the “Risk Factors” section of BBOT’s most recent filings with the Securities and Exchange Commission and available at www.sec.gov.

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 its affiliates undertake any obligation to update these forward-looking statements, except as required by law.

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