Black Diamond Therapeutics Announces Preliminary Phase 2 Data for Silevertinib in 1L NSCLC and Plans for a Phase 2 Trial of Silevertinib in GBM

December 03, 2025

- *Silevertinib delivers robust anti-tumor activity as demonstrated by an ORR of 60% and a CNS response rate of 86% in 43 1L NSCLC patients presenting with 35 different non-classical EGFR mutations; no new safety signals observed to date*
- *PFS data for 1L NSCLC patients expected in Q2 2026; Company continues to explore partnership opportunities for pivotal development of silevertinib*
- *Based on encouraging CNS activity of silevertinib in multiple trials across NSCLC and GBM, Company plans to initiate a randomized Phase 2 trial of silevertinib in newly diagnosed GBM patients in 1H 2026; initial data anticipated in 2028*
- *Cash, cash equivalents, and investments of $135.5 million as of September 30, 2025; expected to be sufficient to fund operations into 2H of 2028*
- *Company to host an investor webcast and conference call today at 8:00 AM ET*

CAMBRIDGE, Mass., Dec. 03, 2025 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with cancer, today announced topline data from its Phase 2 trial of silevertinib in frontline (1L) non-small cell lung cancer (NSCLC) patients with non-classical epidermal growth factor receptor (EGFR) mutations (NCMs) and outlined plans for a randomized Phase 2 trial of silevertinib in patients with newly diagnosed glioblastoma (ND GBM).

“We are pleased to share these initial data in frontline NSCLC patients showing silevertinib’s activity against a broad spectrum of 35 distinct non-classical EGFR mutations,” said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We are particularly encouraged by the CNS activity of silevertinib in treating NSCLC patients with brain metastases, as published data clearly demonstrate that CNS metastases are a key factor in early disease progression for NCM NSCLC patients treated with second- and third-generation EGFR-TKIs. We also believe that silevertinib is uniquely positioned as a potential treatment for patients with newly diagnosed EGFR-altered GBM, and plan to initiate a randomized Phase 2 trial in the first half of 2026, while PFS data matures in our Phase 2 NSCLC study and we continue our partnering discussions.”

Silevertinib Phase 2 1L NSCLC Initial Clinical Results and Program Update

43 frontline NSCLC patients harboring a broad spectrum of 35 distinct non-classical EGFR mutations were enrolled, including 16 patients with brain metastases (7 of whom had measurable CNS target lesions). All patients were enrolled at a 200mg oral daily dose of silevertinib. Efficacy and safety were assessed with a November 3, 2025 data cutoff; median follow-up time as of this date was 7.2 months and the study remains ongoing.

Key data highlights include:

For the 43 patients enrolled, preliminary efficacy data is as follows:

- 25 confirmed partial responses, 1 confirmed complete response
- 60% Objective Response Rate (ORR by RECIST 1.1)
- 86% CNS ORR (by RANO-BM)
- 91% disease control rate (DCR)

Initial duration of treatment data:

- 29 patients remain on therapy (5/29 after progression), longest ongoing for >19 months

Summary of safety data:

- No new safety signals observed
- Adverse events (AEs) experienced by a majority of patients include rash, stomatitis, diarrhea and paronychia
- AEs were managed with standard supportive care and dose interruptions/reductions without compromising response depth or durability to date

The Company expects to present updated results from the Phase 2 NSCLC trial, including Duration of Response (DOR) and Progression-free Survival

(PFS) data in both the recurrent (83 patients) and frontline (43 patients) settings, at a medical meeting in the second quarter of 2026. Black Diamond continues to explore potential partnerships to advance silevertinib into pivotal development.

“These highly encouraging data speak to the potential of silevertinib to be the treatment of choice for frontline NSCLC patients with the full spectrum of non-classical EGFR mutations” said Sergey Yurasov, M.D., Ph.D., Black Diamond’s Chief Medical Officer. “We are struck by the compelling CNS response rate, which may translate to prolonged durability of response for patients with CNS metastases. Based on these data, and promising Phase 0/1 and Phase 1 GBM results, we are preparing to initiate a randomized Phase 2 trial of silevertinib in newly diagnosed GBM patients, one of the highest unmet needs in oncology.”

GBM Program Update and Phase 2 Plans
Approximately 50% of patients with glioblastoma (GBM) present with an oncogenic EGFR alteration that can be targeted by silevertinib; each year approximately 7,000 patients in the U.S. are diagnosed with GBM harboring these EGFR alterations.

“Prior attempts to treat EGFR-altered GBM patients have been limited by poor brain penetrance of targeted therapies and/or lack of potency of these therapies on the full spectrum of EGFR alterations” said Elizabeth Buck, Ph.D., Chief Scientific Officer of Black Diamond. “Based on encouraging CNS activity demonstrated by silevertinib across multiple trials, and its preclinical potency on all EGFR alterations found in GBM, we believe that silevertinib has the potential to be the first targeted therapy for these patients.”

Black Diamond plans to initiate a randomized Phase 2 trial in newly diagnosed GBM patients in the first half of 2026, with preliminary data expected in 2028.

Key trial highlights include:

- Expected to enroll approximately 150 newly diagnosed patients, randomized to receive TMZ (control arm) or silevertinib + TMZ (experimental arm)
- Initial focus will be on EGFRvIII-positive patients (approximately 30% of GBM) who are MGMT-negative (unmethylated)
- Randomization and treatment will begin after patients have had their surgical resection and radiation
- Primary endpoint is PFS (RANO by Blinded Independent Committee Review), with an interim analysis; secondary endpoint is overall survival (OS)
- Trial will be governed by an Independent Data Monitoring Committee (IDMC)

Updated Financial Guidance

- Black Diamond previously reported cash, cash equivalents and investments of approximately $135.5 million as of September 30, 2025, which the Company now believes is sufficient to fund its anticipated operating expenses and capital expenditure requirements into the second half of 2028.
- Financial guidance assumes Black Diamond funds the Phase 2 trial of silevertinib in ND GBM and a potential partner funds pivotal development in NSCLC. Financial guidance does not assume receipt of potential development milestones from the Company’s partnership with Servier Pharmaceuticals LLC for BDTX-4933 (now S241656).

Conference Call Information

Black Diamond will host a conference call and webcast on Wednesday, December 3, 2025, at 8:00 AM ET to discuss the preliminary Phase 2 data for silevertinib in 1L NSCLC and plans for a Phase 2 trial of silevertinib in GBM. The webcast may be accessed online here or by visiting the Events page in the Investors section of the Company’s website at www.blackdiamondtherapeutics.com.

A replay of the webcast will be available for 30 days on the Investors section of Black Diamond’s website.

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with cancer. The Company’s MasterKey therapies are designed to address a broad spectrum of genetically defined tumors, overcome resistance, minimize wild-type mediated toxicities, and be brain penetrant to treat central nervous system disease. The Company is advancing silevertinib, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR-mutant NSCLC and GBM. For more information, please visit www.blackdiamondtherapeutics.com.

From time to time, we may use our website or our LinkedIn profile at www.linkedin.com/company/black-diamond-therapeutics to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.blackdiamondtherapeutics.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this press release.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the continued development and advancement of silevertinib, including the ongoing Phase 2 clinical trial and the timing of clinical updates for silevertinib in patients with NSCLC and in patients with GBM, enrollment in the investigator sponsored Phase 0/1 clinical trial of silevertinib of newly diagnosed GBM patients with EGFR alterations, the expected timing for regulatory feedback and the disclosure of a potential registrational pathway for silevertinib in

NSCLC, the potential of silevertinib to address the unmet medical need for newly diagnosed NSCLC patients with non-classical EGFR mutations and benefit patients with NSCLC across multiple lines of therapy, the potential future development plans for silevertinib in NSCLC and GBM, a potential partnership for silevertinib, and the Company's expected cash runway. 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. Risks that contribute to the uncertain nature of the forward-looking statements include those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2024, filed with the United States Securities and Exchange Commission and in its subsequent filings filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contact

For Investors:
investors@bdtx.com
For Media:
media@bdtx.com