Black Diamond Therapeutics Announces Positive Phase 2 Results for Silevertinib in Frontline NSCLC Patients with EGFR Non-Classical Mutations

May 21, 2026

- *Preliminary mPFS of 15.2 months; mDOR not reached*
- *Robust CNS activity, with 86% CNS ORR; no patients developed de novo brain metastases*
- *ORR 60% in patients with a broad spectrum of EGFR-NCMs, including PACC*
- *Dose dependent and manageable AE profile, no new safety signals observed*
- *Webcast on Thursday, May 21, 2026 at 5:30 pm EDT*

CAMBRIDGE, Mass., May 21, 2026 (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 positive results from its Phase 2 trial of silevertinib in frontline (1L) non-small cell lung cancer (NSCLC) patients with epidermal growth factor receptor (EGFR) non-classical mutations (NCMs). These data will be presented by Julia Rotow, M.D., Clinical Director, Lowe Center for Thoracic Oncology at the Dana-Farber Cancer Institute, at the 2026 American Society of Clinical Oncology® (ASCO®) Annual Meeting on Saturday, May 30, 2026, 1:15 PM-2:45 PM CDT.

“Silevertinib continues to demonstrate potential to become a practice changing frontline therapy for NSCLC patients with EGFR-NCMs, delivering robust preliminary mPFS that far exceeds historical data for currently available therapies” said Sergey Yurasov, M.D., Ph.D., Chief Medical Officer of Black Diamond Therapeutics. “Importantly, silevertinib prevented the development of *de novo* brain metastases in this patient population, where progression via CNS metastases frequently occurs. We look forward to meeting with the FDA later this year to discuss our pivotal development plan.”

“Patients with EGFR non-classical mutations represent a meaningful and underserved subset of NSCLC, with historically poor progression-free survival on available frontline TKIs,” added Dr. Rotow. “The activity we are seeing with silevertinib across the full NCM spectrum, combined with its CNS activity, is highly encouraging, and I look forward to sharing these data with the oncology community at ASCO next week.”

Silevertinib 1L NSCLC Phase 2 Results Summary

Results as of an April 11, 2026 data cutoff date include:

- 43 patients with 1L NSCLC were enrolled at a 200 mg once daily dose of silevertinib
  - Patients presented with a broad spectrum of EGFR-NCMs, including compound and P-Loop and C-Helix Compressing (PACC) mutations
  - 19 patients with brain metastases, 7 of whom had measurable central nervous system (CNS) target lesions
  - 11.2 months median follow-up
- Durability
  - Preliminary median Progression-free Survival (mPFS) is 15.2 months (95% CI: 10.8; NE)
  - Median duration of response (DOR) had not been reached (95%CI: 7.0, NE)
  - 23 of 43 patients (53%) remain on therapy, with longest at 23.5 months
- CNS Activity
  - No patients developed *de novo* brain metastases
  - Previously disclosed CNS Objective Response Rate (ORR by RANO-BM) remained at 86%
- ORR and DCR
  - Previously disclosed Objective Response Rate (ORR by RECIST 1.1) and Disease Control Rate (DCR) remained at 60% and 91%, respectively

- Variant allele frequency (VAF) reduction observed in all evaluable patients across 25 unique EGFR-NCMs, including PACC

- Safety
  - No new safety signals were observed
  - The rate of TRAEs ≥ Grade 3 was reduced to 28% following dose reduction
  - Patients maintained or deepened clinical responses after dose reduction
  - Safety and efficacy data support 150 mg QD for pivotal development

ASCO Abstract: 8519
Title: Safety and efficacy results of the phase 2 study of silevertinib (BDTX-1535) in treatment-naïve patients with non-small cell lung cancer with non-classical EGFR mutations
Presenter: Julia Rotow, M.D., Clinical Director, Lowe Center for Thoracic Oncology at Dana-Farber Cancer Institute
Date and Time: May 30, 2026, 1:15 PM-2:45 PM CDT (slides will be available at the time of the presentation on the Black Diamond website)

Company Webcast Information
Black Diamond will hold a webcast for investors on Thursday, May 21, 2026 at 5:30 p.m. EDT. The webcast can be accessed under “Events and Presentations” on the Investors section of the Black Diamond website at www.blackdiamondtherapeutics.com.

About Silevertinib

Silevertinib is an investigational oral, covalent, brain-penetrant fourth-generation tyrosine kinase inhibitor (TKI) that selectively targets classical and more than 50 non-classical EGFR mutations in NSCLC. It is also designed to potently inhibit key EGFR alterations seen in GBM, including EGFRvIII, while avoiding the paradoxical EGFR activation reported with reversible TKIs. To date, over 200 patients with EGFR-mutant NSCLC or EGFR-altered GBM have been treated with silevertinib.

In addition to the ongoing Phase 2 trial of silevertinib in patients with EGFRm NSCLC, the Company also initiated a randomized Phase 2 trial of silevertinib in patients with newly diagnosed EGFRvIII-positive GBM (NCT07326566) in May 2026.

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, an investigational brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR-mutant NSCLC and GBM. For more information, please visit www.blackdiamondtherapeutics.com.

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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 trials and the timing of clinical updates for silevertinib in patients with NSCLC and in patients with GBM, the potential of silevertinib to address the unmet medical need for newly diagnosed GBM patients and 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, and the competitive landscape and market for silevertinib or any of the Company’s other current or future product candidates, including statements relating to the estimated percentage of newly diagnosed NSCLC patients with non-classical EGFR mutations and the potential addressable patient population. 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, 2025, 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.

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