Black Diamond Therapeutics Announces Positive Updated Silevertinib Phase 2 Results, FDA Feedback Supporting a Clear Path to Potential Registration in 1L EGFR-NCM NSCLC, and Provides Corporate Update

November 10, 2026

- *Updated Phase 2 results demonstrate robust CNS activity, including 86% CNS-ORR and mPFS double that of currently available EGFR TKIs, in patients with untreated brain metastases*
- *Recent End-of-Phase 2 meeting with the FDA supports pivotal development in all 1L EGFR-NCM NSCLC patients with potential for accelerated approval based on CNS-ORR*
- *Cash, cash equivalents, and investments of $102.0 million as of September 30, 2026, is expected to be sufficient to fund operations into the second half of 2028*
- *Company to host an investor call today at 7:30am ET and will also participate in a fireside chat at the Stifel 2026 Healthcare Conference at 3:20pm ET*

CAMBRIDGE, Mass., Nov. 10, 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, including silevertinib, a potential best-in-class brain-penetrant epidermal growth factor receptor (EGFR) inhibitor, today reported updated data from its Phase 2 trial of silevertinib in frontline non-small cell lung cancer (NSCLC) patients with EGFR non-classical mutations (NCMs), the outcome from its End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and associated Phase 3 plans, and financial results for the third quarter ended September 30, 2026.

“There remains significant unmet medical need in NSCLC patients with non-classical EGFR mutations, particularly in patients with brain metastases ,” said Alex Spira M.D., Ph.D., Director of the Thoracic and Phase I Program at Virginia Cancer Specialists and Chief Scientific Officer of NEXT Oncology, and clinical investigator on the silevertinib Phase 2 trial. “Along with the exciting CNS response rate and progression free survival data from this Phase 2 trial, it is remarkable that not a single frontline patient treated with silevertinib has developed de novo brain metastases.”

“Brain is the most common site of distant metastasis for patients with EGFR-mutant NSCLC”, added Sergey Yurasov, M.D., Ph.D., Chief Medical Officer of Black Diamond Therapeutics. “We believe that silevertinib’s ability to significantly delay CNS progression is the key driver of the durable clinical benefit we are seeing in patients both with and without baseline brain metastases and is the foundation of the pivotal program design in 1L NSCLC.”

“Our recent end of Phase 2 meeting with the FDA was highly collaborative, and we believe the feedback we received supports a clear path to potential accelerated and full approval for silevertinib in frontline NSCLC patients with EGFR non-classical mutations,” said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “This trial design offers a differentiated path to potential accelerated approval in EGFR-NCM patients, who represent about 25% of the frontline EGFR mutant patient population.”

Silevertinib Recent Developments and Upcoming Milestones:

- **Silevertinib 1L NSCLC Phase 2 Results Update:** As of an October 7, 2026 data cutoff date, with a median patient follow-up of 15.9 months, updated results from the Phase 2 trial (conducted in the U.S. and Canada) of silevertinib dosed at 200 mg once daily (QD) in 43 frontline NSCLC patients harboring a broad spectrum of EGFR NCMs, were as follows:
  - Intention to Treat (ITT) Population: n=43
    - 60% ORR (RECIST 1.1), 93% DCR, 15.0 month mPFS (95% confidence interval (CI): 11.0, 23.5)
    - 18 patients remained on therapy, with the longest at 26.2 months
    - No new safety signals were observed
  - Patients with untreated brain metastases: n=16 (7 evaluable by RANO-BM)
    - 86% CNS-ORR (RANO-BM)
    - 12.2 months systemic mPFS (95% CI: 8.1, not estimable (NE)) by RECIST 1.1
  - Patients without brain metastases: n= 24
    - 23.5 months mPFS (95% CI:11.0, NE)
    - No patients with progression in the brain
- Cohort 4 (n=20) of the Phase 2 trial is enrolling frontline patients with non-classical EGFRm NSCLC at the planned pivotal dose of 150 mg administered once daily; the first patient was dosed in the third quarter of 2026
- **Summary from End of Phase 2 FDA Meeting on October 1, 2026:**
  - Based on the FDA’s feedback, the Company intends to pursue a Phase 3 development program for silevertinib that will encompass all treatment-naïve patients with locally advanced or metastatic NSCLC whose tumors harbor an oncogenic EGFR mutation other than a classical mutation (ex19del, L858R) or exon 20 insertion.

- The FDA also provided feedback on a potential accelerated approval based on CNS-ORR per RANO-BM by blinded independent central review (BICR) and a potential full approval based on PFS per RECIST v1.1 by BICR.
- The FDA indicated that systemic ORR and overall survival (OS) will need to be evaluated to show systemic ORR similarity to, and no evidence of an OS detriment compared to, the control arm.
- The FDA acknowledged the Company's justification for 150 mg QD as the pivotal dose. Safety data from a sufficient number of patients treated at 150 mg QD in the ongoing Cohort 4 are required to be submitted to the FDA prior to opening the Phase 3 trial.

- **Phase 3 Trial Plan:** The Company is planning a global Phase 3 registrational trial of silevertinib in frontline NSCLC patients with EGFR-NCMs with the potential to initiate in the second quarter of 2027. This trial would enroll 300 patients with EGFR-NCMs and untreated brain metastases randomized 1:1 to receive silevertinib 150 mg once daily or physician's choice of osimertinib or afatinib. The primary endpoints are CNS-ORR (RANO-BM by BICR) for potential accelerated approval and systemic PFS (RECIST 1.1 by BICR) for potential full approval. The Phase 3 trial would also include an additional 80 patient single-arm cohort in frontline NSCLC patients with EGFR-NCMs without brain metastases, and a 20 patient single arm cohort in patients with leptomeningeal disease. Assuming a second quarter of 2027 initiation, preliminary data anticipated in 2028.
- **Phase 2 Trial in Newly Diagnosed GBM:** The randomized portion of the Phase 2 trial of silevertinib in patients with newly diagnosed EGFRvIII+ glioblastoma (GBM) is enrolling patients at 150 mg QD, with the first patient dosed in the fourth quarter of 2026. The primary endpoint is PFS (RANO-BM by BICR), with OS as a secondary endpoint. The 150 mg QD dose of silevertinib for the randomized portion of the study was selected based on 6 patients dosed at 150 mg QD in combination with temozolomide (TMZ) in the completed safety run-in portion of the trial, in which no dose-limiting toxicities were observed. Interim PFS data are expected in the first half of 2028 (NCT07326566).

Third Quarter Ended September 30, 2026 Financial Highlights

- **Cash Position:** Black Diamond ended the third quarter of 2026 with approximately $102.0 million in cash, cash equivalents, and investments compared to $128.7 million as of December 31, 2025. Net cash used in operations was $8.3 million for the third quarter of 2026 compared to net cash used in operations of $7.9 million for the third quarter of 2025.
- **Research and Development Expenses:** Research and development (R&D) expenses were $7.0 million for the third quarter of 2026, compared to $7.4 million for the same period in 2025. The decrease in R&D expenses was primarily due to the progression of our Phase 2 trial for silevertinib in NSCLC, partially offset by increased spend related to the start-up and conduct for the Phase 2 trial for silevertinib in GBM.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $5.1 million for the third quarter of 2026, compared to $3.5 million for the same period in 2025. The increase in G&A expenses was primarily due to an increase in IP-related costs and higher non-income tax expense.
- **Net Loss:** Net loss for the third quarter of 2026 was $10.0 million, as compared to a net loss of $8.5 million for the same period in 2025.

Financial Guidance

- Black Diamond ended the third quarter of 2026 with approximately $102.0 million in cash, cash equivalents, and investments. The Company believes that its existing cash, cash equivalents and investments, will be sufficient to fund its anticipated operating expenses and capital expenditure requirements into the second half of 2028.

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 EGFRm NSCLC or EGFR-altered GBM have been treated with silevertinib.

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

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.

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.

The silevertinib data described in this press release are from a single-arm Phase 2 clinical trial. No head-to-head trials have been conducted, and cross-trial comparisons are limited by differences in trial design, patient population, endpoints and dosing.

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 and data for silevertinib in patients with NSCLC and in patients with GBM; the Company’s planned Phase 3 clinical trial of silevertinib in frontline patients with non-classical EGFRm NSCLC, including its design, size, and the anticipated timing of initiation and data; the Company’s interpretation of feedback received from the FDA at the End of Phase 2 meeting, including the design, endpoints for potential accelerated approval and for full approval, and pivotal dose; the selection of a dose for pivotal development and the timing of submission of data to FDA from Cohort 4 prior to opening the Phase 3 trial; the planned compendia and adjuvant strategies and the potential for compendia listing; 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; the potential for silevertinib to be a best-in-class therapy; the competitive landscape and market for silevertinib or any of the Company's other current or future product candidates, including statements relating to the potential addressable patient population; the completion of the proposed Offering and the expected use of proceeds therefrom, including the sufficiency of such proceeds to fund the Phase 3 program through the CNS-ORR readout; 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 the risk that interim or preliminary clinical data may change as more patient data become available; the risk that feedback from the FDA is not binding and the FDA may change its views, disagree with the Company’s interpretation of such feedback or require additional data or trials; and those risks and uncertainties set forth in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, filed with the United States Securities and Exchange Commission (the “SEC”) and in its subsequent filings with the SEC. 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.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data (Unaudited)
(in thousands)

	September 30, 2026	December 31, 2025
Cash, cash equivalents, and investments	$ 102,030	$ 128,652
Total assets	$ 115,561	$ 143,010
Accumulated deficit	$ (493,693)	$ (464,740)
Total stockholders’ equity	$ 88,078	$ 112,211

Black Diamond Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ —	$ 70,000
Operating expenses:				
Research and development	$ 6,974	$ 7,437	$ 21,370	$ 27,262
General and administrative	5,148	3,541	14,068	12,606
Total operating expenses	12,122	10,978	35,438	39,868
Income (loss) from operations	(12,122)	(10,978)	(35,438)	30,132
Other income (expense):				
Interest income	830	1,164	2,775	2,877
Other income (expense)	1,280	1,316	3,710	4,474
Total other income (expense), net	2,110	2,480	6,485	7,351
Net income (loss)	$ (10,012)	$ (8,498)	$ (28,953)	$ 37,483
Net income (loss) per share - basic	$ (0.17)	$ (0.15)	$ (0.50)	$ 0.66
Net income (loss) per share - diluted	$ (0.17)	$ (0.15)	$ (0.50)	$ 0.65
Weighted average common shares outstanding - basic	57,455,154	56,929,103	57,352,762	56,799,755

Weighted average common shares outstanding - diluted	57,455,154	56,929,103	57,352,762	57,480,512

Contact

For Investors:
investors@bdtx.com

For Media:
media@bdtx.com