Black Diamond Therapeutics Announces Restructuring Plan to Focus Resources on BDTX-1535 and Extend Cash Runway

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Company advancing BDTX-1535 in EGFRm NSCLC towards key inflection points in Q1 2025

Will deprioritize BDTX-4933 and seek potential partners

Anticipated cost savings expected to extend cash runway into Q2 2026

CAMBRIDGE, Mass., Oct. 07, 2024 (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, announced today a corporate restructuring to focus resources on advancing lead program BDTX-1535 into pivotal development, and to extend the Company's expected cash runway into Q2 2026. BDTX-1535 has demonstrated robust Phase 2 clinical activity across a broad spectrum of epidermal growth factor receptor mutations (EGFRm) in patients with recurrent non-small cell lung cancer (NSCLC).

In Q1 2025, Black Diamond anticipates sharing initial Phase 2 data for BDTX-1535 in the frontline setting for patients with EGFRm NSCLC. Also in Q1 2025, the Company plans to present updated Phase 2 results for BDTX-1535 in patients with recurrent EGFRm NSCLC and a potential registration path in the recurrent setting based on feedback from the FDA.

Black Diamond is actively seeking partnerships as it deprioritizes its BDTX-4933 program in RAF/RAS-mutant solid tumors. To enable focused investment in BDTX-1535, Black Diamond has also taken steps to optimize operations, including a reduction in force, while retaining core drug development and management expertise. As part of the restructuring, Chief Business Officer and Chief Financial Officer Fang Ni and Chief People Officer Elizabeth Montgomery are departing the Company. Erika Jones, Senior Vice President of Finance and Principal Accounting Officer, has been appointed Principal Financial Officer of the Company. Cost savings from the restructuring and other actions described above are expected to be sufficient to fund operations into Q2 2026.

"BDTX-1535 is a well-tolerated oral TKI with the potential to benefit patients with EGFRm NSCLC across multiple lines of therapy," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "We remain focused on advancing BDTX-1535 and presenting additional Phase 2 data in Q1 2025. I am deeply grateful to each member of the Black Diamond team, whose hard work and valuable contributions have brought us to the threshold of pivotal development for our lead program."

About BDTX-1535

BDTX-1535 is an oral, brain-penetrant MasterKey inhibitor of oncogenic EGFR mutations in NSCLC, including classical mutations, non-classical mutations, and the C797S resistance mutation. BDTX-1535 is a fourth-generation tyrosine kinase inhibitor (TKI) that potently inhibits, based on preclinical data, more than 50 EGFR mutations expressed across a diverse group of patients with NSCLC in multiple lines of therapy. Based on preclinical data, BDTX-1535 also inhibits EGFR extracellular domain mutations and alterations commonly expressed in glioblastoma (GBM) and avoids paradoxical activation observed with earlier generation reversible TKIs. A "window of opportunity" trial of BDTX-1535 in patients with GBM is ongoing (NCT06072586) and a Phase 2 trial is ongoing in patients with NSCLC (NCT05256290).

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 a Phase 2 NSCLC trial of BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR-mutant NSCLC and GBM. For more information, please visit www.blackdiamondtherapeutics.com.

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 potential of BDTX-1535 to address the unmet medical need for patients with recurrent NSCLC and for newly diagnosed NSCLC patients with non-classical EGFR mutations and benefit patients with NSCLC across multiple lines of therapy, the continued development and advancement of BDTX-1535, including the ongoing clinical trials and the timing of clinical updates for BDTX-1535 in patients with NSCLC; the expected timing for regulatory feedback and the disclosure of potential registrational pathways for BDTX-1535 in NSCLC; potential partnership opportunities for BDTX-4933; the expected cost savings from the restructuring; and 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, 2023, 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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