Black Diamond Therapeutics Presents Real-World Treatment Practices and Patient Outcomes in Newly Diagnosed NSCLC Patients with Non-Classical Mutations at the European Society for Medical Oncology (ESMO) Congress 2024

September 14, 2024

Treatment data were analyzed from 3,276 cases of patients with newly diagnosed EGFR mutant NSCLC from Guardant Health

Analyses of patients with non-classical EGFR mutations reveal that the majority receive frontline chemotherapy and the remainder are treated with osimertinib or afatinib

Short time to treatment discontinuation ranging from four to eight months demonstrates clear unmet need for patients with non-classical EGFR mutant NSCLC

CAMBRIDGE, Mass., Sept. 14, 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, today presented a poster analyzing real-world treatment outcomes for newly diagnosed non-small cell lung cancer (NSCLC) patients with non-classical EGFR mutations (NCMs) at the European Society for Medical Oncology (ESMO) Congress 2024 taking place September 13-17, in Barcelona, Spain.

Of 11,434 sequenced cases of newly diagnosed and treatment-naïve EGFRm NSCLC within the Guardant Health (GuardantINFORM™) clinical-genomic database, first-line treatment information was available and evaluated for 3,276 patients. Results revealed the presence of a broad spectrum of NCMs, including P-loop and αC-helix compressing (PACC) mutations, and allowed correlation with real-world treatment practices and therapeutic outcomes. Findings further demonstrated that current treatment practices for patients with NCMs are heterogenous: 36% of patients received osimertinib or afatinib and 60% of patients received chemotherapy and/or immunotherapy.

“There is a growing unmet need for new treatments for newly diagnosed NSCLC patients with PACC and other non-classical EGFR mutations,” said John Heymach, M.D., Ph.D., Chair of Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center. “Real-world treatment outcomes show that current EGFR TKIs provide little benefit to these patients, and chemotherapy brings significant toxicity, administration burden, and limited efficacy.”

Newly diagnosed patients expressing NCMs discontinued osimertinib therapy at a median of 6.0 months versus patients expressing classical mutations, who remained on therapy for 13.8 months. Patients receiving afatinib discontinued therapy at a median of 8.0 months, and the median time to treatment discontinuation for patients on chemotherapy was 4.2 months.

“BDTX-1535 was designed to address a broad spectrum of EGFR mutations, with emphasis on non-classical mutations that extend beyond PACC mutations,” said Elizabeth Buck, Ph.D., Chief Scientific Officer and co-founder of Black Diamond Therapeutics. “BDTX-1535 is the most advanced fourth- generation EGFR TKI in clinical development to address this underserved patient population.”

The new real-world results build upon findings presented at the 2024 American Association of Cancer Research (AACR) Annual Meeting around the evolving EGFR mutation landscape in NSCLC that revealed more than 100 NCMs, which can be present in 20-30% of newly diagnosed patients. Black Diamond plans to disclose initial Phase 2 data in Q1 2025 in the first-line NCM setting. The company also plans to release initial Phase 2 results in the second/third-line setting later this month.

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 CNS disease. The Company is advancing two clinical-stage programs: BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR mutant NSCLC and GBM, and BDTX-4933, a brain-penetrant RAF MasterKey inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors. 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 unmet need for new treatments for newly diagnosed NSCLC patients with non-classical EGFR mutations and the potential of BDTX-1535 to address this unmet medical need and benefit patients with NSCLC across multiple lines of therapy, the continued development and advancement of BDTX-1535, including the ongoing clinical trial and the timing of clinical updates for BDTX-1535 in patients with NSCLC, and potential future development plans for BDTX-1535 in NSCLC. 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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