Black Diamond Therapeutics Announces First Patient Dosed in Phase 1 Study of BDTX-1535, a MasterKey Inhibitor of EGFR for the Treatment of Glioblastoma and Non-Small Cell Lung Cancer

April 18, 2022

- Clinical update expected in second half of 2023 -

CAMBRIDGE, Mass. and NEW YORK, April 18, 2022 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today announced the dosing of the first patient in the Phase 1 study evaluating BDTX-1535, a MasterKey inhibitor of epidermal growth factor receptor (EGFR) for the treatment of both non-small cell lung cancer (NSCLC) and glioblastoma (GBM)derived from Black Diamond's MAP discovery engine.

"The dosing of the first patient in our Phase 1 study of BDTX-1535, a next generation brain-penetrant inhibitor of oncogenic EGFR MasterKey mutations is an important step as we believe this program is uniquely positioned to address the existing unmet needs of EGFR mutant NSCLC and GBM," said David M. Epstein, Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "This is the second MasterKey inhibitor derived from our MAP drug discovery engine; we are incredibly excited about BDTX-1535's advancement into the clinic and we look forward to providing a clinical update in the second half of 2023."

"Despite recent successes in targeting EGFR-mutated NSCLC, there is still a need for better therapeutics for patients with disease progression following first-line EGFR inhibitors," said Melissa Johnson, MD, Director of Lung Cancer Research for Sarah Cannon Research Institute at Tennessee Oncology. "We hope to assess the ability of BDTX-1535 to inhibit tumors with primary TKI-resistant EGFR mutations or those with on-target acquired resistance mutations."

NSCLC accounts for approximately 85% of lung cancer cases worldwide. About 10-20% of all lung cancer patients in North American and Europe, and up to 50% of those in Asia harbor mutations in EGFR. Intrinsic resistance EGFR mutations, of which G719X, S768I, L861Q are among the most frequent, account for 10-20% of EGFR mutations in NSCLC. The classical Exon19del and L858R mutations, which account for 80-90% of EGFR mutations in NSCLC, are well treated but resistance invariably emerges to current generation EGFR inhibitors.

"GBM is an aggressive form of brain cancer with limited treatment options," said Patrick Y. Wen, MD, Director, Center for Neuro-Oncology at Dana-Farber Cancer Institute. "A majority of GBM tumors will co-express EGFR alterations, including mutations, splice variants and amplification, making EGFR an attractive target for new therapies with CNS penetration and potency against the spectrum of co-expressed EGFR alterations."

Up to 50% of GBM tumors express one or more co-occurring oncogenic EGFR mutations that affect the extracellular region of the receptor tyrosine kinase, and consequently promote oncogenic activation. There are no precision oncology medicines approved to treat these patients. Black Diamond believes that current targeted therapies have been unsuccessful in treating GBM due to insufficiencies in (i) drug selectivity for EGFR GBM alterations versus EGFR wildtype, (ii) drug potency against the full spectrum of co-expressed EGFR alterations, and (iii) brain penetration.

About BDTX-1535
BDTX-1535 is designed as an irreversible, mutant selective, brain-penetrant MasterKey inhibitor of oncogenic mutations of epidermal growth factor receptor (EGFR) expressed in glioblastoma multiforme (GBM) and intrinsic and acquired resistance EGFR mutations in non-small cell lung cancer (NSCLC). In pre-clinical studies, Black Diamond has demonstrated that oncogenic alterations of EGFR, particularly those associated with GBM, result in distinct conformations which impart unique pharmacology and drug resistance. It is estimated that approximately 50% of GBM patients harbor an oncogenic EGFR alteration that has the potential to be addressed by BDTX-1535, representing a potential patient population of greater than 60,000 patients annually across the US, EU, Japan and China. It is estimated that across the US, EU, Japan and China there are approximately 20,000 patients who are diagnosed annually with non-small cell lung cancer (NSCLC) harboring an EGFR intrinsic or acquired resistance mutation.

About Black Diamond
Black Diamond Therapeutics is a precision oncology medicine company pioneering the development of novel MasterKey therapies. Black Diamond is addressing the significant unmet need for novel precision oncology therapies for patients with genetically defined cancers who have limited treatment options. Black Diamond is built upon a deep understanding of cancer genetics, onco-protein function, and drug discovery. The Company's proprietary Mutation-Allostery-Pharmacology, or MAP drug discovery engine, is designed to allow Black Diamond to analyze population-level genetic sequencing tumor data to predict and validate oncogenic mutations that promote cancer across tumor types as MasterKey mutations. Black Diamond discovers and develops selective MasterKey therapies against these families of oncogenic mutations. Black Diamond was founded by David M. Epstein, Ph.D., and Elizabeth Buck, Ph.D. 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 Phase 1 study of BDTX-1535, including timing for future clinical updates, and the unmet need in patients with glioblastoma. Any forward-looking statements in this statement 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 the Company's 2021 annual report on Form 10-K filed with the United States Securities and Exchange Commission and its other 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.

Contacts

For Investors:
Julie Seidel
investors@bdtx.com

For Media:
Kathy Vincent
(310) 403-8951
media@bdtx.com