Black Diamond Therapeutics Announces FDA Allowance of IND Application for BDTX-1535, A MasterKey Inhibitor of EGFR for the Treatment of Gliobastoma and Non-Small Cell Lung Cancer

January 11, 2022

CAMBRIDGE, Mass. and NEW YORK, Jan. 11, 2022 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today announced that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for its MasterKey inhibitor BDTX-1535, an irreversible, mutant selective, brain-penetrant 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). The Company expects to initiate the Phase 1 study of BDTX-1535 in the first quarter of 2022 and expects to provide a clinical update in the second half of 2023.

“We are incredibly pleased to announce the FDA allowance of our IND, representing a significant milestone for Black Diamond as we continue to mature our pipeline of MasterKey therapies,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “Based on the unique approach of our MAP discovery engine platform, we believe that BDTX-1535 is well positioned to address the unmet needs of EGFR mutant GBM and NSCLC with robust brain penetration to ensure adequate CNS exposure and potent and selective inhibition of EGFR mutations that drive intrinsic and acquired resistance to current generation tyrosine kinase inhibitors, coupled with favorable drug-like properties seen in preclinical models. We look forward to the upcoming initiation of the Phase 1 Study in the first quarter of 2022.”

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. In cell-based assays, BDTX-1535 achieved potent and selective inhibition of a range of EGFR mutations expressed in GBM and NSCLC, including canonical, non-canonical, and drug-resistance mutations, such as EGFR-C797S that can arise following treatment with third generation EGFR inhibitor. BDTX-1535 demonstrated a favorable brain-penetrant pharmacokinetic (PK) profile in animal models. In a range of tumor models, including intracranial GBM models and lung cancer drug resistance models expressing the targeted EGFR mutations, BDTX-1535 showed dose-dependent tumor growth inhibition and achieved complete regression without impact on body weight.

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 continued development and advancement of BDTX-1535. 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: the success, cost, and timing of the Company’s product candidate development activities and planned IND-enabling studies and clinical trials, the Company’s ability to execute on its strategy, regulatory developments in the United States, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company’s clinical trials and preclinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2020, filed with the United States Securities and Exchange Commission and in 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