Black Diamond Therapeutics Announces Strategic Priorities and Expected Milestones for 2022

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- *Company announces IND submission for BDTX-1535 for the treatment of GBM and NSCLC including those with CNS tumors;*
- *Company to enroll additional patients into MasterKey-01 Phase 1 safety expansion cohort to obtain more clinical data and inform future development of BDTX-189;*
- *Company anticipates initiation of IND-enabling studies for its CNS-penetrant Class I,II,III BRAF program in 2022;*
- *Existing resources to be prioritized in the near-term for advancement of MasterKey pipeline programs BDTX-1535, BRAF, FGFR and the MAP discovery engine; cash runway extended to 2024*

CAMBRIDGE, Mass. and NEW YORK, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today announced a strategic pipeline update and outlined its expected upcoming milestones.

“MasterKey inhibitors target mutation families and are designed to address the unmet medical need of cancer patients with genetically defined cancers for whom precision therapies are not available,” said David Epstein, Ph.D., Chief Executive Officer of Black Diamond Therapeutics. “We are incredibly pleased to have submitted the IND ahead of schedule for BDTX-1535, a next generation CNS penetrant MasterKey inhibitor designed to target EGFR driver mutations found in certain patients with GBM and NSCLC. The oncogenic alterations of EGFR, particularly those associated with GBM, result in distinct conformations which impart unique pharmacology and drug resistance. BDTX-1535 is designed to exploit this mechanism as a critical point of attack. We believe Black Diamond is uniquely positioned to deliver a pipeline of truly differentiated MasterKey programs as we leverage our expertise in cancer genomics, onco-protein function and drug discovery.”

“As a result of the rapid evolution of the treatment landscape in NSCLC harboring EGFR or HER2 Exon 20 insertion mutations, we have decided to obtain further clinical data from the BDTX-189 safety expansion cohort at the recommended Phase 2 dose in 2022 in order to inform the future development of our BDTX-189 program, gating the start of a Phase 2 trial. The revised strategy enables near-term prioritization of BDTX-1535 clinical development and further investment in our pipeline, while allowing us to obtain more clinical data on BDTX-189, and simultaneously extends our cash runway into 2024.”

Pipeline Updates and Expected Milestones:

BDTX-1535

- Black Diamond announced ahead of schedule the submission of its Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for BDTX-1535 and expects to initiate the Phase 1 study of BDTX-1535 in the first quarter of 2022, subject to allowance of the IND by the FDA.
- BDTX-1535 is designed as a potent, selective, brain-penetrant and irreversible MasterKey inhibitor of epidermal growth factor receptor (EGFR) mutations expressed in glioblastoma multiforme (GBM) and of intrinsic and acquired resistance EGFR mutations to third generation EGFR inhibitors in 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. BDTX-1535 is designed to exploit this mechanism and has demonstrated anti-cancer activity and growth regressions across a panel of patient-derived xenograft models including intracranial tumor models.
- 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.
- The Company expects to provide a clinical data update on BDTX-1535 in the second half of 2023.

BDTX-189

- BDTX-189 is designed as a MasterKey inhibitor targeting families of oncogenic mutations in EGFR and HER2.
- Clinical data obtained from the MasterKey-01 study to date have demonstrated a favorable safety profile for BDTX-189 and early signs of clinical activity in patients whose tumors are driven by MasterKey mutation families, including two confirmed partial responses in heavily pretreated patients who have remained on treatment for more than 10 months.

- Due to the rapid evolution of the treatment landscape in NSCLC harboring either EGFR or HER2 Exon 20 insertion mutations, the Company has decided to gate the initiation of the Phase 2 portion of the MasterKey-01 study and determine next steps in development based on further clinical data obtained from the safety expansion cohort at the recommended Phase 2 dose.
- The Company expects to provide further guidance on the BDTX-189 program in 2022.

BRAF Program

- Black Diamond is developing a CNS-penetrant BRAF inhibitor against a family of Class I, II, III canonical and non-canonical mutations. The Company's lead BRAF compound is designed to be highly selective, potent and to avoid paradoxical activation.
- In cell-based assays, Black Diamond's lead BRAF compound demonstrated potent inhibition of a wide spectrum of BRAF mutations and fusions and exhibited dose-dependent inhibition of protein kinase RNA-like endoplasmic reticulum kinase downstream signaling.
- In preclinical BRAF-driven tumor models, daily dosing of the lead compound demonstrated dose-dependent tumor growth inhibition, tumor regression and survival consistent with potent on-target and on-pathway inhibition.
- The Company's lead BRAF compound demonstrated robust brain penetration properties and achieved intracranial tumor growth inhibition in pre-clinical studies.
- It is estimated that across the US, EU, and Japan there are approximately 190,000 patients with solid tumors who are diagnosed annually with BRAF oncogenic mutations.
- Black Diamond anticipates the initiation of IND-enabling studies for the BRAF program in 2022.

MAP Discovery Engine

- The Company continues to focus on building its Mutation-Allostery-Pharmacology (MAP) Discovery Engine to exploit mutant onco-protein conformations for the delivery of selective MasterKey therapies, with a focus on developing a MasterKey inhibitor that spares wild type fibroblast growth factor receptor 1 (FGFR1) while inhibiting FGFR2 and FGFR3 mutant families, as well as other preclinical stage programs.
- The Company plans to integrate new molecular dynamic modeling tools from its strategic partnership with OpenEye Scientific.

Financial Guidance

- Black Diamond ended 2021 with approximately $210 million in cash, cash equivalents and investments, which the Company believes is sufficient to fund its anticipated operating expenses and capital expenditure requirements into 2024.

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, including expectations for IND allowance and plans for initiating the Phase 1 trial of BDTX-1535, the continuation of the BDTX-189 safety expansion cohort and the resulting data, the continued development of the BRAF program, including the timing for initiating IND-enabling studies, the continued development of the FGFR program, including plans for nominating a development candidate, the continued development of the MAP discovery engine and the Company's cash runway. 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.

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