Black Diamond Therapeutics Granted Fast Track Designation by the FDA for BDTX-189 for the Treatment of Adult Patients with a Solid Tumor Harboring an Allosteric HER2 Mutation or an EGFR or HER2 Exon 20 Insertion Mutation

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CAMBRIDGE, Mass. and NEW YORK, July 28, 2020 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to BDTX-189 for the treatment of adult patients with solid tumors harboring an allosteric human epidermal growth factor receptor 2 (HER2) mutation or an epidermal growth factor receptor (EGFR) or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options. BDTX-189, an orally available, irreversible small molecule inhibitor, is the Company's lead product candidate designed to selectively inhibit the activity of a broad range of previously unaddressed oncogenic driver mutations of the ErbB kinases in EGFR and HER2.

"While targeted therapies, such as kinase inhibitors, have transformed the treatment of cancer, only a small percentage of patients with metastatic cancer have tumors with genetic profiles that could make them eligible for an approved precision oncology medicine. The FDA's decision to grant Fast Track designation is an important recognition of BDTX-189's potential to treat patients with currently unaddressed oncogenic mutations in EGFR and HER2," said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "We look forward to working closely with the FDA as we continue to enroll and dose patients in the MasterKey-01 trial, our Phase 1/2 clinical study of BDTX-189, as part of our mission to discover and develop novel, tumor-agnostic, precision oncology therapies for genetically defined cancers."

The FDA's Fast Track designation provides the potential for an expedited review of new product candidates intended to treat serious or life-threatening conditions with high unmet need, allowing important new drugs to become available more quickly to patients suffering from these conditions. Benefits of Fast Track designation include enhanced interaction with the FDA, as well as potential eligibility to obtain accelerated approval and priority review at the time of a New Drug Application (NDA) filing if relevant criteria are met. More information about FDA Fast Track designation can be found at www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

About MasterKey-01

MasterKey-01 (NCT04209465) is a combined Phase 1/2 open-label, two-part, multicenter study to assess the safety, tolerability, pharmacokinetics, and anti-tumor activity of BDTX-189, in adult patients with advanced solid tumors who have no standard therapy available or for whom standard therapy is considered unsuitable or intolerable. Part A is a Phase 1, first-in-human, open-label dose escalation study, comprised of initial single-patient, accelerated titration cohorts followed by multiple-patient cohorts utilizing a Bayesian design. Part A is designed to determine the recommended Phase 2 dose and schedule in up to 88 patients with allosteric human epidermal growth factor receptor 2 (HER2) or HER3 mutation; epidermal growth factor receptor (EGFR) or HER2 exon 20 insertion mutation; HER2 amplified or overexpressing tumor; or, EGFR exon 19 deletion or L858R mutation. Part B is a Phase 2, open-label, multicenter basket study designed to determine antitumor activity and safety in adult patients with solid tumors that have an allosteric HER2 mutation or EGFR or HER2 exon 20 insertion mutations using next-generation sequencing. This part will utilize a Simon 2-stage design and enroll up to 100 patients in four cohorts: 1) non-small cell lung cancer with EGFR or HER2 exon 20 insertion mutations; 2) breast cancer with an allosteric ErbB mutation; 3) solid tumors (except breast) with S310F/Y mutation; and, 4) other tumors harboring allosteric ErbB mutations not included in cohorts 1-3.

About BDTX-189

BDTX-189 is an orally available, irreversible small molecule inhibitor that is designed to block the function of an undrugged family of oncogenic proteins defined by driver mutations across a range of tumor types, and which affect both of the epidermal growth factor receptor (EGFR) and the tyrosine-protein kinase, ErbB-2, or human epidermal growth factor receptor 2 (HER2). These mutations include extracellular domain allosteric mutations of HER2, as well as EGFR and HER2 kinase domain exon 20 insertions, and additional activating oncogenic drivers of ErbB. The ErbB receptors are a group of receptor tyrosine kinases involved in key cellular functions, including cell growth and survival. BDTX-189 is also designed to spare normal, or wild type EGFR, which we believe has the potential to improve upon the toxicity profiles of current ErbB kinase inhibitors.

Currently, there are no medicines approved by the U.S. Food and Drug Administration to target all of these oncogenic mutations with a single therapy.

About Black Diamond

Black Diamond Therapeutics is a precision oncology medicine company pioneering the discovery of small molecule, tumor-agnostic therapies. Black Diamond targets undrugged mutations in patients with genetically defined cancers. Black Diamond is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. The Company's proprietary technology platform, Mutation-Allostery-Pharmacology (MAP) platform, is designed to allow Black Diamond to analyze population-level genetic sequencing data to identify oncogenic mutations that promote cancer across tumor types, group these mutations into families, and develop a single small molecule therapy in a tumor-agnostic manner that targets a specific family of mutations. Black Diamond was founded by David M. Epstein, Ph.D. and Elizabeth Buck, Ph.D., and, beginning in 2017, together with Versant Ventures, began building the MAP platform and chemistry discovery engine. 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 Fast Track designation to accelerate development and approval of BDTX-189, the Company's future plans or expectations for BDTX-189, including expectations regarding the success of its current clinical trial for BDTX-189 and future plans or expectations for the Mutation-Allostery-Pharmacology platform. 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 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, supply chain, and operations, as well as those risks and uncertainties set forth in its 2019 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.

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