Black Diamond Therapeutics Presents Pre-Clinical Data on Lead Product Candidate BDTX-189 at the 32nd EORTC-NCI-AACR Virtual Symposium

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CAMBRIDGE, Mass. and NEW YORK, Oct. 26, 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 the presentation of pre-clinical data on the Company's lead product candidate BDTX-189 at the 32 nd EORTC-NCI-AACR Virtual Symposium on Molecular Targets and Cancer Therapeutics (ENA 2020).

"These pre-clinical data demonstrate BDTX-189's ability to potently and selectively inhibit a full spectrum of allosteric EGFR and HER2 mutations while sparing wild-type EGFR (WT-EGFR), a profile that supports our hypothesis that BDTX-189 has the potential to achieve clinically relevant dose levels while limiting toxicities associated with inhibition of WT-EGFR," said Elizabeth Buck, Ph.D., Executive Vice President, Discovery and Translational Sciences at Black Diamond Therapeutics. "With a pre-clinical pharmacokinetic (PK)/pharmacodynamic (PD) profile designed for rapid and sustained target inhibition, BDTX-189 has shown dose-dependent regression of allosteric EGFR and HER2 tumors in an *in vivo* setting including patient-derived xenograft (PDX) models, to date, suggesting that BDTX-189 has the potential to offer a differentiated clinical profile for patients with these genetically defined cancers."

In cell-based assays, BDTX-189 achieved potent inhibition of each of the 48 allosteric ErbB mutant variants tested with an average selectivity vs. WT-EGFR of greater than 50-fold, including the family of epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2) Exon 20 insertion mutations. Additionally, the potency and selectivity profile for BDTX-189 against a selection of allosteric EGFR and HER2 mutations was compared to that of other currently approved ErbB tyrosine kinase inhibitors (TKIs) (erlotinib, afatinib, dacomitinib, osimertinib, and neratinib) and with ErbB TKIs currently in clinical development (mobocertinib, poziotinib, and CLN-081). BDTX-189's selectivity compared favorably with the other inhibitors evaluated, which either lacked potency against the broad panel of allosteric ErbB mutant oncogenes or did not achieve targeted selectivity vs. WT-EGFR.

Pre-clinical evaluation of BDTX-189's PK profile revealed that BDTX-189 achieved the desired rapid and sustained target occupancy with rapid clearance, which supports BDTX-189's potential to achieve a long PD effect while minimizing potential toxicities. Additionally, BDTX-189 demonstrated dose-dependent tumor inhibition and regression in both engineered HER2 S310F tumor models and in EGFR Exon 20 insertion PDX models.

"These pre-clinical results provide support for BDTX-189's uniquely differentiated profile as a potent and selective inhibitor of a range of allosteric ErbB oncogenic driver mutations," said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "We look forward to continuing to advance BDTX-189 through Phase 1/2 clinical development with the goal of bringing a novel targeted therapy to patients with otherwise limited therapeutic options."

The presentation from the ENA 2020 meeting is available on the "Scientific Presentations and Publications" section of the Black Diamond Therapeutics website.

About BDTX-189

BDTX-189 is an orally available, irreversible small molecule inhibitor that is designed to block the function of 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). BDTX-189 is designed as a MasterKey inhibitor targeting a family of previously undrugged and functionally similar mutations in a tumor-agnostic manner. 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 (FDA) to target all of these oncogenic mutations with a single therapy.

BDTX-189 is currently being evaluated in a Phase 1/2 clinical trial (MasterKey-01) in adult patients with advanced solid tumors with at least one MasterKey mutation who have no standard therapy available or for whom standard therapy is considered unsuitable or intolerable. In July 2020, the FDA granted Fast Track designation to BDTX-189 for the treatment of adult patients with solid tumors harboring an allosteric HER2 mutation or an EGFR or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options.

About Black Diamond Therapeutics

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 continued development and advancement of BDTX-189. 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.

Contacts:

For Investors:
Natalie Wildenradt
investors@bdtherapeutics.com

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