Black Diamond Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

March 25, 2021

- *Patient enrollment and dosing in the Phase 1/2 clinical trial of BDTX-189 continue to track in line with projections at initiation of the study, with dose-escalation portion on track to complete in first half of 2021; initiation of safety expansion cohort anticipated in the second quarter of 2021 with start of Phase 2 portion planned for second half of 2021*
- *BDTX-1535, a brain-penetrant MasterKey inhibitor of EGFR mutations for glioblastoma multiforme (GBM) and solid tumors, including those that metastasize to the brain, is on track to enter the clinic in 2022*
- *Pre-clinical data for MasterKey inhibitors targeting proprietary families of BRAF and FGFR2/3 mutations supporting differentiated profiles were presented at the European Society for Medical Oncology Targeted Anticancer Therapies Congress (ESMO TAT); programs continue to advance with IND filings anticipated in 2022*
- *Cash, cash equivalents, and investments of $315.1 million as of December 31, 2020, expected to be sufficient to fund operations into 2023*

CAMBRIDGE, Mass. and NEW YORK, March 25, 2021 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of small molecule, MasterKey therapies, today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided a corporate update.

“2020 was a pivotal year for Black Diamond with key progress made across our organization,” said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We initiated and are successfully executing Part A of our MasterKey-01 study of BDTX-189 in patients with solid tumors harboring any MasterKey-targeted epidermal growth factor receptor (EGFR) or human epidermal growth factor receptor 2 (HER2) genomic alterations. We’re looking forward to sharing preliminary clinical data for this program in the first half of this year.”

Dr. Epstein continued: “Importantly, the breadth and versatility of our drug discovery engine leveraging the MAP platform continues to be demonstrated. BDTX-1535, a brain-penetrant wild-type sparing EGFR inhibitor targeting a novel family of EGFR mutations, advanced into IND-enabling studies, and we expect to file an IND in the first half of 2022. Additionally, Black Diamond’s early-stage programs targeting BRAF and FGFR2/3 oncogenes show promise in their ability to address limitations of current-generation targeted therapies. We look forward to maintaining this momentum across our pipeline and sharing additional updates throughout 2021.”

Recent Developments

BDTX-189:

- Black Diamond continued to enroll and dose patients in the MasterKey-01 study, a Phase 1/2 clinical trial of BDTX-189. More than 50 patients have been dosed with BDTX-189 to date. Eligibility included all solid tumors harboring any of the more than 50 pre-defined genomic alterations in EGFR and HER2. The Company is on track to complete the dose-escalation portion of the Phase 1 clinical trial in the first half of 2021.
- Preliminary Phase 1 clinical data will be presented at a scientific conference in the first half of 2021.
- The Company is working toward selection of the recommended Phase 2 dose for BDTX-189 and plans to initiate the safety expansion cohort in the second quarter of 2021. The Phase 2 portion of the MasterKey-01 study is on track to begin in the second half of 2021.
- In March 2021, the U.S. Food and Drug Administration (FDA) notified Black Diamond that, because the Phase 2 portion of the MasterKey-01 study is potentially registrational and may support a new drug application, the Company may only enroll up to 50 patients in Phase 2 before results of routine three-month good laboratory practice (GLP) toxicology studies have been submitted and accepted by the FDA.
- This partial clinical hold on Phase 2 enrollment is not based on any safety findings from the MasterKey-01 trial and has no impact on completion of our Phase 1 study (including the planned safety expansion cohort). The Company has initiated the three-month GLP toxicology studies and does not anticipate any delays to its clinical trial timelines for BDTX-189.

BDTX-1535:

- In November 2020, Black Diamond announced the nomination of BDTX-1535 as the Company's development candidate for the treatment of GBM, as well as the initiation of IND-enabling studies.
- Additionally, Black Diamond is exploring BDTX-1535's potential as a MasterKey inhibitor of a spectrum of allosteric and canonical EGFR mutations including those solid tumors that metastasize to the brain, such as non-small cell lung cancer.
- Black Diamond expects to file an Initial New Drug (IND) application for BDTX-1535 in the first half of 2022.
- In November 2020, the Company presented pre-clinical data on BDTX-1535 at the 2020 Society for Neuro-Oncology Annual Meeting:
    - In cell-based assays, BDTX-1535 achieved potent inhibition of all members of the family of oncogenic EGFR variants believed to be tumor-drivers in GBM, with selectivity versus wild-type-EGFR.
    - In mouse models, BDTX-1535 demonstrated a pharmacokinetic profile that supports its ability to penetrate the blood-brain barrier.
    - BDTX-1535 achieved complete and sustained inhibition of the phosphorylated state of oncogenic EGFR in mouse models bearing Ba/F3 allosteric EGFR mutants, as well as tumor growth inhibition in an intracranial PDX tumor model driven by allosteric EGFR mutation.

Early-Stage Pipeline:

- Recently, Black Diamond presented pre-clinical data for its BRAF and fibroblast growth factor receptor (FGFR) programs at ESMO TAT:
    - Black Diamond's BRAF program candidates have been designed for potency against a spectrum of non-canonical Class II/III (non-V600), as well as to avoid induction of paradoxical activation. Tumor regression in mouse models has been observed.
    - Black Diamond's FGFR program candidates are inhibitors with broad coverage of FGFR2 and FGFR3 oncogenes, while sparing inhibition of FGFR1 and retaining activity against gatekeeper mutations. Tumor regression in mouse models has been observed.
- The Company anticipates IND filings for both programs in 2022.

Corporate:

- Black Diamond recently appointed oncology clinical development veteran Kapil Dhingra, M.D., to its Board of Directors.
- In September 2020, Black Diamond appointed biopharmaceutical veteran Robert A. Ingram as Chairman of its Board of Directors.
- In the second half of 2020, Black Diamond strengthened its executive team with the appointment of Rachel Humphrey, M.D., as Chief Medical Officer and Fang Ni, Pharm.D., as Chief Business Officer.

Financial Highlights

- Black Diamond ended 2020 with $315.1 million in cash, cash equivalents, and investments compared to $154.7 million as of December 31, 2019. Net cash from financing activities for the year ended December 31, 2020 was $214.9 million compared to $127.8 million for the year ended December 31, 2019. Net cash used in operations was $52.1 million for the year ended December 31, 2020 compared to $24.7 million for the year ended December 31, 2019.
- Net loss for the year ended December 31, 2020 was $67.3 million compared to $35.3 million for the year ended December 31, 2019.
- Research and development (R&D) expenses were $48.2 million for the year ended December 31, 2020 compared to $21.8 million for the year ended December 31, 2019. The increase in R&D expenses was primarily related to increase in headcount, pre-clinical development, and IND filing of BDTX-189.
- General and administrative (G&A) expenses were $21.4 million for the year ended December 31, 2020, compared to $7.6 million for the year ended December 31, 2019. The increase in G&A expenses was primarily due to an increase in personnel and other corporate-related costs.

Upcoming Events

- Pre-clinical data on BDTX-189 and BDTX-1535 will be presented as late-breaking poster presentations at the American Association for Cancer Research Virtual Annual Meeting, taking place April 10-15, 2021. Presentation details are as follows:
    - Prospective pre-clinical modeling to estimate clinical pharmacokinetics and doses of BDTX-189, an inhibitor of allosteric ErbB mutations in advanced solid malignancies
        - Date and Time: Saturday, April 10, 8:30 AM ET
        - Abstract Number: LB127
    - CNS penetrant, irreversible inhibitors potently inhibit the family of allosteric oncogenic EGFR mutants expressed in

GBM and demonstrate efficacy in patient-derived xenograft models
    - Date and Time: Saturday, April 10, 8:30 AM ET
    - Abstract Number: LB140
- David M. Epstein, Ph.D., President and CEO of Black Diamond, is scheduled to present at the 10th Annual J.P. Morgan Napa Valley Forum on Wednesday, March 31, 2021 at 3:00 PM ET.

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 100 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 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, MasterKey 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 and drug discovery engine, Mutation-Allostery-Pharmacology, or 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 of BDTX-189 and the timing for completing the dose escalation portion, initiating the safety expansion cohort, or starting the Phase 2 portion of the ongoing clinical trial of BDTX-189, the continued development and advancement of BDTX-1535 in IND-enabling studies, including expectations for filing an IND, and the development of the BRAF and FGFR programs, including timing for nominating development candidates in each program. 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 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 pre-clinical studies, 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.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data (Unaudited)
(in thousands)

	December 31,	
	2020	2019
	(in thousands)	
Cash, cash equivalents, and investments	$ 315,067	$ 154,666
Total assets	$ 329,670	$ 158,295
Derivative liabilities	$ —	$ 16
Convertible preferred stock	$ —	$ 200,573
Accumulated deficit	$ (118,224)	$ (50,970)
Total stockholders' equity (deficit)	$ 307,758	$ (47,157)

Black Diamond Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (inclusive of $71, $1,469, $2,364 and $9,966 respectively, with a related party)	$ 17,756	$ 7,460	$ 48,209	$ 21,753
General and administrative (inclusive of $0, $88, $0 and $445, respectively, with a related party)	5,427	2,884	21,361	7,579
Total operating expenses	23,183	10,344	69,570	29,332
Loss from operations	(23,183)	(10,344)	(69,570)	(29,332)
Other income (expense):				
Interest expense	—	—	(1)	—
Interest income	1,254	440	4,041	461
Change in fair value of derivative liabilities	—	23	—	(6,393)
Other income (expense)	(697)	6	(1,724)	6
Total other income (expense), net	557	469	2,316	(5,926)
Net loss	$ (22,626)	$ (9,875)	$ (67,254)	$ (35,258)
Net loss per share, basic and diluted	$ (0.63)	$ (4.63)	$ (2.05)	$ (16.99)
Weighted average common shares outstanding, basic and diluted	36,023,503	2,139,961	32,907,100	2,075,753

Contacts:
For Investors:
Natalie Wildenradt
investors@bdtx.com

For Media:

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