Black Diamond Therapeutics Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 10, 2020

- *Continued to enroll and dose patients in Phase 1/2 clinical trial of BDTX-189, with Phase 1 portion on track to complete by first half of 2021*
- *Strengthened Board of Directors with appointment of Robert A. Ingram as Chairman*
- *Bolstered executive team with appointment of Rachel Humphrey, M.D., as Chief Medical Officer*
- *Cash, cash equivalents, and investments of $333.1 million as of September 30, 2020, expected to be sufficient to fund operations into 2023*

CAMBRIDGE, Mass. and NEW YORK, Nov. 10, 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 reported financial results for the third quarter ended September 30, 2020 and provided a corporate update.

“At Black Diamond, we are leveraging our proprietary MAP platform to pioneer a differentiated approach to drug development, in which we aggregate novel oncogenic driver mutations into druggable families enabling the design of potent and selective MasterKey inhibitor product candidates,” said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “This MasterKey profile extends not only to our lead product candidate BDTX-189, which is currently progressing through Phase 1/2 clinical development, but also throughout our early-stage pipeline. We believe the addition of Rachel Humphrey to our executive team to shepherd these programs through the clinic, as well as the appointment of Bob Ingram as Chairman of our Board to lend his leadership and industry expertise, will enable us to realize the potential of our science and to deliver precision medicines to patients who currently lack targeted treatment options.”

Recent Developments

- Black Diamond continued to enroll and dose patients in the MasterKey-01 study, a Phase 1/2 clinical trial of BTDX-189. The Company remains on track to complete the Phase 1 portion of the trial in the first half of 2021.
- In October 2020, Black Diamond presented pre-clinical data on BDTX-189 at the 32nd Annual EORTC-NCI-AACR Virtual Symposium:
    - In cell-based assays, BDTX-189 achieved potent inhibition of 48 ErbB mutant variants, including the family of epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2) Exon 20 insertion mutations, while maintaining selectivity vs. wild-type EGFR (WT-EGFR).
    - 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) and with ErbB TKIs currently in clinical development. 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 pharmacokinetic (PK) profile revealed that BDTX-189 achieved the desired rapid and sustained target occupancy with rapid clearance.
    - BDTX-189 demonstrated dose-dependent tumor inhibition and regression in both engineered HER2 S310F tumor models and in EGFR Exon 20 insertion patient-derived xenograft models.
- Black Diamond continued to advance its program in glioblastoma multiforme (GBM) toward nomination of a development candidate, as well as its early-stage pipeline programs derived from the Company’s Mutation-Allostery-Pharmacology (MAP) platform.
- In September 2020, Black Diamond appointed biopharmaceutical veteran Robert A. Ingram as Chairman of its Board of Directors.
- In September 2020, Black Diamond strengthened its executive team with the appointment of Rachel Humphrey, M.D., as Chief Medical Officer.

Financial Highlights

- Black Diamond ended the third quarter of 2020 with $333.1 million in cash, cash equivalents, and investments, compared

to $78.7 million for the third quarter of 2019. Net cash used in operations was $11.5 million for the third quarter of 2020 compared to $5.3 million for the third quarter of 2019.

- Research and development (R&D) expenses were $12.9 million for the third quarter of 2020 compared to $5.6 million for the third quarter of 2019. The increase in R&D expenses was primarily related to an increase in headcount and external fees related to the development of our MAP platform and our product candidates, including BDTX-189.
- General and administrative (G&A) expenses were $5.6 million for the third quarter of 2020 compared to $2.5 million for the third quarter of 2019. The increase in G&A expenses was primarily due to increased headcount and higher legal and other professional fees due to operating as a public company.

Upcoming Events

- The Company will present pre-clinical data on Black Diamond's GBM program at the Society of Neuro-Oncology 2020 Annual Meeting, taking place November 19-21, 2020:
  - *Abstract Title*: Potent, selective, and brain penetrant inhibitors of extracellular domain EGFR oncogenic mutants expressed in GBM demonstrate efficacy in an intracranial patient derived xenograft model
  - *Abstract ID*: EXTH-59
  - *Session*: Experimental and Translation Sciences Session III
- David M. Epstein, Ph.D., President and CEO of Black Diamond, will present at the Jefferies Virtual London Healthcare Conference on Wednesday, November 18, 2020, at 2:40 PM GMT/9:40 AM 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 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 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 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

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 future plans or expectations for the Mutation-Allostery-Pharmacology platform, including the potential of the Company's strategy and product candidates, and the continued development and advancement of the Company's pipeline, including BDTX-189, the GBM program and other early-stage pipeline programs. 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.

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and investments	$ 333,072	$ 154,666
Total assets	$ 346,435	$ 158,295
Derivative liabilities	$ —	$ 16
Convertible preferred stock	$ —	$ 200,573
Accumulated deficit	$ (95,598)	$ (50,970)
Total stockholders' equity (deficit)	$ 327,345	$ (47,157)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (inclusive of $190, $3,480, $2,293 and $8,497 respectively, with a related party)	$ 12,929	$ 5,634	$ 30,453	$ 14,293
General and administrative (inclusive of $0, $176, $0 and $357 respectively, with a related party)	5,551	2,514	15,934	4,695
Total operating expenses	18,480	8,148	46,387	18,988
Loss from operations	(18,480)	(8,148)	(46,387)	(18,988)
Other income (expense):				
Interest expense	—	—	(1)	—
Interest income	1,162	1	2,787	21
Change in fair value of derivative liabilities	—	(1,116)	—	(6,416)

Other (expense) income	(594)	(5)	(1,027)	—
Total other income (expense), net	568	(1,120)	1,759	(6,395)
Net loss	$ (17,912)	$ (9,268)	$ (44,628)	$ (25,383)
Net loss per share, basic and diluted	$ (0.50)	$ (4.50)	$ (1.42)	$ (12.36)
Weighted average common shares outstanding, basic and diluted	35,927,485	2,065,676	31,860,716	2,054,115

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