Black Diamond Therapeutics Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 12, 2021

- *Initial Phase 1 clinical PK, safety, and preliminary efficacy data for BDTX-189 presented at ASCO Annual Meeting; on track to initiate Phase 2 portion of MasterKey-01 study in second half of 2021*
- *Pre-clinical data for BDTX-1535 presented at AACR Annual Meeting; program on track to enter the clinic in 2022*
- *Early-stage pipeline programs targeting BRAF and FGFR remain on track for IND filing in 2022*
- *Biotech industry veteran Mark Velleca, M.D., Ph.D., appointed to Board of Directors*
- *Cash, cash equivalents, and investments of $263.5 million as of June 30, 2021, expected to be sufficient to fund operations into 2023*

CAMBRIDGE, Mass. and NEW YORK, Aug. 12, 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 second quarter ended June 30, 2021 and provided a corporate update.

“We continue to advance our clinical and pre-clinical pipeline of MasterKey therapies, including BDTX-189, for which we expect to initiate the Phase 2 trial in the second half of this year. Our early-stage programs continue to advance as well, and we look forward to submitting Investigational New Drug (IND) applications for our BDTX-1535, BRAF (B-Raf), and fibroblast growth factor receptor (FGFR) programs in 2022,” said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We remain committed to the discovery and development of novel precision medicine therapies to address genetically defined cancers with unmet medical need.”

Recent Developments

BDTX-189:

- Black Diamond completed the Phase 1 dose-escalation portion of the MasterKey-01 study, a Phase 1/2 clinical trial of BDTX-189. The Company has selected the preliminary recommended Phase 2 dose for BDTX-189 and, pending dialogue with the U.S. Food and Drug Administration (FDA), is on track to initiate the Phase 2 portion of the study in the second half of 2021.
- In May 2021, Black Diamond presented initial clinical pharmacokinetic (PK), safety, and preliminary efficacy data from the Phase 1 dose-escalation portion of the MasterKey-01 study of BDTX-189 in advanced solid tumors at the American Society of Clinical Oncology (ASCO) Annual Meeting:
    - BDTX-189 was generally well-tolerated with medically manageable toxicities observed.
    - Preliminary anti-cancer activity was observed in a heavily pre-treated patient population (prior epidermal growth factor receptor (EGFR)-/human epidermal growth factor receptor 2 (HER2)-directed and/or immuno-oncology (I/O) agents) in a variety of tumor types and genomic alterations in EGFR or HER2, including confirmed partial responses.

BDTX-1535:

- Black Diamond continues to advance BDTX-1535 through IND-enabling studies and expects to file an IND application in the first half of 2022.
- In April 2021, the Company presented pre-clinical data on BDTX-1535 at the American Association for Cancer Research (AACR) Annual Meeting:
    - BDTX-1535 demonstrated a favorable brain-penetrant PK profile in mouse, rat, and dog models, and tumor growth inhibition in mouse models bearing intracranial GBM6 patient-derived tumors expressing allosteric EGFR mutants was achieved.
    - BDTX-1535 demonstrated potent and selective inhibition of rare Exon 18 mutations and the C797S mutation, supporting the potential for utility beyond glioblastoma (GBM), such as in non-small cell lung cancer (NSCLC).

Early-Stage Pipeline:

- Black Diamond continues to progress its early-stage pipeline programs designed to target cancers driven by mutations in BRAF and FGFR. The Company anticipates IND filings for the BRAF and FGFR programs in 2022.

Corporate:

- In August 2021, Black Diamond announced the appointment of Elizabeth Buck, Ph.D., as Chief Scientific Officer and Karsten Witt, M.D., as Interim Chief Medical Officer. Additionally, the Company announced the departures of Rachel Humphrey, M.D., the Company's Chief Medical Officer, and Christopher Roberts, Ph.D., the Company's Chief Scientific Officer.
- In August 2021, Black Diamond appointed Mark Velleca, M.D., Ph.D., to its Board of Directors.

Financial Highlights

- Black Diamond ended the second quarter of 2021 with $263.5 million in cash, cash equivalents, and investments compared to $345.0 million as of June 30, 2020. Net cash used in operations was $25.2 million for the second quarter of 2021 compared to $24.9 million for the second quarter of 2020.
- Research and development (R&D) expenses were $26.7 million for the second quarter of 2021 compared to $10.2 million for the second quarter of 2020. The increase in R&D expenses was primarily related to an increase in headcount and increased spend across preclinical and clinical development.
- General and administrative (G&A) expenses were $8.0 million for the second quarter of 2021 compared to $4.9 million for the second quarter of 2020. The increase in G&A expenses was primarily due to an increase in personnel and other corporate-related costs.

About Black Diamond Therapeutics, Inc.

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, the 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 that targets a specific family of mutations, termed a MasterKey therapy. 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 of BDTX-189 and the timing for initiating 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 entering the clinic, and the development of the BRAF and FGFR programs, including timing for filing INDs in each program, and the Company's expected 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 pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in its 2020 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)

	June 30, 2021	December 31, 2020
Cash, cash equivalents, and investments	$ 263,470	$ 315,067
Total assets	$ 287,882	$ 329,670
Accumulated deficit	$ (182,876)	$ (118,224)
Total stockholders' equity	$ 251,020	$ 307,758

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 26,719	$ 10,170	$ 49,539	$ 17,524
General and administrative	7,996	4,858	15,889	10,383

Total operating expenses	34,715	15,028	65,428	27,907
Loss from operations	(34,715)	(15,028)	(65,428)	(27,907)
Other income (expense):				
Interest expense	—	(1)	—	(1)
Interest income	948	881	2,100	1,625
Other (expense) income	(584)	(423)	(1,324)	(433)
Total other income (expense), net	364	457	776	1,191
Net loss	$ (34,351)	$ (14,571)	$ (64,652)	$ (26,716)
Net loss per share, basic and diluted	$ (0.95)	$ (0.41)	$ (1.79)	$ (0.92)
Weighted average common shares outstanding, basic and diluted	36,182,541	35,910,718	36,152,942	29,804,987

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