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

May 7, 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; initial Phase 1 clinical pharmacokinetic (PK), safety, and preliminary efficacy data to be presented at American Society of Clinical Oncology (ASCO) Annual Meeting*
- *Pre-clinical data for BDTX-1535, a brain-penetrant MasterKey inhibitor of epidermal growth factor receptor (EGFR) mutations for glioblastoma multiforme (GBM) and solid tumors, including those that metastasize to the brain, presented at American Association for Cancer Research (AACR) Annual Meeting; program on track to enter the clinic in 2022*
- *Cash, cash equivalents, and investments of $290.1 million as of March 31, 2021, expected to be sufficient to fund operations into 2023*

CAMBRIDGE, Mass. and NEW YORK, May 07, 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 first quarter ended March 31, 2021 and provided a corporate update.

“The first quarter of 2021 has been marked by meaningful progress across Black Diamond’s pipeline of MasterKey inhibitor therapies, each of which is designed by leveraging our proprietary MAP platform to address an unmet need for patients with a range of genetically defined cancers,” said David M. Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We look forward to presenting initial clinical data for our lead program, BDTX-189, at the ASCO Annual Meeting later this quarter, as well as to continuing to report on progress across the pipeline throughout the year.”

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 human epidermal growth factor receptor 2 (HER2). The Company is on track to complete the dose-escalation portion of the Phase 1 clinical trial in the first half of 2021.
- Initial Phase 1 clinical PK, safety, and preliminary efficacy data will be presented at the ASCO Annual Meeting.
- 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 April 2021, the Company presented pre-clinical data on BDTX-189 at the AACR Annual Meeting:
    - Black Diamond employed a novel physiologically based pharmacokinetic (PBPK) modeling strategy, accounting for compound-specific determinants of BDTX-189 metabolism and disposition, to prospectively predict the clinical PK profile and active dose range of BDTX-189.
    - Preclinical PBPK modeling indicated that BDTX-189 would be readily orally absorbed with a short elimination half-life (approximately two hours) while maintaining suppression of ErbB pathway biomarkers over the dosing interval, consistent with the irreversible mechanism of action and the desired PK/pharmacodynamic (PD) profile.
    - Active dose levels in humans were projected to be in the 400–800 mg QD range based on the exposure-tumor growth inhibition relationship in multiple mouse patient-derived xenograft (PDX) models harboring ErbB allosteric mutations.

BDTX-1535:

- In April 2021, the Company presented pre-clinical data on BDTX-1535 at the AACR Annual Meeting:
    - In cell-based assays, BDTX-1535 achieved potent and selective inhibition of all members of the family of oncogenic EGFR variants expressed in GBM.

    - BDTX-1535 demonstrated a favorable brain-penetrant PK profile in mouse, rat, and dog models.
    - 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 GBM, such as in non-small cell lung cancer (NSCLC).
- Black Diamond expects to file an Investigational New Drug (IND) application for BDTX-1535 in the first half of 2022.

Early-Stage Pipeline:

- In March 2021, Black Diamond presented pre-clinical data for its B-Raf Proto-Oncogene (BRAF) and fibroblast growth factor receptor (FGFR) programs at European Society for Medical Oncology Targeted Anticancer Therapies Congress:
    - 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:

- In January 2021, Black Diamond appointed oncology clinical development veteran Kapil Dhingra, M.B.B.S., to its Board of Directors.

Financial Highlights

- Black Diamond ended the first quarter of 2021 with $290.1 million in cash, cash equivalents, and investments compared to $357.2 million as of March 31, 2020. Net cash used in operations was $24.5 million for the first quarter of 2021 compared to $11.3 million for the first quarter of 2020.
- Research and development (R&D) expenses were $22.8 million for the first quarter of 2021 compared to $7.4 million for the first 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 $7.9 million for the first quarter of 2021 compared to $5.5 million for the first quarter of 2020. The increase in G&A expenses was primarily due to an increase in personnel and other corporate-related costs.

Upcoming Events

- Initial PK, safety, and preliminary efficacy data from the Phase 1 dose-escalation portion of the MasterKey-01 clinical trial of BDTX-189 in advanced solid tumors will be presented as poster presentations at the ASCO Annual Meeting. Presentation details are as follows:
    - Title: Safety and Preliminary Efficacy from the Phase 1 Portion of MasterKey-01: A First-in-Human Dose-Escalation Study to Determine the Recommended Phase 2 Dose (RP2D), Pharmacokinetics (PK), and Preliminary Antitumor Activity of BDTX-189, an Inhibitor of Allosteric ErbB mutations, in Patients with Advanced Solid Malignancies
        - Session Type: Poster Session
        - Session: Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
        - Date and Time: Friday, June 4, 9:00 AM ET
        - Abstract ID: 3086
    - Title: Clinical pharmacokinetics of BDTX-189, an inhibitor of allosteric ErbB mutations, in patients with advanced solid malignancies in MasterKey-01 study
        - Session Type: Poster Session
        - Session: Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
        - Date and Time: Friday, June 4, 9:00 AM ET
        - Abstract ID: 3097

About BDTX-189

BDTX-189 is an orally available, irreversible, and ATP competitive small molecule inhibitor that is designed to block the function of a family of oncogenic epidermal growth factor receptor (EGFR) and ErbB-2 (epidermal growth factor receptor 2 [HER2]) proteins across a range of tumor types. BDTX-189 is designed as a MasterKey inhibitor targeting a family of previously undrugged and functionally similar oncogenic 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 expressing a range of alterations of ErbB receptors, including oncogenic MasterKey mutations, HER2-WT amplification, HER3 mutation, EGFR exon 19 deletion, and L858R 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 and the expected announcement of initial Phase 1 clinical pharmacokinetic, safety, and preliminary efficacy data, 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 Initial New Drug applications 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 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)

	March 31, 2021	December 31, 2020
Cash, cash equivalents, and investments	$ 290,055	$ 315,067
Total assets	$ 313,259	$ 329,670
Accumulated deficit	$ (148,525)	$ (118,224)
Total stockholders' equity	$ 280,753	$ 307,758

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 22,820	$ 7,354
General and administrative	7,893	5,525
Total operating expenses	30,713	12,879
Loss from operations	(30,713)	(12,879)
Other income (expense):		
Interest income	1,152	744
Other (expense) income	(740)	(10)
Total other income (expense), net	412	734
Net loss	$ (30,301)	$ (12,145)
Net loss per share, basic and diluted	$ (0.84)	$ (0.51)
Weighted average common shares outstanding, basic and diluted	36,123,083	23,699,255

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