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

August 11, 2020

- *Obtained U.S. FDA Fast Track designation for BDTX-189 for the treatment of adult patients with a solid tumor harboring an allosteric HER2 mutation or an EGFR or HER2 Exon 20 insertion mutation*
- *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 executive team with the appointment of Fang Ni, Pharm.D., as Chief Business Officer*
- *Cash, cash equivalents, and investments of $345.0 million as of June 30, 2020, believed to be sufficient to fund operations into 2023*

CAMBRIDGE, Mass. and NEW YORK, Aug. 11, 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 second quarter ended June 30, 2020, and provided a corporate update.

“Throughout the quarter, we have made meaningful progress in executing on our strategic goals, as we continue to advance the clinical program for BDTX-189 through the enrollment and dosing of patients in the Phase 1 portion of the MasterKey-01 trial,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “In parallel, we continue to invest in and advance our early stage pipeline and expand our proprietary MAP platform technology. We've taken critical steps forward in our efforts to harness the power of the MAP platform to discover and develop new small molecule cancer therapies that have the potential to transform the lives of patients by addressing mutation families for which no approved or effective current treatment options exist.”

Recent Developments

- 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 human epidermal growth factor receptor 2 (HER2) mutation or an epidermal growth factor receptor (EGFR) or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options.
- Black Diamond continued to enroll and dose patients in the MasterKey-01 study, a Phase 1/2 clinical trial of BTDX-189, in line with projections at initiation of the study. The Company remains on track to complete the Phase 1 portion of the trial in the first half of 2021.
- Black Diamond continued to advance its program in glioblastoma multiforme (GBM) toward nomination of a development candidate targeting a range of driver mutations in GBM, as well as its earlier-stage programs derived from the Company’s Mutation-Allostery-Pharmacology (MAP) platform.
- In August 2020, Black Diamond strengthened its executive team with the appointment of Fang Ni, Pharm.D., as Chief Business Officer.

Financial Highlights

- Black Diamond ended the second quarter of 2020 with $345.0 million in cash, cash equivalents, and investments, compared to $39.7 million for the second quarter of 2019. Net cash used in operations was $24.9 million for the second quarter of 2020 compared to $11.9 million for the second quarter of 2019.
- Research and development (R&D) expenses were $10.2 million for the second quarter of 2020 compared to $5.6 million for the second quarter of 2019. The increase in R&D expenses was primarily related to preclinical development, advancement of the BDTX-189 Phase 1/2 clinical trial and an increase in headcount.
- General and administrative (G&A) expenses were $4.9 million for the second quarter of 2020 compared to $1.4 million for the second quarter of 2019. The increase in G&A expenses was primarily due to an increase in personnel and costs associated with operations as a public company.

Upcoming Events

David M. Epstein, Ph.D., President and CEO, is scheduled to present at the following upcoming conferences:

- Wedbush PacGrow Healthcare Conference 2020, on Wednesday, August 12, 2020, at 10:20 AM ET
- Canaccord Genuity 40th Annual Growth Conference, on Thursday, August 13, 2020, at 3:30 PM ET
- Morgan Stanley Virtual 18th Annual Healthcare Conference, on Tuesday, September 15, 2020, at 2:45 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 an undrugged 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). 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 to target all of these oncogenic mutations with a single therapy.

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, 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 Company's business plans and objectives, future plans or expectations for BDTX-189, including expectations regarding the design, implementation, timing, and success of its current clinical trial for BDTX-189, future plans or expectations for the Mutation-Allostery-Pharmacology platform, upcoming milestones and preclinical studies for the Company's other product candidates, expectations regarding its uses of capital, expenses, and other future financial results, and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and operations. 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, and 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 operations, as well as those risks and uncertainties set forth in its 2019 annual report on Form 10-K, most recent quarterly report on Form 10-Q, 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, 2020	December 31, 2019
Cash, cash equivalents, and investments	$ 345,011	$ 154,666
Total assets	$ 349,450	$ 158,295
Derivative liabilities	$ —	$ 16
Convertible preferred stock	$ —	$ 200,573
Accumulated deficit	$ (77,686)	$ (50,970)
Total stockholders' equity (deficit)	$ 343,125	$ (47,157)

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (inclusive of $223, $3,077, $2,103 and $5,017 respectively, with a related party)	$ 10,170	$ 5,646	$ 17,524	$ 8,659
General and administrative (inclusive of $0, $170, $0 and $181 respectively, with a related party)	4,858	1,353	10,383	2,181
Total operating expenses	15,028	6,999	27,907	10,840
Loss from operations	(15,028)	(6,999)	(27,907)	(10,840)
Other income (expense):				
Interest expense	(1)	—	(1)	—
Interest income	881	9	1,625	20
Change in fair value of derivative liabilities	—	(5,300)	—	(5,300)
Other income (expense)	(423)	3	(433)	5
Total other income (expense), net	457	(5,288)	1,191	(5,275)
Net loss	$ (14,571)	$ (12,287)	$ (26,716)	$ (16,115)
Net loss per share, basic and diluted	$ (0.41)	$ (5.99)	$ (0.92)	$ (7.86)
Weighted average common shares outstanding, basic and diluted	35,910,718	2,052,056	29,804,987	2,048,239

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