Black Diamond Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 09, 2023

- *On track to provide clinical update from dose-escalation portion of Phase 1 clinical trial of EGFR MasterKey inhibitor BDTX-1535 in the second half of 2023; Dose Expansion cohorts expected to open in 2023*
- *FDA clearance of IND application for BDTX-4933, RAF MasterKey inhibitor; Anticipate first patient dosing in the second quarter of 2023*
- *Announces nomination of development candidate, BDTX-4876, for FGFR 2/3 selective inhibitor program; Company to evaluate strategic alternatives for this program*
- *Cash, cash equivalents, and investments of $103.4 million as of March 31, 2023; Expected to be sufficient to fund operations into the third quarter of 2024*

CAMBRIDGE, Mass. and NEW YORK, May 09, 2023 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage precision oncology medicine company developing MasterKey therapies designed to overcome limitations of existing therapies by targeting families of oncogenic driver mutations in patients with genetically defined cancers, today reported financial results for the first quarter ended March 31, 2023, and provided a corporate update.

"We are incredibly pleased with the pace of execution since the start of 2023 as we continue to advance our pipeline programs, BDTX-1535 and BDTX-4933 in addition to our newest program, BDTX-4876. Having three investigational new drug (IND) acceptances in three years is exemplary of our breadth of expertise in precision oncology drug discovery and development. We are confident that our momentum will continue to bring tremendous progress across our pipeline as we head further into this transformational year for Black Diamond," said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "2023 brings several key inflection points, including a clinical update from the dose-escalation portion of our Phase 1 trial of BDTX-1535 in patients with non-small cell lung cancer (NSCLC) and glioblastoma multiforme (GBM), the initiation of a Phase 1 clinical trial for BDTX-4933, and today's announcement of a development candidate nomination for our fibroblast growth factor receptor (FGFR) 2/3 selective program. We remain acutely focused on bringing our next-generation precision medicines to patients in need, particularly as we work to expand the addressable patient population within the broader oncogenic mutation landscape. Our sophisticated drug design and our deep-rooted commitment to effectively targeting shared, activated conformations used by oncogenic drivers for tumor growth are all enabled by our Mutation Allostery Pharmacology (MAP) drug discovery engine and ultimately realized by our MasterKey therapies."

Recent Developments & Upcoming Milestones:

BDTX-1535:

- BDTX-1535, an epidermal growth factor receptor (EGFR) MasterKey inhibitor, is being developed to treat genetically defined cancer in patients whose tumors are positive for EGFR MasterKey mutations in NSCLC, as well as in GBM. BDTX-1535 is a fourth generation EGFR inhibitor designed to be irreversible (covalent) and brain-penetrant and is unique in how it targets a family of driver and resistance mutations arising from the use of third generation EGFR inhibitors to treat EGFR-positive NSCLC.
- In April 2023, Black Diamond presented two posters highlighting BDTX-1535's preclinical development as well as the ongoing Phase 1 clinical trial at the 2023 AACR Annual Meeting. Key highlights from the preclinical poster included an outline of the unmet need for next generation EGFR inhibitors that target classical driver mutations as well as acquired and intrinsic resistance mutations expressed in the context of EGFR driver mutations in NSCLC, and EGFR alterations expressed in GBM. Black Diamond also outlined its ongoing Phase 1, open-label, multicenter clinical trial to assess the safety, tolerability, pharmacokinetics, central nervous system (CNS) penetrance and preliminary antitumor activity of BDTX-1535 in locally advanced or metastatic NSCLC with or without CNS disease or in recurrent GBM (rGBM).
- Enrollment in the Phase 1 clinical trial was initiated in 2022 and dose escalation is ongoing. Dose Expansion cohorts are expected to open in 2023. Black Diamond remains on track to provide a clinical update on BDTX-1535 in the second half of 2023.

BDTX-4933:

- BDTX-4933 is designed as a brain-penetrant, oral MasterKey inhibitor of oncogenic BRAF Class I, II and III and RAS mutations, while also avoiding paradoxical activation.
- In the first quarter of 2023, Black Diamond received allowance of its IND application from the U.S. Food and Drug Administration (FDA).

- In April 2023, Black Diamond presented a poster at the 2023 AACR Annual Meeting, outlining its approach to characterizing RAF, RAS and MAPK pathways in addition to the design and preclinical development of BDTX-4933. Based on preclinical data, BDTX-4933 has a potential best-in-class profile to treat cancer patients harboring oncogenic BRAF Class I, II, III and RAS mutations, with or without brain disease.
- Black Diamond expects to dose its first patient in a Phase 1 clinical trial of BDTX-4933 in patients with tumors harboring all-class BRAF or RAS mutations in the second quarter of 2023.

Discovery-Stage Pipeline and MAP Drug Discovery Engine:

- Today, Black Diamond announced that it selected a development candidate, BDTX-4876, for its FGFR program. BDTX-4876 is selective against MasterKey mutations and alterations in FGFR 2 and 3, while sparing FGFR 1 and 4.
- Black Diamond plans to evaluate strategic alternatives for the FGFR program as it deepens focus on its two clinical stage assets.
- Black Diamond continues to leverage its MAP drug discovery engine to advance its discovery-stage pipeline to bring therapies to underserved patients.

Corporate:

- In March 2023, the Company promoted Fang Ni, Pharm.D., from interim Chief Financial Officer to full-time Chief Financial Officer, in addition to his role as Chief Business Officer.

Financial Highlights

- **Cash Position:** Black Diamond ended the first quarter of 2023 with approximately $103.4 million in cash, cash equivalents, and investments compared to $122.8 million as of December 31, 2022. Net cash used in operations was $20.0 million for the first quarter of 2023 compared to $28.6 million for the first quarter of 2022.
- **Research and Development Expenses:** Research and development (R&D) expenses were $14.8 million for the first quarter of 2023, compared to $17.8 million for the same period in 2022. The decrease in R&D expenses was primarily due to reduced clinical trial activities stemming from the discontinuation of the development of BDTX-189 to focus on advancement of the Company's pipeline programs, BDTX-1535 and BDTX-4933.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $6.8 million for the first quarter of 2023, compared to $7.9 million for the same period in 2022. The decrease in G&A expenses was primarily due to a decrease in legal and other professional fees.
- **Net Loss:** Net loss for the first quarter of 2023 was $20.9 million, as compared to $25.5 million for the same period in 2022.

Financial Guidance

- Black Diamond ended the first quarter of 2023 with approximately $103.4 million in cash, cash equivalents and investments, which the Company believes is sufficient to fund its anticipated operating expenses and capital expenditure requirements into the third quarter of 2024.

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage precision oncology medicine company focused on the development of MasterKey therapies that target families of oncogenic mutations in clinically validated targets. Black Diamond leverages a deep understanding of cancer genetics and onco-protein structure and function, to discover and develop innovative MasterKey therapies. The Company's MasterKey therapies are designed to overcome resistance, minimize on-target, wild-type mediated toxicities, and be brain-penetrant to address significant unmet medical needs of patients with genetically defined cancers. The Company is advancing a robust pipeline with lead clinical-stage program BDTX-1535, targeting MasterKey mutations in both EGFR mutant-positive NSCLC and in GBM, and BDTX-4933, a program targeting RAF MasterKey mutations in solid tumors, as well as discovery-stage research programs. The Company's proprietary MAP drug discovery engine is designed to allow Black Diamond to analyze population-level genetic sequencing tumor data and validate MasterKey mutations. 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 and advancement of BDTX-1535, and BDTX-4933, including the ongoing Phase 1 clinical trial and the expected timing for data updates for BDTX-1535 and the timing for initiating a Phase 1 clinical trial of BDTX-4933, the continued development of the FGFR program, exploring strategic alternatives for the FGFR program, the continued development of the MAP drug discovery engine 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 those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the United States Securities and Exchange Commission and in its subsequent 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, 2023	December 31, 2022
	(in thousands)	
Cash, cash equivalents, and investments	$ 103,366	$ 122,807
Total assets	$ 135,582	$ 156,255
Accumulated deficit	$ (355,864)	$ (334,989)
Total stockholders' equity (deficit)	$ 98,190	$ 115,695

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 14,753	$ 17,786
General and administrative	6,808	7,893
Total operating expenses	21,561	25,679
Loss from operations	(21,561)	(25,679)
Other income (expense):		
Interest income	622	406
Other income (expense)	64	(234)
Total other income (expense), net	686	172
Net loss	$ (20,875)	$ (25,507)
Net loss per share, basic and diluted	$ (0.57)	$ (0.70)
Weighted average common shares outstanding, basic and diluted	36,483,878	36,271,291

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