Black Diamond Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 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*
- *FDA clearance of IND application for BDTX-4933 in the first quarter of 2023, a brain-penetrant RAF MasterKey inhibitor for the treatment of all-class RAF and RAS mutant tumors; initiation of Phase 1 clinical trial expected in the first half of 2023*
- *Presented new preclinical data demonstrating the potential of MasterKey programs BDTX-1535 and BDTX-4933 at the 34th EORTC-NCI-AACR Symposium*
- *Cash, cash equivalents, and investments of $122.8 million as of December 31, 2022; expected to be sufficient to fund operations into the third quarter of 2024*

CAMBRIDGE, Mass. and NEW YORK, March 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 fourth quarter and full year ended December 31, 2022, and provided a corporate update.

"We expect 2023 to be a catalyst rich year for Black Diamond following tremendous progress for our two novel MasterKey inhibitors, with BDTX-1535 continuing to advance through our Phase 1 clinical trial and BDTX-4933 meeting critical milestones to further progress toward the clinic. The clearance of the Investigational New Drug (IND) application for BDTX-4933 by the U.S. Food and Drug Administration (FDA) earlier this year marks our third IND allowance in three years and demonstrates the strength of our MAP drug discovery engine along with the expertise of our research and clinical teams. We are driven by the clear unmet need for next-generation precision medicines to treat cancers by overcoming resistance, minimizing on-target and wild-type mediated toxicities, and addressing brain disease. We've designed a robust pipeline of products with brain penetration properties to address these key challenges," said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond. "We anticipate a clinical update for BDTX-1535 in the second half of 2023. We also expect to initiate the Phase 1 clinical trial of BDTX-4933 in the first half of this year and to progress our FGFR program and another undisclosed program toward development candidate nominations in 2023. As we continue to mature our pipeline, we are acutely focused on delivering meaningful benefit to patients and we believe that our approach has the potential to strengthen the treatment landscape for genetically defined cancers."

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 glioblastoma multiforme (GBM), as well as in non-small cell lung cancer (NSCLC). BDTX-1535 is fourth generation EGFR inhibitor designed to be irreversible (covalent) and brain-penetrant, and is unique in that it targets a family of driver mutations in addition to acquired resistance mutations arising from the use of third generation EGFR inhibitors to treat EGFR-positive NSCLC.
- In April 2022, Black Diamond dosed the first patient in its Phase 1 global clinical trial of BDTX-1535 for the treatment of NSCLC, including in patients with brain metastases, and GBM. The dose-escalation portion of the Phase 1 clinical trial is actively recruiting and enrolling patients, and the Company remains on track to provide a clinical update on BDTX-1535 in the second half of 2023.
- In October 2022, Black Diamond presented two posters at the 34th European Organisation for Research and Treatment of Cancer—National Cancer Institute—American Association for Cancer Research (EORTC-NCI-AACR) Symposium in Barcelona, Spain, with new preclinical data. The Company detailed anti-tumor activity of BDTX-1535 in preclinical models and highlighted that BDTX-1535 is designed using Black Diamond's proprietary MAP drug discovery engine to target EGFR mutations of both NSCLC and GBM. Black Diamond also showcased BDTX-1535's ability to achieve potent anti-tumor activity against EGFR alterations and amplification across preclinical models of NSCLC classical driver, intrinsic resistance and acquired resistance EGFR mutations and GBM, including intercranial patient derived xenograft models.

BDTX-4933:

- BDTX-4933 is designed as a brain-penetrant, small molecule MasterKey reversible oral inhibitor of oncogenic BRAF Class I, II and III active RAF dimers promoted by upstream oncogenic alterations expressed by human cancers, while also avoiding paradoxical activation.

- In the first quarter of 2023, Black Diamond received allowance of its IND application from the FDA. The Company expects to initiate a Phase 1 clinical trial of BDTX-4933 in patients with tumors harboring all-class BRAF or RAS mutations in the first half of 2023.
- In October 2022, Black Diamond presented a poster at the 34th EORTC-NCI-AACR Symposium highlighting preclinical data showing BDTX-4933 to be a brain-penetrant RAF MasterKey inhibitor active against tumors that are driven by a Class I, II, or III BRAF mutation, as well as by other oncogenic RAS pathway alterations that promote constitutive RAF dimer activation. BDTX-4933 demonstrated potent, on-target inhibition of the RAF-MEK-ERK signaling pathway and anti-tumor activity in multiple preclinical models, including intracranial tumor models.

Discovery-Stage Pipeline and MAP Drug Discovery Engine:

- Black Diamond continues to leverage its MAP drug discovery engine to advance its discovery-stage pipeline to bring therapies to underserved patients. Black Diamond anticipates progressing its fibroblast growth factor receptor (FGFR) program towards development candidate nomination and nomination of a development candidate against an undisclosed target in 2023.

Corporate:

- In June 2022, Black Diamond appointed Sergey Yurasov, M.D., Ph.D., as its Chief Medical Officer, bringing over 25 years of oncology drug development experience and regulatory expertise.
- In December 2022, Black Diamond announced that existing board member, Mark Velleca, M.D., Ph.D., was appointed to succeed Robert (Bob) A. Ingram as the Chairman of the Board of Directors.
- In December 2022, Black Diamond announced the spinout of Launchpad Therapeutics, Inc. (Launchpad), an antibody-focused precision oncology company incorporating Black Diamond's undisclosed early discovery stage antibody programs enabled by the MAP drug discovery engine. In conjunction with the transaction, a $30 million Series A financing was co-led by Versant Ventures and New Enterprise Associates (NEA) to fund discovery and development activities of the new company. Black Diamond retains a minority equity interest in Launchpad to enable further value creation.

Financial Highlights

- **Cash Position:** Black Diamond ended 2022 with approximately $122.8 million in cash, cash equivalents, and investments compared to $209.8 million as of December 31, 2021. Net cash used in operations was $85.1 million for the year ended December 31, 2022 compared to $100.1 million for the year ended December 31, 2021.
- **Research and Development Expenses:** Research and development (R&D) expenses were $14.6 million for the fourth quarter of 2022, compared to $19.7 million for the same period in 2021. Research and development expenses were $64.4 million for the year ended December 31, 2022, compared to $96.8 million for the year ended December 31, 2021. 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 upcoming milestones for our pipeline programs, BDTX-1535 and BDTX-4933.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $7.2 million for the fourth quarter of 2022, compared to $6.4 million for the same period in 2021, and $28.4 million for the year ended December 31, 2022, compared to $30.0 million for the year ended December 31, 2021. The decrease in G&A expenses was primarily due to a decrease in legal and other professional fees.
- **Net Loss:** Net loss for the fourth quarter of 2022 was $21.1 million, as compared to $25.9 million for the same period in 2021. Net loss for the year ended December 31, 2022 was $91.2 million compared to $125.6 million for the year ended December 31, 2021.

Financial Guidance

- Black Diamond ended 2022 with approximately $122.8 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 non-small cell lung cancer (NSCLC) and in glioblastoma multiforme (GBM), and BDTX-4933, a program targeting RAF MasterKey mutations in solid tumors, as well as discovery-stage research programs. The Company's proprietary Mutation-Allostery-Pharmacology, or 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 I clinical trial of BDTX-4933, the continued development of the FGFR program, including plans for nominating a development candidate, in addition to plans to disclose an additional development candidate against a new target, 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)

	December 31,	
	2022	2021
	(in thousands)	
Cash, cash equivalents, and investments	$ 122,807	$ 209,786
Total assets	$ 156,255	$ 247,682
Accumulated deficit	$ (334,989)	$ (243,820)
Total stockholders' equity (deficit)	$ 115,695	$ 195,900

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,609	$ 19,664	$ 64,437	$ 96,829
General and administrative	7,243	6,416	28,391	30,043
Total operating expenses	21,852	26,080	92,828	126,872
Loss from operations	(21,852)	(26,080)	(92,828)	(126,872)
Other income (expense):				
Interest income	677	588	2,031	3,464
Other income (expense)	115	(375)	(354)	(2,188)
Gain on sale of IP	2,232	—	2,232	—
Total other income (expense), net	3,024	213	3,909	1,276
Equity in (losses) of unconsolidated entity	(2,250)	—	(2,250)	—
Net loss	$ (21,078)	$ (25,867)	$ (91,169)	$ (125,596)
Net loss per share, basic and diluted	$ (0.59)	$ (0.71)	$ (2.52)	$ (3.47)
Weighted average common shares outstanding, basic and diluted	36,389,492	36,229,809	36,325,586	36,189,002

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