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

August 11, 2023

- *Announced initial clinical data from dose-escalation portion of Phase 1 clinical trial of BDTX-1535, an EGFR MasterKey inhibitor, demonstrating a favorable tolerability profile and clinical proof of activity based on radiographic tumor responses and circulating tumor DNA changes in NSCLC patients harboring acquired resistance and intrinsic driver EGFR mutations*
- *Initiated BDTX-1535 NSCLC expansion cohorts in July 2023; clinical update on BDTX-1535 Phase 1 dose escalation in GBM expected in the fourth quarter of 2023*
- *In July 2023, Black Diamond closed an underwritten public offering of 15,000,000 shares of its common stock at a public offering price of $5.00 per share for gross proceeds of approximately $75.0 million, before deducting underwriting discounts and commissions and other offering expenses*
- *Cash, cash equivalents, and investments of $89.5 million as of June 30, 2023; together with net proceeds from the July 2023 underwritten public offering, is expected to be sufficient to fund operations into the first half of 2025*

CAMBRIDGE, Mass. and NEW YORK, Aug. 11, 2023 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage precision oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with genetically defined cancers, today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

“The second quarter of 2023 marked a crucial period of clinical and operational execution for Black Diamond, and I am incredibly pleased with our initial dose escalation data demonstrating a favorable tolerability profile and clinical proof of activity for BDTX-1535 in NSCLC patients harboring acquired resistance and intrinsic driver EGFR mutations. With these data in hand, we believe we are well positioned for rapid advancement of this novel MasterKey inhibitor for NSCLC patients and are looking forward to meeting with FDA later this year to discuss our dose optimization strategy that may enable a potential accelerated approval pathway as well as the opportunity to study BDTX-1535 in newly diagnosed NSCLC patients with intrinsic driver mutations,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “Our recently completed underwritten public offering provides us with a strong cash position and extended runway to execute on the robust set of upcoming milestones for BDTX-1535 and our broader pipeline, all with the goal of bringing our MasterKey therapies to patients in need.”

Recent Developments & Upcoming Milestones:

BDTX-1535:

- In June 2023, Black Diamond announced initial clinical data from the dose escalation portion of the Phase 1 clinical study of BDTX-1535, an epidermal growth factor receptor (EGFR) MasterKey inhibitor, demonstrating a favorable tolerability profile and clinical proof of activity in non-small cell lung cancer (NSCLC) patients harboring both acquired resistance and intrinsic driver EGFR mutations. Key highlights from the readout include:
  - Confirmed radiographic partial response (PR) by RECIST 1.1 achieved across predicted therapeutic doses in 5 of 12 NSCLC patients in a subgroup, who had measurable disease at study start, and underwent post baseline tumor assessment by RECIST 1.1. One additional patient demonstrated unconfirmed PR, while the remaining six patients had stable disease.
  - Confirmed PRs were observed in NSCLC patients with a wide range of EGFR mutations including classical and intrinsic driver mutations and acquired C797S resistance mutation, as well as complex mutations that include a combination of classical, intrinsic, and acquired resistance mutations. Two NSCLC patients demonstrated radiographic improvement in the peripheral disease and central nervous system (CNS) metastases.
  - BDTX-1535 was generally well tolerated by NSCLC and glioblastoma multiforme (GBM) patients and the overall safety profile was consistent with the EGFR tyrosine kinase inhibitor (TKI) class of drugs. The most common drug-related adverse events were mild to moderate rash, diarrhea, stomatitis, paronychia, nausea and fatigue. No patients experienced dose limiting toxicity at 15-200 mg once-daily (QD) doses. One of 15 patients treated at the 300 mg QD dose experienced dose limiting diarrhea and 5 of 12 patients at the 400 mg QD dose experienced dose limiting toxicity (diarrhea, 2 patients; rash, stomatitis, fatigue and decreased appetite, 1 patient each). No unexpected safety signal was identified during dose escalation.
- In July 2023, Black Diamond initiated expansion cohorts to assess overall response rate (ORR) by RECIST 1.1 in NSCLC patients with EGFR acquired resistance mutations after progression on a third generation EGFR TKI and intrinsic driver mutations after progression on an EGFR TKI.
- Black Diamond anticipates the following key milestones for BDTX-1535:

- Presentation of the full BDTX-1535 dose escalation data in NSCLC at a medical conference in the fourth quarter of 2023.
- Meeting with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023 to align on dosing strategy to enable a potential accelerated approval pathway in NSCLC.
- Initiation of an expansion cohort in newly diagnosed NSCLC patients with intrinsic driver mutations after discussion with the FDA.
- Clinical update on BDTX-1535 Phase 1 dose escalation data in recurrent GBM patients in the fourth quarter 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 April 2023, Black Diamond presented a poster at the 2023 American Association of Cancer Research (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 initiated a Phase 1 clinical trial for BDTX-4933 in select indications for patients harboring all-class BRAF or RAS mutations in the second quarter of 2023.

BDTX-4876:

- BDTX-4876 is a development candidate FGFR 2/3 MasterKey inhibitor, selective against FGFR 2 and 3 alterations, while sparing FGFR 1 and 4.
- Black Diamond is evaluating strategic alternatives for BDTX-4876 as it deepens focus on its two clinical-stage assets.

Discovery-Stage Pipeline and MAP Drug Discovery Engine:

- Black Diamond continues to leverage its Mutation-Allostery-Pharmacology (MAP) drug discovery engine to advance its discovery-stage pipeline to bring therapies to underserved patients and expects to progress another undisclosed program in solid tumors to development candidate nomination in 2023.

Corporate:

- In June 2023, Black Diamond announced the promotion of Melanie Morrison to Chief Development Officer.
- In July 2023, Black Diamond closed an underwritten public offering (Follow-on Offering) of 15,000,000 shares of its common stock at a public offering price of $5.00 per share for gross proceeds of approximately $75.0 million, before deducting underwriting discounts and commissions and other offering expenses.

Financial Highlights

- **Cash Position:** Black Diamond ended the second quarter of 2023 with approximately $89.5 million in cash, cash equivalents, and investments compared to $122.8 million as of December 31, 2022. Net cash used in operations was $14.4 million for the second quarter of 2023 compared to $18.1 million for the second quarter of 2022.
- **Research and Development Expenses:** Research and development (R&D) expenses were $13.2 million for the second quarter of 2023, compared to $16.2 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 $6.9 million for the second quarter of 2023, compared to $7.0 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 second quarter of 2023 was $20.0 million, as compared to $23.2 million for the same period in 2022.

Financial Guidance

- Black Diamond ended the second quarter of 2023 with approximately $89.5 million in cash, cash equivalents and investments. The Company believes that the net proceeds from the Follow-on Offering, together with its existing cash, cash equivalents and investments, will enable the Company to fund its operating expenses and capital expenditure requirements into the first half of 2025.

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 a potential accelerated approval pathway for BDTX-1535 in NSCLC and the upcoming clinical update on BDTX-1535 in recurrent GBM patients, exploring strategic alternatives for BDTX-4876, 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)

	June 30, 2023	December 31, 2022
	(in thousands)	
Cash, cash equivalents, and investments	$ 89,527	$ 122,807
Total assets	$ 119,879	$ 156,255
Accumulated deficit	$ (375,016)	$ (334,989)
Total stockholders' equity (deficit)	$ 82,199	$ 115,695

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,154	$ 16,195	$ 27,907	$ 33,981
General and administrative	6,878	6,978	13,686	14,871
Total operating expenses	20,032	23,173	41,593	48,852
Loss from operations	(20,032)	(23,173)	(41,593)	(48,852)
Other income (expense):				
Interest income	539	386	1,161	792
Other income (expense)	341	(143)	405	(377)
Total other income (expense), net	880	243	1,566	415
Net loss	$ (19,152)	$ (22,930)	$ (40,027)	$ (48,437)
Net loss per share, basic and diluted	$ (0.52)	$ (0.63)	$ (1.09)	$ (1.33)
Weighted average common shares outstanding, basic and diluted	36,516,114	36,293,856	36,500,085	36,282,636

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