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

November 06, 2023

- *Presented BDTX-1535 Phase 1 dose escalation data showing durable anti-tumor activity and favorable safety profile in NSCLC patients across heterogeneous EGFR mutations at the October 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics*
- *BDTX-1535 NSCLC expansion cohorts enrolling, initial data expected in 2024*
- *BDTX-1535 Phase 1 dose escalation data in GBM expected later this year*
- *Dosed first patient in a Phase 1 trial of BDTX-4933, a brain-penetrant RAF inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors*
- *Cash, cash equivalents, and investments of $144.3 million as of September 30, 2023, expected to be sufficient to fund operations into the first half of 2025*

CAMBRIDGE, Mass. and NEW YORK, Nov. 06, 2023 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with genetically defined cancers, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"We made significant progress advancing our lead program BDTX-1535 and presented positive results in patients with NSCLC from our Phase 1 clinical trial at the AACR-NCI-EORTC Meeting and are now rapidly enrolling the dose expansion cohorts of the trial," said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "We have a strong cash position that will allow us to reach numerous important milestones, including dose expansion data for BDTX-1535 in patients with NSCLC, dose escalation data for BDTX-1535 in patients with GBM, and initial Phase 1 data for BDTX-4933 in KRAS, NRAS, and BRAF mutated cancers with an emphasis on NSCLC."

Recent Developments & Upcoming Milestones:

BDTX-1535:

- In September 2023, Black Diamond announced the dosing of the first patients in the BDTX-1535 Phase 1 clinical trial expansion cohorts. This trial is assessing overall response rate (ORR) by RECIST 1.1 and durability of response in patients with non-small cell lung cancer (NSCLC) across two cohorts: one cohort for patients with the epidermal growth factor receptor (EGFR) acquired resistance C797S mutation after progression on a third generation EGFR tyrosine kinase inhibitor (TKI), and a second cohort for patients with non-classical (intrinsic) driver mutations after progression on an EGFR TKI (NCT05256290).
- In October 2023, Black Diamond presented a poster with new clinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics from the dose escalation portion of the Phase 1 clinical trial of BDTX-1535 in patients with NSCLC. Data shared at this conference reflect 27 patients with advanced/metastatic NSCLC who received a range of doses spanning 25mg to 400mg once daily. These results demonstrated a favorable tolerability profile and durable responses in patients with NSCLC expressing both acquired resistance C797S and non-classical driver EGFR mutations.
- Key highlights from the presentation include:
    - **Durable clinical responses at starting dose of 100mg or above in patients with NSCLC who had multiple lines of prior therapy.** Five of the 13 patients with either non-classical driver, acquired resistance C797S or complex mutations had a confirmed partial response (PR) by RECIST 1.1. Evidence of reduction in brain metastases was observed, including a patient with more than three prior therapies. Three responders continue on therapy for greater than six months (two confirmed PRs, one unconfirmed PR). One patient with confirmed PR remained on therapy for six months. Two additional patients with stable disease continue on therapy for greater than 12 months. Eradication of targeted variant alleles and significant circulating tumor DNA (ctDNA) reductions were observed for all NSCLC EGFR mutation subtypes in patients treated with BDTX-1535 across dose levels.
    - **Favorable emerging safety profile.** The majority of adverse events (AEs) at doses of 100mg and 200mg were mild or moderate, and no unexpected safety signals were identified. No dose limiting toxicities (DLTs) were observed at 200mg or below.
- In October 2023, enrollment began in a Phase 0/1 "window of opportunity" clinical trial of BDTX-1535 in patients with recurrent high-grade glioma. The trial is sponsored by the Ivy Brain Tumor Center in Phoenix, Arizona and is enrolling

patients prior to a planned resection. Patients achieving adequate drug levels in the gadolinium non-enhancing regions of the tumor will continue with treatment following surgery.

- Black Diamond anticipates the following upcoming key milestones for BDTX-1535:
  - End-of-Phase 1 Meeting with the U.S. Food and Drug Administration (FDA) later this year.
  - Expansion cohort data in patients with non-classical driver and acquired resistance EGFR mutant NSCLC in 2024.
  - Phase 1 dose escalation data in patients with relapsed and recurrent GBM later this year.
  - Initial results from an investigator sponsored “window of opportunity” trial in patients with GBM in the second quarter of 2024.

BDTX-4933:

- BDTX-4933 is an oral, brain-penetrant RAF MasterKey inhibitor designed to address oncogenic alterations in KRAS, NRAS and BRAF, while also avoiding paradoxical activation.
- A Phase 1 clinical trial for BDTX-4933 was initiated in the second quarter of 2023 in patients with BRAF and select RAS/MAPK mutation-positive cancers, with an emphasis on patients with KRAS mutant NSCLC. The trial is currently in dose escalation (NCT05786924).
- In October 2023, Black Diamond presented a poster at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics detailing preclinical data for BDTX-4933.
- Preclinical results showed that BDTX-4933 potently and selectively inhibited the proliferation of tumor cells expressing a range of KRAS, NRAS and BRAF mutations, suggesting clear differentiation compared to other RAF inhibitors. BDTX-4933 demonstrated strong anti-tumor activity and regression across preclinical models expressing several MAPK pathway mutations, including KRAS G12D, KRAS G12V, and KRAS G13C mutant NSCLC models. BDTX-4933 exhibited high central nervous system (CNS) exposure with dose-dependent tumor growth inhibition and survival benefit in an intracranial xenograft model.

Corporate:

- In September 2023, Black Diamond announced a CEO transition, appointing Chairman of the Board Mark Velleca, M.D., Ph.D. to President and Chief Executive Officer.

Financial Highlights

- **Cash Position:** Black Diamond ended the third quarter of 2023 with approximately $144.3 million in cash, cash equivalents, and investments compared to $122.8 million as of December 31, 2022. Net cash used in operations was $18.4 million for the third quarter of 2023 compared to $16.5 million for the third quarter of 2022.
- **Research and Development Expenses:** Research and development (R&D) expenses were $16.2 million for the third quarter of 2023, compared to $15.8 million for the same period in 2022. The increase in R&D expenses was primarily due to the advancement of the Company’s pipeline programs, BDTX-1535 and BDTX-4933.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $7.9 million for the third quarter of 2023, compared to $6.3 million for the same period in 2022. The increase in G&A expenses was primarily due to costs related to the transition of its former President and Chief Executive Officer in the third quarter of 2023, as well as an increase in legal and other professional fees.
- **Net Loss:** Net loss for the third quarter of 2023 was $23.0 million, as compared to $21.7 million for the same period in 2022.

Financial Guidance

- Black Diamond ended the third quarter of 2023 with approximately $144.3 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 first half of 2025.

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage oncology company focused on the development of MasterKey therapies that address families of oncogenic mutations in clinically validated targets. The Company’s MasterKey therapies are designed to address broad genetically defined patient populations, overcome resistance, minimize wild-type mediated toxicities, and be brain-penetrant to treat CNS disease. The Company is advancing two clinical stage programs: BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR mutant NSCLC and GBM, and BDTX-4933, a brain penetrant RAF MasterKey inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors. 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

clinical updates on the dose expansion cohorts of the BDTX-1535 in patients with NSCLC and on dose escalation data for BDTX-1535 in patients with recurrent GBM, the timing of meeting with regulatory agencies 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)

	September 30, 2023	December 31, 2022
	(in thousands)	
Cash, cash equivalents, and investments	$ 144,256	$ 122,807
Total assets	$ 172,382	$ 156,255
Accumulated deficit	$ (398,023)	$ (334,989)
Total stockholders' equity (deficit)	$ 134,317	$ 115,695

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 16,154	$ 15,847	$ 44,061	$ 49,828
General and administrative	7,858	6,277	21,544	21,148
Total operating expenses	24,012	22,124	65,605	70,976
Loss from operations	(24,012)	(22,124)	(65,605)	(70,976)
Other income (expense):				
Interest income	439	562	1,600	1,354
Other income (expense)	566	(92)	971	(469)
Total other income (expense), net	1,005	470	2,571	885
Net loss	$ (23,007)	$ (21,654)	$ (63,034)	$ (70,091)
Net loss per share, basic and diluted	$ (0.45)	$ (0.60)	$ (1.54)	$ (1.93)
Weighted average common shares outstanding, basic and diluted	50,943,155	36,346,181	41,367,347	36,304,050

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