Black Diamond Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 12, 2024

- *Dosed first patient in Phase 2 trial of BDTX-1535 in 1L patients with non-classical EGFRm NSCLC*
- *Clinical data on track for Q3 2024 in Phase 2 trial of BDTX-1535 in 2L/3L patients with acquired resistance or non-classical EGFRm NSCLC*
- *Oral presentation at AACR annual meeting in April 2024 describing real world evidence of an evolving EGFR mutation landscape in NSCLC, and the potential of BDTX-1535 to benefit patients across multiple lines of therapy*
- *Additional planned data releases for 2024 include GBM results for BDTX-1535 in Q2, and initial results for BDTX-4933 in non-G12C KRASm NSCLC in Q4*
- *Cash, cash equivalents, and investments of $131.4 million as of December 31, 2023, expected to be sufficient to fund operations into the second quarter of 2025*

CAMBRIDGE, Mass., March 12, 2024 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage oncology company focused on the development of MasterKey therapies to treat patients with genetically defined tumors, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

“The year 2023 was exciting, with generation of clinical data that positions BDTX-1535 as a potential first and best in class 4th generation EGFR TKI, and we recently began dosing first-line patients in a Phase 2 trial in NSCLC with non-classical mutations,” said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “This year will be data rich across our pipeline, with Phase 2 data for BDTX-1535 in NSCLC, additional GBM results, and initial Phase 1 data for BDTX-4933 in non-G12C KRAS mutated NSCLC.”

Recent Developments & Upcoming Milestones:

BDTX-1535:

- In October 2023, Black Diamond presented a poster with updated clinical data at the European Organization for Research and Treatment of Cancer-National Cancer Institute-American Association for Cancer Research (EORTC-NCI-AACR) Symposium on Molecular Targets and Cancer Therapeutics from the dose escalation portion of the Phase 1 clinical trial of BDTX-1535 in patients with non-small cell lung cancer (NSCLC). The presentation included clinical data from 27 patients with advanced/metastatic NSCLC who received once daily doses ranging from 25mg to 400mg. These results demonstrated a favorable tolerability profile and durable responses in patients with NSCLC expressing both acquired resistance C797S and non-classical driver epidermal growth factor receptor (EGFR) mutations.
- Following receipt of End of Phase 1 feedback from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023, Black Diamond initiated a Phase 2 cohort in first-line (1L) patients with non-classical EGFR mutations in early 2024. (NCT05256290)
- Phase 0/1 “window of opportunity” clinical trial of BDTX-1535 began enrollment in October 2023 to evaluate the pharmacokinetic, pharmacodynamic, and clinical response in patients with recurrent high-grade glioma (HGG) with EGFR alterations and/or fusions who are undergoing a planned surgical resection. The trial is sponsored by the Ivy Brain Tumor Center in Phoenix, Arizona. (NCT06072586)
- Top-line results disclosed in December 2023 from the Phase 1 dose escalation trial of BDTX-1535 in patients with relapsed/recurrent glioblastoma (GBM) showed clinical activity in heavily pretreated patients. BDTX-1535 was shown to be generally well tolerated, with no new safety signals observed.
- Black Diamond anticipates the following upcoming key milestones for BDTX-1535:
  - Oral presentation describing real world data of the evolving EGFR mutation landscape in patients with NSCLC, and the MasterKey profile of BDTX-1535 addressing a broad spectrum of mutations at the American Association for Cancer Research (AACR) annual meeting on April 7, 2024.
  - Phase 2 clinical data in patients with NSCLC and non-classical driver or acquired resistance EGFR mutations in the third quarter of 2024.
  - Phase 1 dose escalation data in patients with relapsed/recurrent GBM, and initial results from the investigator sponsored “window of opportunity” trial in patients with recurrent HGG are expected to be presented at a medical meeting in the second quarter of 2024.

BDTX-4933:

- In October 2023, Black Diamond presented a poster at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics detailing preclinical data for the clinical-stage MasterKey RAF inhibitor BDTX-4933, a brain-penetrant oral inhibitor of oncogenic alterations in KRAS, NRAS and BRAF. 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.

- 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 with an update anticipated in the fourth quarter of 2024. (NCT05786924)

Financial Highlights

- **Cash Position:** Black Diamond ended 2023 with approximately $131.4 million in cash, cash equivalents, and investments compared to $122.8 million as of December 31, 2022. Net cash used in operations was $66.7 million for the year ended December 31, 2023 compared to $85.1 million for the year ended December 31, 2022.
- **Research and Development Expenses:** Research and development (R&D) expenses were $15.3 million for the fourth quarter of 2023, compared to $14.6 million for the same period in 2022. Research and development expenses were $59.4 million for the year ended December 31, 2023, compared to $64.4 million for the year ended December 31, 2022. The decrease in R&D expenses was primarily due to reduced spending on early discovery projects as we deepen our focus on our clinical-stage assets.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $5.6 million for the fourth quarter of 2023, compared to $7.2 million for the same period in 2022, and $27.1 million for the year ended December 31, 2023, compared to $28.4 million for the year ended December 31, 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 fourth quarter of 2023 was $19.4 million, as compared to $21.1 million for the same period in 2022. Net loss for the year ended December 31, 2023 was $82.4 million compared to $91.2 million for the year ended December 31, 2022.

Financial Guidance

- Black Diamond ended 2023 with approximately $131.4 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 second quarter 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 clinical trials and the timing of clinical updates for BDTX-1535 in patients with NSCLC and in patients with recurrent GBM, and for Phase 1 clinical trial results for BDTX-4933, the expected timing for additional updates on data from the "window of opportunity" clinical trial of BDTX-1535 in patients with recurrent HGG, potential future development plans for BDTX-1535 in NSCLC and GBM, including in first-line settings, 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, 2023, 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,	
	2023	2022
	(in thousands)	

Cash, cash equivalents, and investments	$ 131,400	$ 122,807
Total assets	$ 158,567	$ 156,255
Accumulated deficit	$ (417,431)	$ (334,989)
Total stockholders' equity	$ 116,736	$ 115,695

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 15,289	$ 14,609	$ 59,350	$ 64,437
General and administrative	5,566	7,243	27,110	28,391
Total operating expenses	20,855	21,852	86,460	92,828
Loss from operations	(20,855)	(21,852)	(86,460)	(92,828)
Other income (expense):				
Interest income	324	677	1,924	2,031
Other income (expense)	1,123	115	2,094	(354)
Gain on sale of IP	—	2,232	—	2,232
Total other income (expense), net	1,447	3,024	4,018	3,909
Equity in (losses) of unconsolidated entity	—	(2,250)	—	(2,250)
Net loss	$ (19,408)	$ (21,078)	$ (82,442)	$ (91,169)
Net loss per share, basic and diluted	$ (0.34)	$ (0.59)	$ (1.88)	$ (2.52)
Weighted average common shares outstanding, basic and diluted	51,637,433	36,389,492	43,954,649	36,325,586

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