Black Diamond Therapeutics Announces Corporate Update and Expected 2024 Milestones

January 04, 2024

FDA feedback on BDTX-1535 enables initiation of Phase 2 cohort in first-line treatment of non-classical EGFR mutant NSCLC

Fast Track Designation granted for BDTX-1535 as second-line treatment for EGFR mutant/C797S NSCLC

BDTX-1535 Phase 2 results for 2L/3L patients with EGFR mutant NSCLC expected Q3 2024

BDTX-1535 Phase 1 clinical trial results and "window of opportunity" data in patients with EGFR mutant GBM expected to be presented at a medical meeting in Q2 2024

BDTX-4933 Phase 1 results in patients with KRAS mutant NSCLC expected Q4 2024

Existing cash, cash equivalents and investments expected to be sufficient to fund milestone achievements and operations into Q2 2025

CAMBRIDGE, Mass., Jan. 04, 2024 (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 provided a corporate update outlining clinical development plans and anticipated corporate milestones for 2024.

"We made significant progress in 2023 and sharpened our focus on our clinical programs: BDTX-1535 in both EGFR mutant NSCLC and GBM, and BDTX-4933 in KRAS mutant NSCLC," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "In 2024, we anticipate key readouts from each of these programs, including Phase 2 data from BDTX-1535 in NSCLC. Moreover, recent FDA feedback enables the enrollment of first-line NSCLC patients into the Phase 2 trial, reflecting the potential of BDTX-1535 to benefit patients in earlier lines of therapy. Due to disciplined spend, we expect our cash to be sufficient for this year's milestones and to extend into the second quarter of 2025."

Clinical Program Updates/Anticipated 2024 Milestones

BDTX-1535 in patients with Epidermal Growth Factor Receptor (EGFR) mutant Non-Small Cell Lung Cancer (NSCLC)

- Dose escalation results were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2023. Phase 2 data in second/third-line patients with EGFR mutant NSCLC are expected in the third quarter of 2024. The Company intends to discuss Phase 2 results with the U.S. Food and Drug Administration (FDA) to finalize a pivotal clinical trial design.
- BDTX-1535 received Fast Track Designation for the treatment of patients with EGFR mutant C797S-positive NSCLC whose disease has progressed on/after a third-generation EGFR tyrosine kinase inhibitor (TKI).
- Following End of Phase 1 feedback received from the FDA in the fourth quarter of 2023, a Phase 2 cohort in first-line patients with non-classical EGFR mutant NSCLC is being initiated.
- The Company is also exploring the potential development of BDTX-1535 in first-line patients who are post-osimertinib adjuvant treatment.

BDTX-1535 in patients with EGFR mutant Glioblastoma (GBM)

- Following release of top-line Phase 1 data in December 2023, presentation of Phase 1 trial results is anticipated at a medical meeting in the second quarter of 2024.
- Enrollment is ongoing in a "window of opportunity" trial sponsored by the Ivy Brain Tumor Center in patients with recurrent glioma who are undergoing a planned resection. Results from this trial are expected to be presented at a medical meeting in the second quarter of 2024.
- The Company expects that results from the dose escalation and "window of opportunity" trials will inform the next steps in the GBM development program, including a potential randomized trial in the first-line setting.

BDTX-4933 in patients with KRAS mutant NSCLC

- BDTX-4933 was designed as a "RAF/RAS clamp" to target the activated RAF conformation in the context of either RAF or RAS mutations, a mechanism distinct from earlier generation RAF inhibitors.
- Enrollment in a Phase 1 trial began in September 2023 in patients with KRAS mutant NSCLC. Results from this trial are anticipated in the fourth quarter of 2024.

About BDTX-1535
BDTX-1535 is an oral, brain-penetrant MasterKey inhibitor of oncogenic epidermal growth factor receptor (EGFR) mutations in non-small cell lung cancer (NSCLC), including classical driver mutations, families of non-classical driver mutations (e.g., L747P, L718Q), acquired resistance C797S mutation, and complex mutations. BDTX-1535 is a fourth-generation tyrosine kinase inhibitor (TKI) that potently inhibits, based on preclinical data, more than 50 oncogenic EGFR mutations expressed across a diverse group of patients with NSCLC in multiple lines of therapy. Based on preclinical data, BDTX-1535 also inhibits EGFR extracellular domain mutations and alterations commonly expressed in glioblastoma (GBM) and avoids paradoxical activation observed with earlier generation reversible TKIs. A "window of opportunity" trial of BDTX-1535 in patients with GBM is ongoing (NCT06072586) and a Phase 2 trial is currently ongoing in patients with NSCLC (NCT05256290).

About BDTX-4933
BDTX-4933 is an oral, brain-penetrant RAF MasterKey inhibitor designed to target oncogenic alterations in KRAS, NRAS and BRAF, while also avoiding paradoxical activation. In preclinical studies, BDTX-4933 has demonstrated a potential best-in-class profile, showing potent target engagement, inhibition of MAPK signaling and strong anti-tumor activity/tumor regression across tumor models driven by either KRAS, NRAS or BRAF mutations. BDTX-4933 also exhibits high central nervous system (CNS) exposure leading to dose-dependent tumor growth inhibition and a survival benefit in an intracranial tumor model harboring oncogenic BRAF mutation. The ongoing BDTX-4933 Phase 1 clinical trial is currently in dose escalation with emphasis on KRAS mutant NSCLC patients (NCT05786924).

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 potential of BDTX-1535 to benefit patients with NSCLC in earlier lines of therapy, 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, 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.

Contacts

For Investors:
Mario Corso, Head of Investor Relations, Black Diamond Therapeutics
mcorso@bdtx.com

For Media:
media@bdtx.com