



Bolt Biotherapeutics Announces First Patient Dosed in Phase 1/2 Study of BDC-3042 in Patients with Advanced Cancers

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- BDC-3042, a novel Dectin-2 agonistic antibody that stimulates the innate immune system, is being evaluated in a Phase 1/2 dose-escalation and expansion study in patients with a broad range of solid tumors

REDWOOD CITY, Calif., Oct. 17, 2023 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today announced that the first patient has been dosed with BDC-3042 in the single-agent dose-escalation portion of this first-in-human Phase 1/2 clinical study. The study will evaluate BDC-3042 in patients with metastatic or unresectable triple-negative breast cancer (TNBC), colorectal cancer, clear cell renal cell carcinoma, head and neck cancer, non-small cell lung cancer (NSCLC), or ovarian cancer.

"We are excited to have dosed the first patient in this first-in-human clinical trial, which will evaluate the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of BDC-3042 in a diverse set of advanced cancers," said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. "BDC-3042 is a monoclonal antibody that repolarizes tumor-associated macrophages (TAMs) to attack tumor cells and is the first-in-class Dectin-2 agonist. As Dectin-2 gene expression is elevated in TAMs across a broad range of solid tumor types, we see potential for this novel immunotherapy to be used for a wide range of cancers. We are enthusiastic to advance our second innovative immunotherapy program to the clinic with a focus on providing breakthroughs for patients."

"TAMs are a major component of the immune infiltrate in most cancers and play a key role in establishing an immunosuppressive tumor microenvironment that enables tumor progression," explained Shelley Ackerman, Ph.D., Director & BDC-3042 Preclinical Project Team Lead. "In preclinical studies, BDC-3042 has shown the ability to repolarize TAMs from a tumor-supportive to a tumor-destructive phenotype."

About the Phase 1 Trial

The Phase 1 trial (NCT06052852) is a multi-center, open-label, dose-escalation and dose-expansion study enrolling patients in the US with advanced malignancies including triple-negative breast cancer, clear cell renal cell carcinoma, colorectal cancer, head and neck cancer, non-small cell lung cancer, and ovarian cancer. The study has four parts. Part 1 is a dose escalation of BDC-3042 as a single agent to determine the recommended Phase 2 dose (RP2D) for Part 3. In Part 3, the selected dose will be administered as monotherapy to patients with selected advanced malignancies. Part 2 is a dose escalation of BDC-3042 in combination with a checkpoint inhibitor to determine the RPD2 for Part 4. In Part 4, the selected dose will be administered in combination with a checkpoint inhibitor to patients with select malignancies.

About BDC-3042

Bolt Biotherapeutics' myeloid-modulating antibody, BDC-3042, leverages the power of myeloid cells to stimulate anti-tumor activity. It agonizes Dectin-2, an immune-activating pattern recognition receptor expressed by tumor-associated macrophages (TAMs) which are frequently found in the tumor microenvironment. TAMs play a key role in establishing an immunosuppressive tumor microenvironment that is conducive to tumor survival and progression. By agonizing Dectin-2, BDC-3042 activates TAMs to produce pro-inflammatory cytokines and chemokines and repolarizes TAMs into immunostimulatory macrophages. In addition, BDC-3042 induces expression of key antigen presentation machinery, which helps to expand tumor-reactive T cells and elicit anti-tumor immunity.

About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics is a clinical-stage biopharmaceutical company leveraging the immune system for a better way to treat cancer. The company is developing novel immunotherapies using an approach that teaches the immune system to recognize and kill cancer in a way that is immediately personalized to each patient. Its pipeline candidates are built on the Company's deep expertise in myeloid biology and cancer drug development and include BDC-1001, a HER2-targeting Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) being evaluated in a Phase 2 trial, and BDC-3042, a myeloid-modulating agonist antibody targeting Dectin-2, being evaluated in a Phase 1 trial. Bolt Biotherapeutics is also developing multiple Boltbody™ ISACs in strategic collaborations with leading biopharmaceutical companies. For more information, please visit <https://www.boltbio.com/>.

Forward-Looking Statements

This press release contains forward-looking statements about us and our industry that involve substantial risks and uncertainties and are based on our beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts contained in this press release, including statements regarding the advancement and success of our clinical trials and any potential future patent term extensions or adjustments, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "on track," "plan," "potential," "predict," "project," "should," "will," or "would," or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our current beliefs, estimates and assumptions only as of the date of this press release and information contained in this press release should not be relied upon as representing our

estimates as of any subsequent date. These statements, and related risks, uncertainties, factors and assumptions, include, but are not limited to: the potential product candidates that we develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; clinical trials may not demonstrate the desired safety, potency or other product characteristics described or assumed in this press release; and such product candidates may not be beneficial to patients or become commercialized. These risks are not exhaustive. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Further information on factors that could cause actual results to differ materially from the results anticipated by our forward-looking statements is included in the reports we have filed or will file with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022. These filings, when available, are available on the investor relations section of our website at investors.boltbio.com and on the SEC's website at www.sec.gov.

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