Bolt Biotherapeutics Initiates Phase 2 Clinical Studies of BDC-1001 in Patients With HER2-Positive Cancer

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- BDC-1001 is a Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) in development for HER2-positive breast, colorectal, endometrial, and gastroesophageal cancers
- BDC-1001 administered to initial patients in Phase 2 dose-expansion cohorts

REDWOOD CITY, Calif., Aug. 03, 2023 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics, Inc. (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today announced that the first patients have been dosed in a Phase 2 dose-expansion clinical trial investigating BDC-1001, a HER2-targeting Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC). The trial will explore BDC-1001 monotherapy treatment in three discrete cohorts for patients with HER2-positive colorectal, endometrial and gastroesophageal cancers.

“This is an important milestone for our company that builds on the positive signal of monotherapy activity that we observed in the Phase 1 portion of the study,” said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. “Despite considerable advances in anti-cancer therapy, HER2-positive tumors remain difficult to treat, and new therapeutic options are urgently needed. Our ISAC platform brings a novel mechanism with the potential to address refractory and recurrent disease to the treatment of HER2+ cancers and BDC-1001 has demonstrated promise. We are committed to advancing this study for the benefit of the many patients in need.”

Bolt’s BDC-1001 Phase 2 program includes discrete cohorts across four different HER2-positive tumor types and utilizes a Simon two-stage design with the aim of replicating the approximately 30% objective response rate previously demonstrated in the Phase 1 study. The Phase 2 dose-expansion trial is initially investigating BDC-1001 as a monotherapy in each of the three separate cohorts (HER2-positive colorectal, endometrial, and gastroesophageal cancer). This multi-center, open-label Phase 2 trial will evaluate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of BDC-1001 administered intravenously at 20 mg/kg every other week (q2w). Please refer to clinicaltrials.gov [NCT04278144] for additional information.

The company is conducting an additional Phase 2 study, a randomized two-arm Phase 2 trial investigating BDC-1001 in patients with HER2-positive metastatic breast cancer whose disease progressed following treatment with Enhertu®.

About BDC-1001

Bolt Biotherapeutics’ lead program, BDC-1001, is a human epidermal growth factor receptor 2 (HER2) ISAC comprising a HER2-targeting biosimilar of trastuzumab conjugated with a non-cleavable linker to a proprietary TLR7/8 agonist. Following the successful completion of the BDC-1001 dose-escalation trial for the treatment of patients with HER2-expressing solid tumors, Bolt is now conducting two Phase 2 clinical trials (NCT04278144 and NCT05954143) in patients with HER2-positive solid tumors in the U.S., Europe, and South Korea.

About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform

Bolt Biotherapeutics’ Boltbody ISAC platform harnesses the precision of antibodies with the power of the innate and adaptive immune system to reprogram the tumor microenvironment to generate a productive anti-cancer response. Each Boltbody ISAC candidate comprises a tumor-targeting antibody, a non-cleavable linker and a proprietary immune stimulant. The antibody is designed to target one or more markers on the surface of a tumor cell, and the immune stimulant is designed to recruit and activate myeloid cells. Activated myeloid cells initiate a positive feedback loop by releasing cytokines and chemokines, chemical signals that attract other immune cells and lower the activation threshold for an immune response. This increases the population of activated immune system cells in the tumor microenvironment and promotes a robust immune response with the goal of generating durable therapeutic responses for patients with cancer.

About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics is a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer. Bolt Biotherapeutics’ pipeline candidates are built on the Company’s deep expertise in myeloid biology and cancer drug development. The Company’s pipeline includes BDC-1001, a HER2-targeting Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC); BDC-3042, a myeloid-modulating antibody; and multiple Boltbody ISAC collaboration programs. BDC-1001 is currently in Phase 2 clinical development following the successful completion of a Phase 1 dose-escalation trial that demonstrated tolerability and early clinical efficacy. BDC-3042, an agonist antibody targeting Dectin-2, is expected to initiate a Phase 1 trial in the second half of 2023. In preclinical development, BDC-3042 demonstrated the ability to convert tumor-supportive macrophages to tumor-destructive macrophages. 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, the potential profile of BDC-1001, and the commencement of future clinical trials, 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 confirm any safety, potency or other product characteristics described or assumed in this press release; such product candidates may not be beneficial to patients or become commercialized; and our ability to maintain our current collaborations and establish further collaborations. 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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