Bolt Biotherapeutics to Present Clinical Data from Phase 1 Dose-Escalation Trial of BDC-1001 in HER2-Expressing Tumors at 2023 ASCO Annual Meeting

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- Comprehensive Phase 1 data at ASCO support initiation of two Phase 2 trials

REDWOOD CITY, Calif., April 26, 2023 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics, Inc. (Nasdaq: BOLT), a clinical-stage biopharmaceutical company pioneering novel immuno-oncology therapeutics for the treatment of cancer, today announced that it will present a poster with clinical data from its completed Phase 1 dose-escalation study of BDC-1001 at the 2023 American Society for Clinical Oncology (ASCO) Annual Meeting. The conference is being held at McCormick Place in Chicago, Illinois and virtually from June 2-6, 2023.

BDC-1001 is an investigational Immune-Stimulating Antibody Conjugate (ISAC) in development for the treatment of patients with HER2-expressing cancer. The ASCO presentation will include comprehensive results from the company's Phase 1 single-agent and combination dose-escalation trial of BDC-1001 that enrolled more than 100 patients.

"We look forward to presenting a comprehensive data set at ASCO that provides detailed safety, efficacy, pharmacokinetic and pharmacodynamic results from our recently completed Phase 1 dose-escalation trial evaluating BDC-1001 as a single agent and in combination with nivolumab," said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. "These data support the recommended Phase 2 dose and schedule for BDC-1001. We are making steady progress towards initiating two Phase 2 studies in 2023 evaluating BDC-1001 in multiple single-agent solid tumor settings, and in combination with nivolumab supplied by our partner BMS and with pertuzumab supplied by our partner Roche."

Details about the presentation can be found below and on the ASCO website. Additionally, a copy of the poster will be available on the Publications page of the Bolt Biotherapeutics website following the conference.

- **Title**: A phase 1/2 study of a first-in-human immune-stimulating antibody conjugate (ISAC) BDC-1001 in patients with advanced HER2-expressing solid tumors
- **Presenter:** Bob Li, M.D., Ph.D., MPH, medical oncologist, and principal investigator at Memorial Sloan Kettering Cancer Center (MSK)
- **Abstract Presentation Number:** 2538
- **Poster Session:** Developmental Therapeutics—Immunotherapy
- **Details:** Saturday, June 3, 2023, 8:00 a.m. - 11:00 a.m. CDT

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 completion of the BDC-1001 dose-escalation trial for the treatment of patients with HER2-expressing solid tumors, BDC-1001 is entering two Phase 2 clinical trials (NCT04278144) in patients with HER2-positive solid tumors. Despite the availability of multiple HER2-targeted agents, patients with advanced disease and many with early disease require multiple lines of therapy to achieve disease control, improve quality of life and extend survival. This includes patients with tumor types other than breast cancer, where HER2 protein overexpression or gene amplification have been well documented in a wide range of malignancies. The Phase 2 clinical plan for BDC-1001 includes two distinct studies to be conducted in U.S., Europe, and South Korea, each using a Simon two-stage design. A Phase 2 dose-expansion will initially investigate BDC-1001 as a monotherapy, enrolling three separate cohorts for patients with HER2-positive colorectal, endometrial, and gastroesophageal cancer; combination arms with nivolumab are expected to initiate in each indication following demonstration of monotherapy anti-tumor activity. The second study is a randomized two-arm Phase 2 clinical trial investigating BDC-1001 as monotherapy and in combination with pertuzumab in patients with HER2-positive metastatic breast cancer whose disease has progressed following treatment with Enhertu.

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 has completed a Phase 1 dose-escalation study demonstrating tolerability and early clinical efficacy, and the Company plans to initiate Phase 2 studies in 2023. Bolt Biotherapeutics is advancing BDC-3042, an agonist antibody targeting Dectin-2, through IND-enabling activities and expects 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 leveraging its ability to engineer and optimize novel applications of its Boltbody ISACs to develop multiple immuno-oncology candidates through 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 poster presentation at ASCO 2023, the advancement and success of our clinical trials and the expansion of our clinical trials across Europe, and the success of our collaborations and the ability of our clinical collaboration partners to supply nivolumab and pertuzumab 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.

Dr. Li has provided uncompensated advisory board services to Bolt Biotherapeutics.

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