Bolt Biotherapeutics to Present New Clinical Data from Completed Phase 1/2 Dose-Escalation Trial of BDC-1001 in HER2-Expressing Solid Tumors at the ESMO Congress 2023

October 16, 2023

REDWOOD CITY, Calif., Oct. 16, 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 updated clinical data from its Phase 1/2 dose-escalation study of BDC-1001 will be presented in a mini-oral presentation at the European Society for Medical Oncology (ESMO) Congress 2023, being held in Madrid, Spain and virtually from October 20-24, 2023.

BDC-1001 is an investigational Immune-Stimulating Antibody Conjugate (ISAC) in development for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive cancer. The ESMO presentation will include new results from the recently completed first-in-human Phase 1/2 dose-escalation study of BDC-1001 in patients with advanced HER2-expressing solid tumors.

“The upcoming presentation at ESMO builds on the positive data we presented at ASCO 2023 with additional insights into efficacy, safety, and biomarkers. These data provide further support for the recommended Phase 2 dose (RP2D) being used in the ongoing Phase 2 study of BDC-1001,” said Edith A. Perez, Chief Medical Officer of Bolt Biotherapeutics. “We are proud of the significant progress we have made with BDC-1001 and these latest data reinforce that Boltbody™ ISACs can activate a patient’s immune system to fight cancer. We continue to advance BDC-1001 through the Phase 2 clinical studies in four HER2-positive solid tumor types.”

Details about the presentation can be found below and on the ESMO website.

- **Title:** Recommended phase 2 dose (RP2D) selection and pharmacodynamic (PD) data of the first-in-human immune-stimulating antibody conjugate (ISAC) BDC-1001 in patients (pts) 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)
- **Presentation Number:** 657
- **Time:** Monday, October 23, 2023, 4:35 – 4:40 p.m. CET

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 in the U.S., Europe, and South Korea: NCT04278144 for patients with colorectal, endometrial, and gastroesophageal cancers and NCT05954143 for patients with breast cancer.

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 ability of BDC-1001 to address unmet patient needs, the potential for orphan drug designation to help with development, the benefits afforded by orphan drug designation, and advancement and success of our 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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