Bolt Biotherapeutics Receives Orphan Drug Designation for BDC-1001 for Treatment of Gastric Cancers

September 28, 2023

- BDC-1001 is a Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) in Phase 2 development for HER2-positive breast, colorectal, endometrial, and gastroesophageal cancers
- The FDA granted BDC-1001 Orphan Drug Designation for the treatment of gastric cancer, including gastroesophageal junction cancer

REDWOOD CITY, Calif., Sept. 28, 2023 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for BDC-1001 for the treatment of gastric cancer, including gastroesophageal junction cancer.

“Receiving Orphan Drug Designation from the FDA is an important step forward in the development of BDC-1001 and reinforces the potential of BDC-1001 to address unmet needs for patients with gastric cancers,” said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. “Our Boltbody™ ISAC platform is the only one with emerging clinical validation, and we are working diligently to advance our ongoing Phase 2 program. In addition to gastric cancer, we are also evaluating BDC-1001 in three other tumor types with significant unmet medical need: HER2-positive breast, colorectal, and endometrial cancers. We look forward to advancing BDC-1001 in clinical development and bringing this novel immunotherapy to patients in need of further treatment options.”

The Office of Orphan Products Development of FDA grants Orphan Drug Designation to drugs and biologics intended for the treatment, diagnosis, or prevention of rare diseases, or conditions affecting fewer than 200,000 people in the United States. The designation affords Bolt the potential for certain benefits, including up to seven years of post-approval market exclusivity, assistance in the drug development process, tax credits for clinical development, and exemptions from certain FDA fees.

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.

Investor Relations and Media Contact:
Maeve Conneighton
Argot Partners
(212) 600-1902
boltbio@argotpartners.com