



Bolt Biotherapeutics Announces Clinical Collaboration with Bristol Myers Squibb to Study BDC-1001 in Combination with Opdivo® for Treatment of HER2-Expressing Solid Tumors

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REDWOOD CITY, Calif., Sept. 08, 2021 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics, Inc. (Nasdaq: BOLT), a clinical-stage biotechnology company pioneering a new class of immuno-oncology agents that combine the targeting precision of antibodies with the power of both the innate and adaptive immune systems, today announced that it has entered into a clinical collaboration and supply agreement with Bristol Myers Squibb (NYSE: BMY) to investigate Bolt Biotherapeutics' BDC-1001 in combination with Bristol Myers Squibb's PD-1 checkpoint inhibitor Opdivo® (nivolumab). BDC-1001 is a HER2-targeting Boltbody™ immune-stimulating antibody conjugate (ISAC) in development for the treatment of patients with HER2-expressing solid tumors.

"We look forward to working with BMS in our continued development of BDC-1001, which has shown promising results in preclinical and early clinical studies," said Randall Schatzman, CEO of Bolt Biotherapeutics. "Our unique ISAC approach initiates an innate and an adaptive immune response that may be synergistic with BMS' innovative PD-1 inhibitor *Opdivo*. The combination of BDC-1001 and *Opdivo* holds potential as a treatment for cancer patients, and we welcome the opportunity to investigate this in a clinical setting." He added, "We remain grateful to all of the healthcare professionals, scientists, patients, and families involved with Bolt's clinical studies."

BDC-1001 is a human epidermal growth factor receptor 2 (HER2) ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of Bolt's proprietary TLR7/8 agonists with an intervening non-cleavable linker, for the treatment of patients with HER2-expressing solid tumors. It is currently being investigated in a Phase 1/2 clinical trial (NCT04278144) in patients with solid tumors, including breast, gastroesophageal and colorectal, that are HER2+ or HER2-low, for which Bolt recently presented preliminary data detailing safety, tolerability, and signs of activity at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. The trial is being conducted in four parts, with dose-escalation and dose-expansion parts exploring both monotherapy and combination with a PD-1 checkpoint inhibitor. BMS will provide *Opdivo* for the combination dose escalation and combination dose expansion portions of the trial. Bolt Biotherapeutics is the study sponsor and will be responsible for costs associated with the trial execution. The combination dose escalation is expected to start later in 2021.

Opdivo® is a trademark of Bristol-Myers Squibb Company.

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

ISACs are a new category of immunotherapy that combines the precision of antibody targeting with the strength of the innate and adaptive immune systems. Boltbody ISACs are comprised of three primary components: a tumor-targeting antibody, a non-cleavable linker, and a proprietary immune stimulant to activate the patient's innate immune system. By initially targeting a single marker on the surface of a patient's tumor cells, an ISAC can create a new immune response by activating and recruiting myeloid cells. The activated myeloid cells start a feed-forward loop by releasing cytokines and chemokines, chemical signals that attract other immune cells and lower the activation threshold for an immune response. This reprograms the tumor microenvironment and invokes an adaptive immune response that targets the tumor, with the goal of durable responses for patients with cancer.

About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics, Inc. is a clinical-stage biotechnology company pioneering a new class of immuno-oncology agents that combine the targeting precision of antibodies with the power of both the innate and adaptive immune systems. Bolt's proprietary Boltbody™ Immune-stimulating Antibody Conjugates (ISACs) are designed to target tumor cells for elimination by myeloid cells, which then activates the myeloid cells to recruit the adaptive immune system in the anti-tumor response. This leads to the conversion of immunologically "cold" tumors to "hot" tumors. Bolt's lead candidate, BDC-1001, is a Boltbody ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated with a non-cleavable linker to one of Bolt's proprietary TLR7/8 agonists for the treatment of patients with HER2-expressing solid tumors. Bolt is also advancing BDC-2034, a Boltbody ISAC targeting CEA, and a pipeline of other immuno-oncology products.

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 our ability to collaborate with Bristol-Myers Squibb to investigate combination therapeutics for the treatment of cancer, our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, 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," "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. 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 SEC, including our Quarterly Report on Form 10-Q for the three months ended March 31, 2021. 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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