Bolt Biotherapeutics Doses First Patient with BDC-1001 in Combination with OPDIVO® (nivolumab) in Ongoing Phase 1/2 Clinical Trial for the Treatment of HER2-Expressing Solid Tumors

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REDWOOD CITY, Calif., Jan. 06, 2022 (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 the first patient has been dosed in a new combination arm of the ongoing multi-center, multi-dose Phase 1/2 clinical trial of BDC-1001. This arm is evaluating BDC-1001 in combination with Bristol Myers Squibb's PD-1 checkpoint inhibitor OPDIVO® (nivolumab). In parallel, Bolt continues to advance the single-agent portion of the study, following the presentation of interim dose-escalation data at the European Society of Medical Oncology Immuno-Oncology (ESMO I-O) Congress 2021. BDC-1001 is a HER2-targeting Boltbody™ immune-stimulating antibody conjugate (ISAC) (trastuzumab biosimilar conjugated to a toll-like receptor 7 and 8 agonist) in development for the treatment of patients with HER2-expressing solid tumors.

"We are excited to evaluate BDC-1001 in combination with nivolumab, a leading PD-1 checkpoint inhibitor. Pairing BDC-1001's mechanism of action with the checkpoint inhibitor approach has the potential to yield a stronger, targeted modulation of the immune system. Initial safety and early efficacy findings reported from the ongoing monotherapy arm of the Phase 1/2 clinical trial make BDC-1001 a potentially promising candidate for the treatment of patients with HER2-expressing solid tumors," said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. "In the early clinical development of BDC-1001, our strategy is to follow the science, elucidating how this novel approach to engaging a patient's immune system can eliminate tumors not addressed by currently available therapies. We look forward to investigating BDC-1001 in this first combination arm as we also continue investigation of its single-agent activity."

Bristol Myers Squibb 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.

About BDC-1001
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 an innovative TLR7/8 agonist. It is currently being investigated in a Phase 1/2 clinical trial (NCT04278144) in patients with HER2-expressing solid tumors, including breast, gastroesophageal and colorectal. The trial is being conducted in four parts, and the dose-escalation monotherapy part will continue in parallel with the combination therapy study. Interim monotherapy data presented by Bolt at the European Society of Medical Oncology Immuno-Oncology (ESMO I-O) Congress 2021 demonstrated a safe and well-tolerated profile with early clinical activity, supporting continued dose escalation and evaluation of a weekly dosing regimen.

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 comprise 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, and our ability to achieve upcoming milestones for our product candidates and the success and results of our pipeline programs, 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 Annual Report on Form 10-K for the year ended December 31, 2020. 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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