

# Bolt Biotherapeutics Presents Preliminary Results from Phase 1/2 Trial of Lead HER2-targeting Boltbody™ ISAC BDC-1001 at ASCO 2021

- Poster showcases positive preliminary data from first 20 patients treated with the HER2targeting Boltbody™ ISAC BDC-1001 as of January 29<sup>th</sup> cutoff date
- Monotherapy dose expansion and anti-PD-1 antibody combination parts of study expected to start in 2H 2021

REDWOOD CITY, Calif., June 4, 2021 -- 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 a poster presentation discussing preliminary data from the Phase 1/2 clinical trial of BDC-1001, Bolt's lead candidate, was presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, being held virtually from June 4-8, 2021. The poster is titled "Preliminary results from a phase 1/2 study of BDC-1001, a novel HER2 targeting TLR7/8 immune-stimulating antibody conjugate (ISAC), in patients (pts) with advanced HER2-expressing solid tumors."

BDC-1001 is a human epidermal growth factor receptor 2, or HER2, ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of Bolt's proprietary TLR7/8 agonists, for the treatment of patients with HER2-expressing solid tumors, including HER2-low tumors. As of January 29, 2021, Bolt had treated 20 patients and BDC-1001 appeared to be well tolerated with mild to moderate adverse events; no dose-limiting toxicities or drug-related serious adverse events were observed. Clinical activity was seen in the form of stable disease, reductions in tumor volume including a confirmed partial response and increases in pharmacodynamic markers that Bolt believes are consistent with its proposed mechanism of action.

"This poster reinforces the favorable safety and tolerability demonstrated in the first 20 patients treated with BDC-1001 in this first-in-human study in patients with HER2-expressing cancers," said Manish R. Sharma, M.D., of START Midwest, a principal investigator in Bolt's ongoing BDC-1001 Phase 1/2 trial. "We have seen signs of activity, including a patient with a confirmed partial response and others with stable disease, in a population with diverse tumor types and a median of four prior lines of therapy."

The BDC-1001 Phase 1/2 trial is expected to enroll up to a total of 390 patients and is being conducted in four parts, with dose-escalation dose-expansion parts exploring both monotherapy and combination with a PD-1 checkpoint inhibitor. The monotherapy dose-escalation part of the trial continues to proceed according to plan, and full results are expected to be presented in the second half of 2021. Bolt

plans to advance to the monotherapy Phase 2 dose-expansion cohorts and the dose-escalation combining BDC-1001 with an anti-PD-1 antibody later this year.

"I am grateful to everyone on the team for their hard work throughout this trial, especially during the pandemic," said Ecaterina Dumbrava, M.D., of The University of Texas MD Anderson Cancer Center, a principal investigator of the BDC-1001 Phase 1/2 trial. "These initial data provide additional support for the ISAC targeted approach that stimulates both the innate and adaptive immune systems in the treatment of cancer patients."

The abstract and poster from the ASCO presentation can be found on the ASCO website, as well as on the Bolt website.

## About Bolt Biotherapeutics' Immune-stimulating Antibody Conjugate (ISAC) Platform Technology

The Boltbody<sup>™</sup> ISAC platform technology harnesses the ability of innate immune agonists to convert cold tumors into immunologically hot tumors, thereby illuminating tumors to the immune system and allowing them to be invaded by tumor-killing cells. Boltbody ISACs have demonstrated the ability to eliminate tumors following systemic administration as monotherapy in preclinical models and have also led to the development of immunological memory, which is predicted to translate into more durable clinical responses for patients.

### About the Ongoing BDC-1001 Phase 1/2 Study in Patients with HER2-Expressing Solid Tumors

The Phase 1/2, multi-center, open-label study is evaluating the safety, pharmacokinetics, pharmacodynamics and proof of mechanism of BDC-1001 in patients with HER2-expressing solid tumors. The first portion of the study includes a monotherapy dose-escalation phase in which cohorts of patients will receive ascending intravenous doses of BDC-1001 to determine the maximum tolerated dose and/or the recommended dose to advance into expansion cohorts and Phase 2 based on safety and tolerability. The second portion of the study is a dose expansion phase in which patients will receive BDC-1001 monotherapy to further evaluate the safety, tolerability and clinical antitumor activity of the recommended Phase 2 dose. The study also includes similar dose escalation and expansion portions evaluating the combination of BDC-1001 with an anti-PD1 checkpoint inhibitor. Please refer to www.clinicaltrials.gov NCT04278144 for additional clinical trial information.

### About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics, Inc. is a clinical-stage biotechnology company pioneering a new class of immunooncology agents that combine the targeting precision of antibodies with the power of both the innate and adaptive immune systems Bolt's proprietary Boltbody<sup>™</sup> Immune-stimulating Antibody Conjugate (ISAC) approach uses immunostimulants to engage and activate myeloid cells that directly kill tumor cells. 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 to one of Bolt's proprietary TLR7/8 agonists for the treatment of patients with HER2expressing solid tumors. Bolt is also advancing additional Boltbody ISAC product candidates targeting CEA and PD-L1. For more information, visit <u>https://www.boltbio.com/</u>.

#### **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 clinical trials, the timing of enrollment for our Phase 1/2 trial for BDC-1001 for the treatment of patients with HER2-expressing solid tumors, the potential of BDC-1001's anti-tumor activity while minimizing the formation of anti-drug antibodies, the potential that APCs may result in a productive and durable anti-tumor immune response, and the prediction that Boltbody ISACs may translate into more durable clinical responses for patients. 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 Securities and Exchange Commission, 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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