



Bolt Biotherapeutics Presents BDC-1001 Ongoing Clinical Trial Design and Supportive Preclinical Data at Society for Immunotherapy of Cancer Annual Meeting

Ongoing Phase 1/2 trial supported by preclinical data that demonstrate superiority with potent, complete, durable responses

REDWOOD CITY, CA, November 9, 2020 – Bolt Biotherapeutics, a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems, today presented the trial design of its ongoing Phase 1/2 clinical trial and preclinical data demonstrating proof-of-concept of its lead clinical drug candidate, BDC-1001. The clinical observations and preclinical data are now available in three posters at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, being held virtually November 9-14.

“We are proud to present our recent scientific advances at the SITC Annual Meeting highlighting that systemically-delivered trastuzumab ISACs induce a robust, target-dependent activation of the immune system in preclinical models as well as further mechanistic insight for the observed robust anti-tumor activity , said David Dornan, senior vice president of research and manufacturing at Bolt. “We hope to confirm the promising results from our preclinical work in our clinical trial that is currently ongoing.”

The in-progress clinical trial poster titled, “[Phase 1/2 study of novel HER2-targeting, TLR7/8 immune-stimulating antibody conjugate \(ISAC\) BDC-1001 with or without immune checkpoint inhibitor in patients with advanced HER2-expressing solid tumors](#),” highlighted the framework of Bolt’s Phase 1/2 clinical trial, an actively enrolling global study in patients with refractory HER2-expressing solid tumors. The primary objectives of the study are to evaluate safety and tolerability and determine the recommended Phase 2 dose for both monotherapy and combination with a checkpoint inhibitor. BDC-1001 is a novel treatment which combines the targeting and antitumor effect of trastuzumab with localized stimulation of the immune system via dual TLR7 and TLR8 agonism.

The preclinical results were shown in two posters. The first titled, “[Covalent attachment of a TLR7/8 agonist to tumor-targeting antibodies drives potent anti-tumor efficacy by synergistically activating FcγR- and TLR-signaling and enables safe systemic administration](#),” demonstrated that Bolt’s immune stimulating antibody conjugates (ISACs) are safe and well-tolerated in mice and non-human primates. The ISACs enable potent toll-like receptor (TLR) agonists to be safely administered systemically in preclinical models. ISACs provided distinct and unexpected biological advantage over unconjugated TLR agonists leading to more robust and effective anti-tumor efficacy.

The final poster titled, "[Systemically administered HER2-targeted ISACs provoke a rapid, local response that engages the innate and adaptive arms of the immune system to eradicate tumors in preclinical models,](#)" demonstrated that within 24 hours of administration, HER2-directed ISACs induced robust, target-dependent activation of the immune system. There was robust activation of immune cells following anti-HER2 ISAC treatment. In contrast to other immune therapies, such as anti-PD1/PD-L1 and anti-CD40, systemically administered ISACs locally engage both the innate and adaptive immune system to eradicate tumors.

"These preclinical data further validate our tumor-targeting BDC-1001 Boltbody ISAC as a promising candidate to treat HER2-expressing solid tumors in our ongoing Phase 1/2 trial. Recruitment is going well thanks to our dedicated investigators and patients," said Edith Perez, M.D., Chief Medical Officer at Bolt. "We look forward to reporting the initial data readout of our clinical trial soon."

About Bolt Biotherapeutics' Immune Stimulating Antibody Conjugate (ISAC) Platform Technology

The Boltbody™ 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. Please refer to www.clinicaltrials.gov NCT04278144 for additional clinical trial information.

About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics, based in the San Francisco Bay Area, is a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems. Bolt's proprietary Boltbody ISAC approach utilizes immunostimulants to engage and activate myeloid cells, including macrophages and dendritic cells, in an anti-tumor response that illuminates tumors for the immune system and triggers recruitment of tumor-killing cells. This approach constitutes a new class of immuno-oncology therapeutics that have eliminated tumors following systemic administration in preclinical studies and results in the development of immunological memory, which may lead to more durable clinical responses for patients. Bolt's platform technology is applicable to a broad spectrum of antibodies targeting tumor antigens expressed on all types of cancer, including patients who are refractory to the current generation of checkpoint inhibitors. The company was founded by Dr. Ed Engleman, and its platform is based on technology exclusively licensed from Stanford University. The company is financed by world-class investors, including Novo Holdings, Vivo Capital, Pivotal bioVenture Partners, Sofinnova Investments, Nan Fung Life Sciences, RA Capital

Management, Surveyor Capital (a Citadel Company), Rock Springs Capital, Pfizer Ventures, and Samsara BioCapital. For more information about Bolt Biotherapeutics, please visit www.boltbio.com

Media Contacts:

Maggie Beller or David Schull

Russo Partners, LLC

646-942-5631

maggie.beller@russopartnersllc.com

david.schull@russopartnersllc.com

Investor Relations Contact:

Sarah McCabe

Stern Investor Relations, Inc.

212-362-1200

sarah.mccabe@sternir.com