



## **Bolt Biotherapeutics Announces Initiation of BDC-1001 Clinical Trial in Patients with HER2-Expressed Solid Tumors**

- First Boltbody™ ISAC to Enter Clinical Development -

**REDWOOD CITY, CA, March 26, 2020** – Bolt Biotherapeutics, Inc., a private biotechnology company developing its Immune-Stimulating Antibody Conjugate (ISAC) platform technology to harness the power of the immune system to treat cancer, today announced that patient dosing has begun in the company’s Phase 1, open-label, dose-escalation and dose expansion study of BDC-1001 monotherapy for patients with HER2-expressed solid tumors. BDC-1001 is an ISAC comprised of trastuzumab conjugated to Bolt’s proprietary TLR7/8 agonist payload.

“The initiation of this study represents a significant milestone for the company as it is our first Boltbody™ therapeutic program to enter the clinic,” stated Randall Schatzman, Ph.D., chief executive officer of Bolt. “Bolt’s leadership in the ISAC field will continue to drive the development of myeloid-based cancer therapeutics. There is a significant unmet need for patients with solid tumors that express HER2 that cannot be addressed by current immuno-oncology therapeutics.”

Dr. Schatzman continued, “Based on an assessment of our ongoing program by the safety committee, we are now proceeding with the second cohort of our study. Bolt is eager to explore the potential of BDC-1001 for treating HER2-expressing cancers, which includes patients with breast and gastric cancers that are refractory to Herceptin® and Kadcyla®, as well as cancers for which no HER2-targeting therapies have yet been approved. We look forward to working with the medical community to bring the promise of this exciting new approach to patients and anticipate initial data will drive our future development plans.”

The program has generated compelling preclinical data demonstrating complete, durable regression of established tumors resistant to trastuzumab and immunological memory providing protection against tumor cells that no longer express the HER2 antigen in syngeneic mouse cancer models.

### **About the BDC-1001 Phase 1 Study in HER2-Expressed Solid Tumors**

The Phase 1, multi-center, open-label study will evaluate the safety, pharmacokinetics, pharmacodynamics and proof of mechanism of BDC-1001 in 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 for the 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 evaluate antitumor activity of the recommended Phase 2 dose and to further evaluate the safety and tolerability of BDC-1001. Please refer to [clinicaltrials.gov NCT04278144](https://clinicaltrials.gov/NCT04278144) for additional clinical trial information.

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

The Boltbody™ platform consists of Immune Stimulating Antibody Conjugates (ISACs) that harness 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 Bolt Biotherapeutics, Inc.**

Bolt Biotherapeutics, based in the San Francisco Bay Area, is a private biotechnology company developing Boltbody™ Immune-stimulating Antibody Conjugates (ISACs), a new class of immunology 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, Pivotal bioVenture Partners, Vivo Capital and Nan Fung Life Sciences. For more information about Bolt Biotherapeutics, please visit [www.boltbio.com](http://www.boltbio.com).

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