



## **Data Published in *Nature Cancer* Highlight Preclinical Proof of Concept of Bolt Biotherapeutics' Boltbody™ ISAC Platform**

*- Peer-reviewed publication demonstrates that Boltbody ISAC treatment leads to complete clearance of large HER2-expressing tumors and protective immunological memory in preclinical models -*

**REDWOOD CITY, CA, December 7, 2020** – Bolt Biotherapeutics, Inc., a clinical-stage immuno-oncology company developing tumor-targeted therapies that leverage the power of the innate and adaptive immune systems, today announced the publication of a manuscript in [Nature Cancer](#) highlighting the development and use of Boltbody™ Immune Stimulating Antibody Conjugates (ISACs) for the treatment of HER2-expressing tumors in preclinical models.

The paper, titled “Immune-stimulating antibody conjugates elicit robust myeloid activation and durable anti-tumor immunity,” describes that Boltbody ISACs initiated tumor killing and antigen presentation by myeloid cells with subsequent T cell-mediated anti-tumor immunity. The data indicate that Boltbody ISACs activate the innate and adaptive immune systems, ultimately resulting in complete tumor regressions in multiple tumor models and durable anti-tumor immunity. ISAC-mediated immunological memory was not limited to the target antigen as ISAC-treated mice were protected from rechallenge with the parental tumor lacking HER2 expression. These results provide a strong rationale for the currently ongoing Phase 1/2, multi-center, open-label study of the company’s lead candidate, BDC-1001, and the continued development of the Boltbody ISAC technology platform and Bolt’s immuno-oncology pipeline.

Michael Alonso, Ph.D., scientific co-founder and vice president of immunology and pharmacology at Bolt, stated, “This publication lays the framework for therapeutic strategies that harness Boltbody ISACs and the profound biological synergies that occur following covalent attachment of an immunostimulant to a tumor-targeting antibody – notably, the complete elimination of well-established tumors and mobilization of T cells that prevent tumor recurrence.”

Shelley Ackerman, Ph.D, lead author and co-inventor of the platform, said, “The publication of this peer-reviewed manuscript is an important milestone for Bolt with the first demonstration of the potential of our Boltbody ISAC platform. The data demonstrate the advantages achieved through requiring tumor target engagement, Fc receptor-mediated phagocytosis and subsequent TLR activation to induce a potent and localized anti-tumor response. This process effectively bridges the innate and adaptive immune systems to launch a coordinated anti-tumor response.”

David Dornan, Ph.D., senior vice president of research and manufacturing at Bolt, added, “The work described is a culmination of years of experimentation and collaboration supported by our dedicated and talented team. This novel technology can be applied across a diverse range of tumor targets and has the potential to enable cancer patients to generate immunological memory against their own tumors. Our published data highlight the fact that while our Boltbody ISACs are administered systemically, the immune activation takes place where it is needed – in the tumor microenvironment. We look forward to reporting data from our ongoing Phase 1/2 clinical study assessing intravenous administration of our lead clinical molecule, BDC-1001, for the treatment of HER2-expressing tumors.”

#### **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 [clinicaltrials.gov NCT04278144](https://clinicaltrials.gov/ct2/show/study/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](http://www.boltbio.com).

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