Background Despite advances made in management of patients with HER2-driven solid tumors, unmet need remains for novel approaches to improve patient outcomes. BDC-1001 is an ISAC consisting of a trastuzumab biosimilar conjugated to a proprietary cell membrane impermeable TLR7/8 agonist via a non-cleavable linker. It is designed to trigger the innate immune system and generate a durable tumor-targeted adaptive immune response. Preclinical studies indicate that HER2-targeted ISACs elicit potent and durable immune-mediated antitumor immunity. Preliminary antitumor activity of BDC-1001 alone and in combination with nivolumab (Part 4) using Simon’s 2-stage design in up to 231 patients. The primary objective of the phase 2 will be to identify biomarkers associated with BDC-1001 safety, pharmacokinetics, and immunogenicity of BDC-1001 alone and in combination with nivolumab. Exploratory objectives will be pharmacodynamic biomarkers in tumor tissue and in peripheral blood, to help elucidate the mechanism of action and identify biomarkers associated with BDC-1001’s biological activity. Enrollment is ongoing in the United States, Europe, and South Korea.

Trial Registration ClinicalTrials.gov (NCT04278144)

REFERENCES

Ethics Approval Protocols, protocol amendments, and informed consents are approved by Institutional review boards or independent ethics committees of participating sites. The study will be conducted in compliance with the Declaration of Helsinki and International Conference on Harmonization Guidelines for Good Clinical Practice. All patients will provide written informed consent.

http://dx.doi.org/10.1136/jitc-2023-SITC2023.0716