Silverback Therapeutics Initiates Phase 1 Clinical Study of SBT6050

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SEATTLE--(BUSINESS WIRE)--Silverback Therapeutics (“Silverback”), a biopharmaceutical company advancing a pipeline of therapies that are systemically delivered but locally active, today announced initiation of a Phase 1 clinical study of SBT6050, a novel therapeutic comprising a specific small molecule toll-like receptor 8 (TLR8) agonist conjugated to a HER2-directed monoclonal antibody.

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TLR8 is highly expressed in myeloid cells that are prevalent in human tumors and TLR8 agonism can potently activate a broad spectrum of anti-tumor immune mechanisms. SBT6050 is designed to activate human myeloid cells in tumors expressing moderate or high levels of HER2. Myeloid cell activation and reprogramming in the tumor microenvironment has emerged as a promising approach to harness the innate immune system to drive anti-tumor responses, including in tumors lacking T cells, as these tumors are often replete with myeloid cells.

“SBT6050 is designed for systemic administration and tumor-localized activation of myeloid cells, in order to circumvent toxicities associated with untargeted myeloid cell agonists,” said Valerie Odegard, Ph.D., Silverback’s chief scientific officer. “In preclinical studies, SBT6050 demonstrated a broad therapeutic window and this profile has enabled the selection of a first-in-human starting dose projected to be pharmacologically active.”

Dosing has initiated in the Phase 1 clinical study, an open-label, multicenter, dose escalation and expansion cohort study that will evaluate the safety and tolerability, pharmacokinetics, pharmacodynamics, and anti-tumor activity of SBT6050 in adults with HER2-expressing solid tumors.

“Our preclinical data highlight SBT6050’s potential to maximize anti-tumor immune responses, even in tumors lacking T cells. This is important because the majority of cancer patients, including those whose tumors express HER2, do not respond to checkpoint inhibitors,” said Laura Shawver, Ph.D., president and chief executive officer of Silverback Therapeutics. “We look forward to working with our investigators to evaluate SBT6050 as an innovative precision immunotherapeutic for these patients.”

About Silverback Therapeutics™

Silverback Therapeutics, Inc. is a privately held, clinical-stage biopharmaceutical company advancing a pipeline of therapies that are systemically delivered, but locally active and target fundamental disease pathways. Silverback’s ImmunoTAC™ technology is a targeted therapy platform designed to promote local modulation of important biologic pathways which enables innovative therapeutic approaches for oncology, virology, and fibrosis.

Silverback’s lead candidate, SBT6050, is a novel immuno-oncology therapeutic comprised of a TLR8 specific agonist conjugated to a HER2-directed monoclonal antibody. Solid tumors, including those resistant to T cell targeted immunotherapy, are replete with myeloid cells. Activation and reprogramming of myeloid cells drives an innate immune response resulting in direct tumor killing and can also nucleate a T cell response. Successful activation of myeloid cells can lead to anti-tumor immunity, even in tumors that are resistant to immune checkpoint blockade. SBT6050 is currently being evaluated in an ongoing Phase 1 clinical study (ClinicalTrials.gov Identifier: NCT04460456). Silverback Therapeutics is located in Seattle, Washington. To learn more, visit www.silverbacktx.com.

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