VelosBio Announces First Patient Dosed in Phase 2 Trial of VLS-101 in Solid Tumors

SAN DIEGO--(BUSINESS WIRE)-- VelosBio Inc. (VelosBio), a clinical-stage biopharmaceutical company committed to developing first-in-class cancer therapies targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), today announced that the first patient has been dosed in a Phase 2 trial of VLS-101 in patients with solid tumors. VLS-101, the company's lead product candidate, is an antibody-drug conjugate (ADC) that targets ROR1.

ROR1 is a cell-surface protein that is expressed during embryofetal development but disappears before birth and is usually not expressed on normal cells in children or adults. However, ROR1 can reappear on malignant tissues, including on solid tumors. By targeting ROR1, VLS-101 is designed to deliver cancer-fighting therapeutics selectively to tumor cells, while sparing normal cells.

"VLS-101 dosing of the first patient in our Phase 2 solid tumor trial represents a key milestone for our lead ROR1-directed clinical program," said Dave Johnson, Chief Executive Officer at VelosBio. "Based on the broad expression of ROR1 across different cancer types, and our pre-clinical data showing VLS-101 antitumor activity in solid tumors, we are excited to advance this investigational candidate as a potential new therapy for difficult-to-treat cancers."

The Phase 2 trial will enroll patients with previously treated solid tumors, including breast cancer, lung cancer, and other cancers that are believed to express ROR1. Patients will receive VLS-101 2.5 mg/kg intravenously once every three weeks for as long as they are safely benefiting from VLS-101 therapy. The primary endpoint is objective response rate as determined by standard response criteria. The clinical trial will also assess safety, pharmacokinetics, pharmacodynamics, and immunogenicity of VLS-101 and explore the influence of biomarkers on outcome. For additional information about the clinical trial, visit www.clinicaltrials.gov (NCT04504916).

About VLS-101

VLS-101 is an investigational antibody-drug conjugate (ADC) comprising a ROR1-targeting monoclonal antibody that is linked to a cytotoxin called monomethyl auristatin E (MMAE). After the antibody binds to ROR1 on cancer cells, the ADC is designed to enter those cells and release MMAE to destroy the cancer cells. In mouse models of human hematologic malignancies and solid tumors, VLS-101 showed robust antitumor activity. VLS-101 is in clinical development for patients with previously treated hematologic malignancies and solid tumors.

About VelosBio

VelosBio Inc. is a clinical-stage biopharmaceutical company committed to transforming the lives of patients with cancer by developing first-in-class therapies targeting ROR1. Its lead candidate, VLS-101, is a ROR1-directed ADC being developed for patients with hematologic malignancies and solid tumors. The company is utilizing its ROR1-targeting antibody-based technology to develop a pipeline of ADCs and bispecific antibody product candidates for the treatment of hematologic malignancies and solid tumors. VelosBio is headquartered in San Diego. For more information, please visit www.velosbio.com.

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