



VelosBio Announces FDA Fast Track and Orphan Drug Designations for VLS-101 in Patients with Mantle Cell Lymphoma

SAN DIEGO--(BUSINESS WIRE)-- VelosBio Inc. ("VelosBio"), a clinical-stage biopharmaceutical company committed to developing novel, first-in-class cancer therapies targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), today announced that the U.S. Food and Drug Administration (FDA) has granted the company Fast Track and Orphan Drug designation for VLS-101 for the treatment of patients with mantle cell lymphoma (MCL). VLS-101 is a ROR1-directed antibody-drug conjugate (ADC) that is currently being studied in a first-in-human Phase 1 clinical trial in patients with relapsed or refractory hematologic cancers.

FDA Fast Track designation is a program designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, with the goal of getting important new drugs to patients earlier. Fast Track designation also confers important benefits to the sponsor, including potential eligibility for Priority Review of a New Drug Application, if relevant criteria are met.

The FDA Office of Orphan Drug Products grants Orphan Drug status to support the development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the U.S. Orphan Drug designation provides to VelosBio certain benefits, including market exclusivity upon regulatory approval if received, exemption from FDA application fees, and tax credits for qualified clinical trials.

"We are pleased to receive FDA Fast Track and Orphan Drug designation for VLS-101 in mantle cell lymphoma, which is a significant milestone for VelosBio as we continue to advance our pipeline of ROR1-directed therapeutics," said Dave Johnson, Chief Executive Officer, VelosBio. "We look forward to working closely with the FDA to advance our investigational therapeutic and believe VLS-101 could be an important new treatment option for patients with mantle cell lymphoma."

Mantle cell lymphoma is an aggressive, rare form of non-Hodgkin lymphoma (NHL). MCL is more common in men than in women, and it most often appears in people older than 60. When MCL is diagnosed, it is usually widespread in the lymph nodes, bone marrow, and often the spleen.

About VelosBio

VelosBio Inc. is a clinical-stage biopharmaceutical company committed to developing novel, first-in-class, ROR1-directed therapeutics to transform the lives of patients with cancer. Its lead candidate, VLS-101, is a ROR1-directed ADC being developed for patients with hematologic and solid tumor malignancies. The company is developing a broad pipeline of therapeutics targeting ROR1 in oncologic indications with high unmet medical need. VelosBio is headquartered in San Diego. For more information, please visit www.velosbio.com

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