Merus Announces First Patient Dosed in Phase 1/2 Trial Evaluating Bispecific Antibody Candidate MCLA-117 in Patients with AML

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UTRECHT, The Netherlands (GLOBE NEWSWIRE) — Merus B.V., a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, announced today that the first patient has been dosed in the Company's Phase 1/2 clinic al trial evaluating MCLA-117 as a potential treatment of patients with acute myeloid leukemia (AML). MCLA-117 is a bispecific antibody candidate, which the Company refers to as Biclonics, that is designed to recruit and activate an AML patient's own T-cells to kill AML tumor cells and stem cells.

The trial is a single-arm, open-label, multi-national study to assess the safety, tolerability and anti-tumor activity of MCLA-117. The first phase of the study is designed as a dose escalation study, followed by a second safety dose expansion phase. The study will enrol up to 50 evaluable adult AML patients, who have relapsed or refractory disease and/or are newly diagnosed patients older than 65 years and are not usually eligible as candidates for intensive or conventional approved treatments. The primary endpoint is the safety and tolerability of MCLA-117; secondary endpoints include, among others, pharmacokinetic measures as well as the anti-tumor response and clinical benefit of MCLA-117.

"Acute myeloid leukemia is a rapidly-progressing cancer, and little progress has been made over the past four decades to improve disease-free survival and overall survival rates in the AML population," said Prof. Gert Ossenkoppele, hemato-oncologist at the Free University Medical Center, Amsterdam and the lead investigator of the study. "We are eager to explore MCLA-117 in the clinic as we continue to expand our understanding of the role of CLEC12A in AML. Based on the preclinical data observed to date, we believe MCLA-117 is a promising immunotherapy designed to selectively target leukemic cells and represents a potential breakthrough in the treatment of AML."

"Initiation of the MCLA-117 clinical program is an important milestone for this bispecific antibody candidate," said Setareh Shamsili, MD, PhD, Chief Medical Officer of Merus. "MCLA-117 is designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell-surface molecule present on AML tumor cells and stem cells in approximately 90 to 95% of newly diagnosed and relapsed AML patients. We believe that many patients with AML could potentially benefit from treatment with MCLA-117."

In preclinical data presented at the 2015 American Society of Hematology Meeting, MCLA-117 was effective and efficient in killing AML tumor cells by targeting the CLEC12A molecule, a leukemic stem cell-associated antigen.

About MCLA-117

MCLA-117 is a Biclonics that is designed to bind to CD3 expressed by T-cells and CLEC12A expressed by acute myeloid leukemia (AML) tumor cells and stem cells. In preclinical studies, MCLA-117 has been shown to recruit and activate the immune system's own T-cells to kill AML tumor cells and stem cells.

About Merus B.V.

Merus is a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, referred to as Biclonics. Biclonics are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical studies to have several of the same features of conventional monoclonal antibodies, such as long half-life and low immunogenicity. Merus' lead bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 1/2 clinical trial in Europe as a potential treatment for HER2-expressing solid tumors. Merus' second bispecific antibody candidate, MCLA-117, is being developed as a potential treatment for acute myeloid leukemia. The Company also has a pipeline of proprietary bispecific antibody candidates in preclinical development, including MCLA-158, which is designed to bind to cancer stem cells and is being developed as a potential treatment for colorectal cancer and other solid tumors, and Biclonics designed to bind to various combinations of immunomodulatory molecules, including PD-1 and PD-L1.

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