Merus starts Phase I/II clinical trial for MCLA-128, an ADCC-enhanced bispecific antibody for solid tumors

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– First patient dosed in trial with potent bispecific antibody overcoming resistance to HER2-targeted therapies –

Utrecht, The Netherlands, February 4, 2015 — Merus B.V., a leader in developing best-in-class bispecific antibody therapeutics to treat cancer patients, today announced the initiation of a phase I/II clinical study of MCLA-128 for the treatment of solid tumors. MCLA-128 is an ADCC-enhanced, full-length IgG bispecific antibody that simultaneously targets the growth factor receptors HER2 and HER3.

“Tumors with intrinsic or acquired resistance to HER2-targeted therapies often upregulate HER3 or its ligand, heregulin, resulting in increased tumorigenicity,” said Setareh Shamsili, Chief Medical Officer and Head of Clinical Development of Merus. “Preclinical work has shown that MCLA-128 has the unprecedented ability to completely block heregulin-driven growth in tumor cell lines that are resistant to current HER2-targeting therapies. The ADCC-enhanced version of MCLA-128 was shown to further increase the immune-mediated killing capacity of this unique bispecific antibody. The full-length IgG format ensures a long half-life, rapid intravenous administration and attractive dosing schedules for patients.”

“MCLA-128 is Merus’ first compound to enter clinical trials,” said Ton Logtenberg, Chief Executive Officer of Merus. “This bispecific antibody was selected among thousands of candidates tested in functional assays and shows tumor cell killing activities that cannot be achieved with combinations of conventional HER2 and HER3 monoclonal antibodies. With the start of this clinical trial, the company reaches a significant milestone and takes another step in its mission to develop a range of therapeutic bispecific antibodies that improve and extend the lives of cancer patients”.

The trial is an open-label, European multi-center dose escalation study to assess the safety, tolerability and anti-tumor activity of MCLA-128. The first part of the study is designed as a dose escalation study, followed by a second part to further characterize the safety, tolerability and clinical efficacy of MCLA-128. Initially, the study will enroll 52 patients with advanced epithelial tumors. Primary endpoint is safety; secondary endpoints include, among others, the immunogenicity of MCLA-128 as well as anti-tumor response and clinical benefit.

About Merus B.V.

Merus is a Dutch biotechnology company developing cancer therapeutics based on human bispecific antibodies. Merus’ bispecific antibodies have the robust and proven full-length IgG format, they are manufactured using industry standard processes and have predictable in vivo behavior such as long half-life and low immunogenicity. Merus has two lead programs in development, MCLA-128 for the treatment of HER2 expressing solid tumors, and MCLA-117 for the treatment of acute myeloid leukemia and myelodysplastic syndrome. The company is also developing a broad pipeline of preclinical programs in immuno-oncology using its unique technology platforms.

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