Merus to Present Interim Clinical Data from Ongoing Phase 1/2 Clinical Trial of its Lead Bispecific Antibody Candidate, MCLA-128, at the American Association for Cancer Research 2016 Annual Meeting

April 15, 2016

MCLA-128 Shows Favorable Safety Profile and Early Signs of Anti-Tumor Activity in Patients with Advanced Solid Tumors

UTRECHT, The Netherlands, April 15, 2016 (GLOBE NEWSWIRE) -- Merus B.V., a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics), today announced a scheduled poster presentation at the American Association for Cancer Research (AACR) 2016 Annual Meeting being held April 16-20, 2016 in New Orleans.

Merus will be presenting interim clinical data for its lead bispecific antibody candidate MCLA-128 from a first-in-human Phase 1/2 clinical trial. MCLA-128 is a novel full-length Immunoglobulin G (IgG) bispecific antibody with enhanced antibody-dependent cellular cytotoxicity (ADCC) that is designed to bind to human epidermal growth factor receptors, HER2 and HER3, present on a variety of solid tumor cells. Merus will present on the open-label dose escalation phase (Part 1) of the Phase 1/2 clinical trial. The primary objectives in Part 1 of the clinical trial are to determine a maximum tolerated dose and to establish the recommended dose for a Phase 2 clinical trial of MCLA-128; the secondary objectives are to assess its safety, tolerability, pharmacokinetics (PK), pharmacodynamics, and anti-tumor activity.

"We believe the interim data we are presenting from Part 1 of this first clinical trial of MCLA-128 demonstrates a favorable safety profile and early signs of anti-tumor activity," said Setareh Shamsili, MD, PhD, Chief Medical Officer of Merus. "In Part 2 of this clinical trial, we will continue to evaluate MCLA-128 for safety and efficacy in patients with selected tumor types and patients with HER2 amplification in other tumor types. We expect to report top-line data from both parts of this trial in the first half of 2017."

"We are proud to have reached this milestone for the company, the MCLA-128 program and our Biclonics platform," commented Ton Logtenberg, PhD, Chief Executive Officer of Merus. "The timely delivery of this clinical milestone follows the rapid progression of MCLA-128 through preclinical discovery and manufacturing, which we believe validates the strength of the Biclonics platform. We look forward to the next part of this clinical trial while we continue to use the Biclonics platform to build a pipeline of therapeutics that we believe has the potential to address the unmet needs of cancer patients."

The details for the poster presentation are as follows:

Poster Title: A Phase I/II Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2/HER3, in Patients with Solid Tumors
Date & Time: Monday, April 18, 2016, 1:00 PM – 5:00 PM CDT
Abstract Number: CT050
Session ID: PO.CT01.01. Phase 1 Clinical Trials 1
Location: Section 13
Summary: In Part 1, the dose escalation phase of this Phase 1/2 clinical trial, patients with advanced solid tumors that are relapsed or refractory to at least one prior regiment of available standard treatment or for whom no curative therapy is available were enrolled. MCLA-128 was administered every 3 weeks (q3w) as an intravenous infusion over 60-120 minutes. Toxicities were assessed at escalating dose levels. Twenty-eight patients received MCLA-128 in 9 dose escalation cohorts (in a range of 40 mg to 900 mg flat dose).

A maximum tolerated dose was not reached at the dose level of 900 mg. The cumulative safety and available PK data, along with the aid of a PK simulation study, were used to support a recommended dose for a Phase 2 clinical trial of 750 mg q3w, administered over 120 minutes. We believe encouraging signs of anti-tumor activity (assessed by RECIST v.1.1) were observed. Three patients remain in the trial to date, including one metastatic non-small cell lung cancer patient who is experiencing an ongoing partial response after more than 9 months, one metastatic gastroesophageal junction cancer patient with stable disease after more than 5 months, and one metastatic colorectal cancer patient with stable disease after more than 6 months. In addition, one metastatic breast cancer patient with stable disease received 5 months of MCLA-128 treatment before disease progression. MCLA-128 was well-tolerated with a favorable safety profile in patients with advanced tumors treated at doses up to 900 mg q3w. The expansion phase (Part 2) of the clinical trial is ongoing at the recommended Phase 2 dose of 750 mg q3w, enrolling patients with selected tumor types with HER2 amplification.

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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