# Merus Announces Promising Results from MCLA-128 Phase 1/2 Study in Metastatic Breast Cancer

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*Results to be presented at the 2017 American Society of Clinical Oncology Annual Meeting*

*Phase 2 clinical trial to be initiated in second half of 2017 exploring two metastatic breast cancer populations: HER2-positive patients and hormone receptor-positive/HER2-low patients*

UTRECHT, The Netherlands, May 17, 2017 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, today announced the results of their first-in-human Phase 1/2 study of MCLA-128 in solid tumors, including final Phase 1 data and promising preliminary activity in patients with HER2-positive metastatic breast cancer (MBC) from the Phase 2 portion of the trial. MCLA-128 is a full-length IgG bispecific antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) activity targeting HER2 and HER3 receptors. The results will be presented in a poster session on the morning of June 5, 2017 at the American Society of Clinical Oncology (ASCO) Annual Meeting.

In the Phase 1 portion of the Phase 1/2 study, the recommended Phase 2 dose (RP2D) for future studies with MCLA-128 was established as 750 mg every 3 weeks, based on safety and pharmacokinetic data. The Phase 2 portion of the study is ongoing, exploring selected metastatic indications including breast, endometrial, ovarian, gastric and non-small cell lung cancers. MCLA-128 was well tolerated, with the ongoing Phase 2 portion confirming the safety profile seen in the dose escalation cohort. The most frequent adverse events observed were mild (G1/G2) infusion-related reactions and gastrointestinal toxicities. No clinically significant cardiotoxicity was reported.

As part of the ongoing study, a cohort of 11 HER2-positive MBC patients has been treated with single agent MCLA-128 (9 patients at RP2D and 2 patients at 480 mg q3 weeks from part 1). These MBC patients were all heavily pretreated, having received a median of 6 prior lines of metastatic therapy, all having 2-5 prior HER2 inhibitor therapies, and some of the patients with outright disease progression to the last line of therapy. One MBC patient achieved a confirmed partial response (>8+ months) and 7 had stable disease (including 4 sustained stabilizations lasting ≥5 months). The clinical benefit rate (complete and partial responses plus stable disease lasting at least 12 weeks) among the cohort of MBC patients was 64% (7/11). Evaluation of additional MBC patients and other indications is ongoing.

With single agent activity established in MBC, Merus also announced today plans to initiate a Phase 2, open-label, multicenter, international clinical study to evaluate MCLA-128-based combinations in two MBC populations: 1) confirmed HER2-positive MBC patients (progressing on anti-HER2 therapies including TDM-1) who will receive MCLA-128 in combination with trastuzumab and chemotherapy, and 2) confirmed hormone receptor positive status and HER2-low (IHC HER2 1+ or 2+ and FISH negative for HER2 amplification) MBC patients progressing on hormone therapies and CDK4/6 who will receive MCLA-128 in combination with fulvestrant. In addition to these early clinical results, study of MCLA-128 in these combinations and populations is supported by activity observed in preclinical models. This Phase 2 study is expected to be launched in Europe and the US in the second half of 2017.

“These clinical results demonstrate that single agent MCLA-128 is active and well tolerated in heavily pretreated metastatic breast cancer patients,” said Professor Josep Tabernero, MD, PhD, Head of Medical Oncology and the Institute of Oncology at Vall d'Hebron University Hospital. “This positions MCLA-128 as a promising agent for further development as combination therapy in the treatment paradigm of metastatic breast cancer. I look forward to seeing how these results translate in the planned Phase 2 combination studies.”

“With demonstrated activity in an aggressive disease population, our goal now is to understand where MCLA-128, in combination with current standards of care, can address unmet needs in this disease and deliver improved outcomes and greater optionality to patients in need,” said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. “We see opportunities in HER2-positive MBC and hormone-resistant estrogen receptor positive MBC, where escape from hormone therapy is often via HER2/3 signaling. We also look forward to continuing to evaluate MCLA-128 in other tumor types, including endometrial, ovarian, gastric and NSCLC cancers in this ongoing study.”

**About MCLA-128**
MCLA-128 is designed to block HER3/heregulin-dependent tumor growth and survival as well as enhance immune-mediated cytotoxicity in tumors. MCLA-128 employs a ‘dock and block’ mechanism in which the mode of HER2 receptor binding orientates the HER3 binding arm to effectively block oncogenic signaling through the HER2:HER3 heterodimer even under high heregulin concentrations. In addition, MCLA-128 is engineered for enhanced ADCC in order to recruit and activate immune effector cells to directly kill tumor cells.

**About Merus N.V.**
Merus is a clinical-stage immuno-oncology company developing innovative full-length human 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 share several 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 in a Phase 1 clinical trial in patients with 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, as well as Biclonics® designed to bind to various combinations of immunomodulatory molecules, including PD-1 and PD-L1.

**Forward Looking Statement**
Except for the historical information set forth herein, this press release contains predictions, estimates and other forward-looking statements, including without limitation, statements regarding: the impact of our collaboration with Incyte on the clinical development of our bispecific antibody candidates, anticipated clinical data

points for 2017, the timing of presentations, clinical data announcements, and regulatory filings, the potential payments under our collaboration agreement with Incyte, each statement under “Anticipated Milestones,” and the treatment potential of our bispecific antibody candidates.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our need for additional funding, which may not be available and which may require us to restrict our operations or require us to relinquish rights to our technologies or bispecific antibody candidates; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; the unpredictable nature of our early stage development efforts for marketable drugs; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; we may not identify suitable bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; and our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts.

These and other important factors discussed under the caption “Risk Factors” in our Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 28, 2017, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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