Merus Announces First Patient Dosed in a Phase 2 Clinical Trial of MCLA-128 in Two Metastatic Breast Cancer Patient Populations

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Combination trial to evaluate MCLA-128 in HER2-positive and hormone receptor-positive/HER2-low metastatic breast cancer patients

UTRECHT, the Netherlands, Jan. 26, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced that the first patient has been dosed in a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in two metastatic breast cancer (MBC) populations including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients.

MCLA-128 is a full-length IgG bispecific antibody with enhanced antibody-dependent cellular cytotoxicity (ADCC) targeting HER2 and HER3 receptors. MCLA-128 blocks the HER3 signaling pathway by employing a Dock & Block™ mechanism. MCLA-128 is designed to dock onto a specific region of the HER2 receptor to orientate MCLA-128's HER3 binding arm to block HER2:HER3 heterodimerization. Oncogenic signaling through the HER3 pathway, even in the presence of high heregulin concentrations, may thus be effectively blocked.

"Initiation of the Phase 2 clinical trial in patients with HER2-positive MBC populations and hormone receptor-positive/HER2-low MBC populations represents another key milestone for Merus," said Ton Logtenberg, PhD., Chief Executive Officer. "With promising single agent activity observed in heavily-pretreated patients underscoring the potential of MCLA-128 in MBC, this study is designed to elucidate the activity of this important HER2/HER3-targeted candidate in combination with current standards of care in areas of unmet need. Concurrently, our study evaluating single agent activity for MCLA-128 in gastric, ovarian, endometrial and non-small cell lung (NSCL) cancers is ongoing and we anticipate defining a clinical plan for MCLA-128 in solid tumors beyond metastatic breast cancer starting the second quarter of 2018. In addition, we remain committed to the remainder of our pipeline candidates, including MCLA-117 in acute myeloid leukemia, which is currently in the clinic, MCLA-158 for the potential treatment of colorectal cancer, which we expect to enter the clinic in the first quarter of 2018, as well as MCLA-145, which we are developing with Incyte Corporation in solid tumors."

The MCLA-128 Phase 2 clinical trial is expected to enroll approximately 120 patients in total across the U.S. and Europe. The first cohort, HER2-positive MBC patients who are progressing on anti-HER2 therapies including TDM-1, will receive MCLA-128 in combination with trastuzumab and chemotherapy. In preclinical studies, synergistic activity of MCLA-128 and trastuzumab has been demonstrated to inhibit heregulin-driven tumor cell growth. The second cohort, MBC patients with confirmed hormone receptor positive status and HER2-low (immuno-histo-chemistry (IHC) HER2 1+ or 2+ and fluorescent in-situ hybridization (FISH) negative for HER2 amplification) who are progressing on hormone therapies and CDK4/6 inhibitors, will receive MCLA-128 in combination with endocrine therapy. In preclinical models, blocking of signaling through the HER3 pathway has been shown to synergize with endocrine therapy. The primary endpoint for both cohorts is the clinical benefit rate at 24 weeks. Additional details about the study can be found on ClinicalTrials.gov, using identifier NCT: NCT03321981.

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 modified 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®, which are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical and clinical studies to have several of the same features of conventional human monoclonal antibodies, such as long half-life and low immunogenicity. Merus' most advanced bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 2 combination trial in two metastatic breast cancer populations. MCLA-128 is also being evaluated in a Phase 1/2 clinical trial in Europe in gastric, ovarian, endometrial and NSCL cancers. Merus' second most advanced 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 MCLA-145, which is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target, which is being developed in collaboration with Incyte Corporation.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding clinical development plans for MCLA-128, including defining a clinical plan for MCLA-128 in other solid tumors in 2018, the expected enrollment for and design of the Phase 2 clinical trial of MCLA-128, expected advancement of MCLA-158 into the clinic in 2018, the clinical development of MCLA-145, and the design and treatment potential of MCLA-128, MCLA-158 and MCLA-145.

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 Biclonics® and bispecific antibody candidates; potential delays in regulatory approval, which would impact our 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 Biclonics® or bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; protection of our proprietary technology; our patents may be found invalid, unenforceable, circumvented by competitors and our patent applications may be found not to comply with the rules and regulations of patentability; we may fail to prevail in existing and potential lawsuits for infringement of third-party intellectual property; and our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks.

These and other important factors discussed under the caption “Risk Factors” in our Annual Report on 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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