Merus Presents Clinical Data on MCLA-145 at the ESMO Immuno-Oncology Congress 2021

December 6, 2021

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Dec. 06, 2021 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (“Merus”, “the Company”, “we”, or “our”), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®), today released clinical data on MCLA-145 from the phase 1 trial in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021 being held virtually.

“We are encouraged by the progress we are making with MCLA-145,” said Dr. Andrew Joe, Chief Medical Officer. “Patients have been treated at 8 dose levels with preliminary evidence of antitumor activity observed, as we continue to explore MCLA-145 as monotherapy.”

MCLA-145

The reported data are from the phase 1 open-label, multicenter dose escalation study, of bispecific antibody MCLA-145 in patients with solid tumors. The primary objective is to evaluate the safety, tolerability, and dose-limiting toxicity (DLT) of MCLA-145 and to determine maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE).

Observations in the presentation include:

- As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors with median age of 60.5 (range 27-81) years have been treated at 8 dose levels ranging from 0.4-75mg Q2W
- Median (range) duration of treatment with MCLA 145 was approximately 6 (1–74) weeks
- Reported adverse events (AEs) have been managed with drug interruption and/or administration of steroids in some patients
    - Treatment-emergent AEs (TEAEs) occurred in 33 patients (97.1%); treatment-related TEAEs occurred in 23 patients (67.6%), most commonly fatigue (n=6, 17.6%) and decreased neutrophil count (n=6, 17.6%)
    - DLTs defined as within 28 days from the first infusion occurred in 4 patients (11.8%)
    - Laboratory alanine transaminase/aspartate transaminase (ALT/AST) elevations of any grade were observed in 15 patients (44.1%), with grade ≥3 ALT/AST elevations in 6 patients (17.6%)
- Preliminary evidence of antitumor activity has been observed at doses ≥25 mg biweekly
- Peripheral blood shows robust T-cell activation, including activation of cytotoxic CD8+ cells and cytokines, across the 10 to 75 mg biweekly dosing range
- Further evaluation of optimal dose and efficacy in PD-L1+ tumors is planned.

The phase 1 clinical trial of MCLA-145 consists of a dose escalation phase, followed by a planned dose expansion phase. MCLA-145 is the first drug candidate co-developed under Merus’ global collaboration and license agreement with Incyte, which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform. Merus retains full rights to develop and commercialize MCLA-145, if approved, in the United States; and Incyte holds full rights to develop and commercialize MCLA-145 outside the United States.

About Merus N.V.
Merus is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as Multiclonics®. Multiclonics® 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. For additional information, please visit Merus’ website and https://twitter.com/MerusNV.

Forward-Looking Statements

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 the content and timing of clinical trials, data readouts and clinical updates for our product candidates, the treatment potential of our product candidates, their mechanism of action, future clinical trial developments or interim analyses, the impact, if any, of preliminary evidence of antitumor activity or other statements regarding MCLA-145’s mechanism of action and potential of this Biclonics® in preclinical or clinical development to treat cancer, our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform, including 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 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; impacts of the COVID-19 pandemic; we may not identify suitable Biclonics® or bispecific antibody candidates under our collaborations or our collaborators may fail to perform adequately under our collaborations; 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 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 Quarterly Report on Form 10-Q for the period ended September 30, 2021 filed with the Securities and Exchange Commission, or SEC, on November 2, 2021, 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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