

Merus

Merus Announces First Patient Treated in Phase 1/2 Clinical Trial of MCLA-129 in Advanced Lung Cancer and Other Solid Tumors

May 3, 2021

Merus' Fourth Sponsored Bispecific Antibody Currently in Clinical Trials

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 03, 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 (Biclomics® and Triclomics®), today announced that the first patient has been treated in its phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. MCLA-129 is a Biclomics®, which binds to EGFR and c-MET. EGFR is an important oncogenic driver in many cancers, and upregulation of c-MET signaling has been associated with resistance to EGFR inhibition.

"The initiation of our phase 1/2 trial of MCLA-129 is an important step in our goal to provide meaningful treatments to patients with cancer, including NSCLC," said Dr. Andrew Joe, Chief Medical Officer of Merus. "Despite the successes with targeted therapies, patients will often develop resistance to currently approved treatments. Based on our preclinical data and other data, we are excited to investigate MCLA-129 as a potential new treatment option for patients with lung and other cancers, especially those that do not respond to EGFR inhibitors."

The phase 1/2, open-label clinical trial of MCLA-129 consists of dose escalation followed by dose expansion. Primary objectives of phase 1 are to determine the maximum tolerated dose and/or the recommended phase 2 dose, and the objectives of phase 2 are to evaluate safety, tolerability and potential clinical activity of the recommended phase 2 dose in patients with advanced solid tumors.

More details of the trial can be found at [clinicaltrials.gov](#).

MCLA-129 is the subject of a collaboration agreement between Merus and Betta Pharmaceuticals Co. Ltd. (Betta). In January 2019, Merus and Betta announced this strategic collaboration to develop MCLA-129, where Merus granted Betta an exclusive license to develop and potentially commercialize MCLA-129 in China, with Merus retaining all rights outside of China. In January 2021, Betta announced that the Chinese National Medical Product Administration accepted its Investigational New Drug application of MCLA-129 injection.

About MCLA-129

[MCLA-129](#) is an antibody-dependent cellular cytotoxicity-enhanced Biclomics® that is designed to inhibit the EGFR and c-MET signaling pathways in solid tumors. Preclinical data have shown that MCLA-129 can effectively treat TKI-resistant NSCLC in xenograft models of cancer. MCLA-129 is designed to have two complementary mechanisms of action: blocking growth and survival pathways to stop tumor expansion and recruitment and enhancement of immune effector cells to eliminate the tumor.

About Merus N.V.

[Merus](#) is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as [Multiclomics®](#). Multiclomics® 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 [Twitter](#).

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 design and treatment potential of our bispecific antibody candidate, MCLA-129, the clinical study design and objectives of the phase 1/2 study, our goal to provide meaningful treatments to patients with cancer, including NSCLC the preclinical data; our belief of the potential benefit of MCLA-129 as a potential new treatment option for patients with lung and other cancers, especially those that do not respond to EGFR inhibitors; and the impact and benefit, if any, from our collaboration with Betta, or Betta's development of MCLA-129 in China. 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 Biclomics® 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 Annual Report on Form 10-K for the period ended December 31, 2020 filed with the Securities and Exchange Commission, or SEC, on March 16, 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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The logo for Merus, featuring the word "Merus" in a bold, blue, sans-serif font.