

Merus

Merus Announces First Patient Treated in Phase 1 Clinical Trial of MCLA-145 for Advanced Solid Tumors

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UTRECHT, Netherlands, May 09, 2019 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS), a clinical-stage immuno-oncology company developing Biclomics®, innovative full-length human bispecific antibody therapeutics, today announced that the first patient has been treated in its Phase 1 trial evaluating safety, tolerability, and preliminary efficacy of MCLA-145 for the treatment of patients with advanced solid tumors. MCLA-145 is a potential first-in-class PD-L1 x CD137 Biclomics® being developed in collaboration with Incyte (NASDAQ:INCY) for the treatment of solid tumors.

"We are very pleased to announce the initiation of our Phase 1 trial for MCLA-145," said Andres Sirulnik, M.D., Ph. D., Executive Vice President and Chief Medical Officer of Merus. "MCLA-145's unique triple action is designed to recruit T-cells, activate T-cells and also prevent T-cell exhaustion. Importantly, MCLA-145 has potential to overcome known systemic side effects of CD137 agonists currently in development through more targeted delivery to the tumor microenvironment, and to address a significant unmet need in patient populations not benefitting from current immunotherapeutic agents."

The Phase 1, open-label, single-agent clinical trial of MCLA-145 consists of dose escalation followed by dose expansion. Primary objectives of the Phase 1 trial are dose finding, evaluation of safety and tolerability of MCLA-145 in patients with advanced solid tumors. The Phase 1 trial will also examine potential preliminary antitumor activity and functional target engagement of single-agent MCLA-145.

More details of the trial can be found at <https://clinicaltrials.gov/ct2/show/NCT03922204>.

Discovered through an unbiased functional screening of multiple immunomodulatory target combinations, MCLA-145 is a Biclomics® T-cell agonist that also blocks T-cell inhibitor signals, and binds with high affinity and specificity to human PD-L1 and CD137 in preclinical models. The unique immunostimulatory profile of MCLA-145 derives from the ability to potently activate immune effector cells in the context of the tumor microenvironment while simultaneously blocking inhibitory signals in the same immune cell population.

Merus is developing MCLA-145 as part of a collaboration entered into with Incyte in December 2016 to potentially develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclomics® platform. Under the terms of the collaboration, Merus will retain all rights to develop and commercialize MCLA-145, if approved, in the United States, while Incyte has rights to develop and commercialize MCLA-145, if approved, outside the United States.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclomics®. Biclomics, 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. For additional information, please visit Merus' website, www.merus.nl.

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 the characteristics, design and immunostimulatory profile of MCLA-145; the potential for MCLA-145 to overcome known side effects of CD137 agonists currently in development and to address a significant unmet need in patient populations not benefitting from current immunotherapeutic agents; the design of our Phase 1, open-label, single-agent clinical trial of MCLA-145 to determine dose, safety, and tolerability of MCLA-145 in patients with advanced solid tumors, and to examine potential preliminary antitumor activity and functional target engagement of single-agent MCLA-145; the continuing collaboration with Incyte on MCLA-145's global development, and potential to develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclomics® platform; and whether any of the programs under the collaboration will be successful, including for 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 Biclomics® 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 Biclomics® 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 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 3, 2019, 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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