Merus Announces Publication in Nature Communications on MCLA-145's Novel Mechanism of Action Promoting Tumor Immunity and Context Dependent T-Cell Costimulation

July 21, 2021

UTRECHT, The Netherlands and CAMBRIDGE, Mass., July 21, 2021 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®), today announced the novel mechanism of action (MOA) of MCLA-145, the Company's clinical stage Biclonics ® T-cell agonist. MCLA-145 binds with high affinity and specificity to PD-L1 and CD137. The unique immunostimulatory mechanism of action of MCLA-145 was published in Nature Communications on June 21, 2021, titled "A human CD137×PD-L1 bispecific antibody promotes anti-tumor immunity via context dependent T cell costimulation and checkpoint blockade."

"Our recent Nature Communications publication is another example of the power and potential of our unique Biclonics® platform technology allowing for high throughput functional screening to discover novel Biclonics® —human, common light chain, IgG antibodies in the bispecific format—that can unlock innovative biology," said Cecile Geuijen, Chief Scientific Officer. "Preclinically, MCLA-145 has been observed to potently activate immune effector cells, only in the context of the tumor microenvironment, and can simultaneously block inhibitory signals in the same immune cell population."

MCLA-145 was identified by screening hundreds of bispecific IgG antibodies for immune activation via PD-L1 engagement among other characteristics. MCLA-145 was shown to potently activate T cells even in the presence of suppressive conditions. Furthermore, MCLA-145 was shown to enhance T cell priming and to promote long-term T cell immunity. These in vitro findings were translated to in vivo experiments where MCLA-145 anti-tumor activity was superior to the current standard immune checkpoint inhibitor comparators and linked to recruitment and intratumor expansion of CD8+ T cells.

MCLA-145 is currently being evaluated in a phase 1 open-label, multicenter dose escalation study, including a planned safety dose expansion phase, in patients with solid tumors. 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 our 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 MCLA-145

Discovered through an unbiased functional screening of multiple immunomodulatory target combinations, MCLA-145 is a Biclonics® T-cell agonist that 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 potential to potently activate immune effector cells in the context of the tumor microenvironment while simultaneously blocking inhibitory signals in the same immune cell population.

About Merus

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 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, the power and potential of our unique Biclonics® platform technology allowing for high throughput functional screening to discover novel, Biclonics® —human, common light chain, IgG antibodies in the bispecific format—that can unlock innovative biology; the potential of the design, activity and efficacy of MCLA-145 as described in preclinical studies, including, without limitation statements regarding the characteristics and immunostimulatory profile of MCLA-145; the clinical study design, MCLA-145's evaluation in a phase 1 open-label, multicenter dose escalation study, and planned safety dose expansion phase, the development and or timing of MCLA-145, Biclonics® program; 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 Biclonics® 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 Biclonics®, Triclonics® and multispecific 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 March 31, 2021 filed with the Securities and Exchange Commission, or SEC, on May 6, 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.

Multiclonics®, Biclonics® and Triclonics® are a registered trademarks of Merus N.V.

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