Merus Announces Strategic Collaboration with Betta Pharmaceuticals to Develop and Commercialize MCLA-129 in China

January 2, 2019

Merus to retain all global rights outside of China
Betta Pharmaceuticals to fund global IND-enabling activities

UTRECHT, the Netherlands, Jan. 02, 2019 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", "we", "our" or the "Company"), a clinical-stage immuno-oncology company developing Biclonics®, innovative full-length human bispecific antibody therapeutics, today announced that it has agreed to grant Betta Pharmaceuticals Co Ltd (SHE: 300558) an exclusive license to develop and commercialize Merus Biclonics® MCLA-129 in China. Merus will retain all rights outside of China.

Under the terms of the agreement, Betta Pharmaceuticals has agreed to be responsible for clinical development and commercialization of MCLA-129 in China. As a key strategic component of the collaboration, Betta will retain a contract manufacturing organization with experience in filing Initial New Drug (IND) applications with U.S. and European regulatory authorities in order to produce clinical trial materials for the Chinese market and rest of world. Betta will facilitate regulatory filings and early stage clinical trial materials supply for potential use by Merus for development of MCLA-129 outside of China.

"This latest collaboration is representative of our long term strategy to unlock Biclonics® platform value beyond our core programs," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "Betta Pharma is a market leader in EGFR inhibitors in China and we anticipate will be a strong partner for Merus in MCLA-129 development."

MCLA-129 is a Biclonics® binding to EGFR and cMET for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers; the upregulation of c-MET signaling has been associated with resistance to EGFR inhibition.

MCLA-129 has two distinct mechanisms of action. First, Merus' Dock & Block® mechanism of action blocks the signaling of EGFR as well as c-MET, with the potential to inhibit tumor growth and survival. Second, MCLA-129 utilizes GlymaxX® antibody-dependent cell-mediated cytotoxicity (ADCC)-enhancement technology designed for greater cell-killing potential. Because the Dock & Block and ADCC mechanism of action is based on the co-expression of EGFR and c-MET, it is expected to have less toxicity compared to agents targeting EGFR alone.

In preclinical studies, MCLA-129 showed a significant reduction in tumor volume for EGFR inhibitor resistant lung cancer models lacking immune cells. Additionally, in cell lines that co-express both EGFR and c-MET, MCLA-129 effectively induced tumor cell lysis at low antibody concentrations.

In addition to receiving an upfront payment, Merus will be eligible to receive payments contingent upon Betta Pharmaceuticals achieving certain specified development and commercial goals in China. Merus will also be eligible to receive tiered royalty payments on sales in China from Betta Pharmaceuticals. Betta Pharmaceuticals will be eligible to receive payments contingent upon Merus achieving certain specified development and commercial goals, and will be eligible to receive tiered royalty payments on sales outside of China from Merus.

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. 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 potential for Betta Pharmaceuticals to be strong partner for Merus in MCLA-129 development, Merus' ability to use Betta Pharmaceutical's regulatory filings and early stage clinical trial materials for potential ex-China development of MCLA-129, Merus' ability to unlock Biclonics® platform value beyond our core programs, the potential efficacy of MCLA-129 and potential lower toxicity than agents targeting EGFR alone, and Merus' eligibility to receive payments contingent upon Betta Pharmaceuticals achieving certain specified development and commercial goals, and Merus' eligibility to receive tiered royalty payments based on sales in China from Betta Pharmaceuticals.

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 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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