

# Merus

## **Merus Announces the U.S. Court of Appeals for the Federal Circuit Denies Regeneron's Petition to Rehear the Panel's Decision Affirming Merus' Inequitable Conduct Claim Against Regeneron**

December 27, 2017

UTRECHT, The Netherlands, Dec. 27, 2017 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced that the United States Court of Appeals for the Federal Circuit denied Regeneron Pharmaceutical Inc.'s ("Regeneron") request for a rehearing en banc to reconsider its decision affirming that Regeneron engaged in inequitable conduct before the United States Patent and Trademark Office while prosecuting U.S. Patent No. 8,502,018 ('018 patent), entitled "Methods of Modifying Eukaryotic Cells."

"The decision by the full Federal Circuit, declining further review of Regeneron's inequitable conduct, validates the thorough opinions issued by the trial court and Federal Circuit panel," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "With this order and the strength of Merus' Biclonics® technology, Merus believes it is well-positioned as an innovator in developing bispecific antibody therapeutics to address significant unmet medical needs."

In March 2014, Regeneron filed a complaint against Merus alleging that it infringed one or more claims in the '018 patent. Merus filed counterclaims seeking, among other things, a declaratory judgment that Merus did not infringe the '018 patent, that the '018 patent was invalid and a declaratory judgment of unenforceability of the '018 patent on the basis that the patent was procured by inequitable conduct. Merus prevailed at the trial court on all three counterclaims. Regeneron stipulated to non-infringement and invalidity of the patent following the district court's decision on claim construction. And after a trial in June 2015, the trial court concluded that Regeneron's agents who applied for the patent made misleading statements to the United States Patent Office when obtaining the '018 patent, and that Regeneron committed inequitable conduct. On July 27, 2017, the Federal Circuit affirmed, concluding that Regeneron made "false" assertions, relied on a "misleading presentation," and withheld material information from the United States Patent Office, and further, that Regeneron's "litigation misconduct" "obfuscated its prosecution misconduct." On December 26, 2017, the full Federal Circuit denied Regeneron's request to rehear the matter.

### **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 studies to have similar features as conventional monoclonal antibodies, such as long half-life and low immunogenicity. Merus' most advanced bispecific antibody candidate, MCLA-128, is expected to soon be evaluated in a Phase 2 combination trial in two metastatic breast cancer populations. MCLA-128 is also being evaluated in a Phase 1/2 clinical trial in Europe in gastric, ovarian, endometrial and non-small cell lung cancers. Merus' second most advanced bispecific antibody candidate, MCLA-117, is being developed in a Phase 1 clinical trial in patients with acute myeloid leukemia. The Company also has a pipeline of proprietary bispecific antibody candidates in preclinical development, including MCLA-158, which is designed to bind to cancer stem cells and is being developed as a potential treatment for colorectal cancer and other solid tumors, as well as MCLA-145, which is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target and is being developed in collaboration with Incyte Corporation. For additional information, please visit Merus' website, [www.merus.nl](http://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 strength of Merus' Biclonics® technology, Merus' belief that it is well-positioned as an innovator in developing bispecific antibody therapeutics to address significant unmet medical needs and the commencement of clinical trials of MCLA-128 in metastatic breast cancer populations.

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 existing and 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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