Merus Announces Global Settlement and End to All Patent Litigation with Regeneron Pharmaceuticals

December 20, 2018

Merus and Regeneron to cross-license patents relating to certain antibody generation platform technologies

Regeneron to purchase $15 million of Merus common shares

UTRECHT, The Netherlands, Dec. 20, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced a settlement of all pending patent litigation and administrative proceedings between Merus and Regeneron Pharmaceuticals, Inc. pertaining to certain antibody generation platforms of each company.

As part of the settlement, both parties have signed a global patent cross-license agreement, and Regeneron has agreed to provide an investment in Merus of $15 million through the purchase of 600,000 common shares at a price of $25 per share representing a premium of 118% from the close of trading on December 20, 2018. The cross-license and stock purchase are being made in conjunction with the dismissal of all claims to approximately $10.5 million for the reimbursement of attorney fees and other expenses, plus interest, awarded to Merus by the trial court on July 10, 2018. The settlement marks the end of all adversarial proceedings.

“This settlement marks the conclusion of a multi-year and multi-jurisdiction dispute,” said Ton Logtenberg, Ph.D., President and Chief Executive Officer of Merus. “Today’s agreement to resolve these matters in an amicable manner is a positive result, and we believe, continues to ensure that Merus is able to further advance our Biclonics® platform to discover and develop differentiated bispecific antibody therapeutics for cancer patients in need.”

Under the terms of settlement, all worldwide patent proceedings related to the parties’ respective antibody generation platforms have been resolved. Under the global patent cross-license agreement, the parties have granted certain royalty-free rights to each other, while maintaining the uniqueness of their respective platform technologies. Neither party is licensed to exploit the other party’s products.

The settlement also resolves a pending Dutch proceeding of a related counterpart patent, which has been stayed since 2014, and a number of opposition proceedings in multiple jurisdictions the parties have outstanding.

“Merus’ platform technology and associated patents reflect the Company’s ongoing groundbreaking work in the field of bispecific antibody generation and development,” said Peter B. Silverman, J.D., EVP and General Counsel of Merus. “This settlement further validates the strength of our IP portfolio and our ability to develop innovative Biclonics® candidates.”

Both parties have agreed to keep details relating to the global settlement confidential, other than what is disclosed in this press release or is otherwise required to be disclosed by law.

About U.S. Patent No. 8,502,018 (‘018 patent) Litigation
In March 2014, Regeneron filed a complaint against Merus alleging that it infringed one or more claims in the U.S. Patent No. 8,502,018 (‘018 patent), entitled “Methods of Modifying Eukaryotic Cells.” 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 these 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 ‘018 patent was unenforceable. On July 27, 2017, the Federal Circuit affirmed. On December 26, 2017, the full Federal Circuit denied Regeneron’s request to rehear the matter, and the Supreme Court denied Regeneron’s petition for certiorari on October 1, 2018, ending the case in favor of Merus.

On March 26, 2018, the trial court granted Merus’ motion for attorneys’ fees, expert fees, and costs, and on July 10, 2018, granted Merus’ motion for approximately $10.5 million plus interest. Regeneron appealed the decision to the Federal Circuit. The parties have now agreed to dismiss the appeal and the claim for fees as a result of the settlement and Regeneron’s $15 million investment in 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. Merus’ most advanced bispecific antibody candidate, MCLA-128, is being 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 gastric, ovarian, endometrial and non-small cell lung cancers. Additional pipeline programs include MCLA-117, which is currently being studied in a Phase 1 clinical trial in patients with acute myeloid leukemia, and MCLA-158 being studied in a Phase 1 clinical trial in patients with solid tumors with an initial focus on metastatic colorectal cancer. Through its collaboration with Incyte Corporation, Merus is also developing MCLA-145, a preclinical bispecific antibody designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. For additional information on the company and programs, please visit Merus’ website, www.merus.nl.

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, Merus’ ability to further advance its Biclonics® platform and develop innovative Biclonics® candidates, the strength of Merus’ IP portfolio, and the ongoing, groundbreaking work in the field of bispecific antibody generation and development.

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 (the "SEC") on April 30, 2018, 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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