Merus Receives FDA extension of PDUFA for zenocutuzumab

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UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 05, 2024 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (Merus, the Company, we, or our), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®), today announced that the United States Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for zenocutuzumab (Zeno) Biologics License Application (BLA) currently under priority review.

The US FDA has extended the PDUFA goal date to February 4, 2025 to enable sufficient time to review information recently submitted by the Company in response to a CMC information request. No additional clinical data have been requested.

Merus believes that obtaining a commercialization partnership agreement is an important step in bringing Zeno to patients with NRG1+ cancer, if approved.

About Merus N.V.

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 LinkedIn.

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, statements regarding the content and timing of regulatory developments and updates for zenocutuzumab; the BLA review, goal PDUFA date; and our belief that obtaining a commercialization partnership agreement is an important step in bringing Zeno to patients with NRG1+ cancer, if approved. 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 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 volatility in the global economy, including global instability, including the ongoing conflicts in Europe and the Middle East; 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 September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on October 31, 2024, 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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