Merus Granted FDA Fast Track Designation of Zenocutuzumab for the Treatment of Patients with Neuregulin 1 Fusion Cancers

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NRG1 fusions are rare mutations in many types of solid tumors, including non-small cell lung cancer and pancreatic cancer

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Jan. 07, 2021 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics™) for cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to Zenocutuzumab (Zeno) for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions (NRG1+ cancers) that have progressed on standard of care therapy.

Fast Track is a designation granted by the FDA that is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

NRG1 gene fusions are a group of rare genomic alterations emerging as potential actionable drivers of tumorigenesis and growth across many types of solid tumors, including lung, breast, pancreatic, ovarian, and colorectal cancers. Merus is currently enrolling patients into the Phase 1/2 eNRGy trial evaluating Zeno monotherapy in patients with NRG1+ cancers, in three cohorts: non-small cell lung cancer; pancreatic cancer; and other solid tumors.

“Receiving Fast Track Designation is another important milestone for Zeno, and it validates the potential for addressing the unmet need of patients with NRG1+ cancers,” said Andrew Joe, MD, Chief Medical Officer. “We continue to add clinical trial sites to and enroll patients in the eNRGy trial and look forward to providing a substantial clinical program update at a major medical meeting in the second quarter of 2021.”

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, www.merus.nl and https://twitter.com/MerusNV.

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 potential benefits of Fast Track designation for Zeno’s development for the treatment of patients diagnosed with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard of care therapy; the Zeno clinical study design, occurrence of and potential for NRG1 fusion to be an actionable driver of tumorigenesis and growth across many types of solid tumors; the addition of clinical trial sites, the enrollment of the eNRGy trial and planned update on the eNRGy trial in the second quarter of 2021. 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 quarterly period ended September 30, 2020 filed with the Securities and Exchange Commission, or SEC, on November 5, 2020, 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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