Merus Announces U.S. FDA Acceptance and Priority Review of Biologics License Application for Zeno for the Treatment of NRG1+ NSCLC and PDAC

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If approved, Zeno will be the first targeted therapy for NRG1+ cancer

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 06, 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 U.S. Food and Drug Administration (FDA) has accepted for priority review a Biologics License Application (BLA) for the bispecific antibody zenocutuzumab (Zeno) in patients with neuregulin 1 fusion (NRG1+) non-small cell lung (NSCLC) and NRG1+ pancreatic (PDAC) cancer.

“FDA acceptance of our first BLA represents an important achievement for Merus and an important potential treatment opportunity for patients with NRG1+ cancer, a disease with poor prognosis and high unmet need,” said Dr. Andrew Joe, Chief Medical Officer at Merus. “Zenocutuzumab has the potential to be the first and only targeted therapy for patients with NRG1+ lung and pancreatic cancer, and may offer a substantial improvement over currently available therapies.”

The BLA includes a comprehensive clinical data package, including data from the phase 1/2 eNRGy trial, which is investigating the safety and anti-tumor activity of Zeno monotherapy in NRG1+ NSCLC, PDAC and other solid tumors. Data from the open-label trial were presented previously at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting, and subsequently updated at ASCO 2022 and the European Society for Medical Oncology (ESMO) Congress 2023.

The FDA has granted Breakthrough Therapy Designation (BTD) to Zeno for the treatment of patients with advanced unresectable or metastatic NRG1+ pancreatic cancer following progression with prior systemic therapy or who have no satisfactory alternative treatment options. Additionally, the FDA has granted BTD to Zeno for the treatment of patients with advanced unresectable or metastatic NRG1+ NSCLC, following progression with prior systemic therapy.

Zeno is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority.

About Zeno

Zeno is a Biclonics® that utilizes the Merus Dock & Block® mechanism to inhibit the neuregulin/HER3 tumor-signaling pathway in solid tumors with NRG1 fusions (NRG1+ cancer). Through its unique mechanism of binding to HER2 and potently blocking the interaction of HER3 with its ligand NRG1 or NRG1-fusion proteins, Zeno has the potential to be particularly effective against NRG1+ cancer. In preclinical studies, Zeno potently inhibits HER2/HER3 heterodimer formation thereby inhibiting oncogenic signaling pathways, leading to inhibition of tumor cell proliferation and blocking tumor cell survival. In clinical studies, Zeno has demonstrated anti-tumor activity in multiple types of NRG1+ cancer, including NRG1+ NSCLC and NRG1+ PDAC.

About NRG1 Fusions

The NRG1 gene encodes neuregulin (also known as heregulin), the ligand for HER3. Fusions between NRG1 and partner genes are rare, tumorigenic genomic events occurring in certain cancer types including NSCLC and PDAC.

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, X 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 cost and timing of our product development activities for Zeno, the advancement of our clinical trials and our ability to successfully advance our Zeno through the regulatory and potential commercialization processes, the potential of Zeno as a treatment opportunity for patients with NRG1+ cancer and to be the first and only targeted therapy for patients with NRG1+ lung and pancreatic cancer, the potential of Zeno to provide a substantial improvement over currently available therapies. 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 market volatility; 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 Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission, or SEC, on February 28, 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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