Petosemtamab granted Breakthrough Therapy Designation by the U.S. FDA

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- Petosemtamab granted BTD for the treatment of previously treated HNSCC

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 13, 2024 (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 Breakthrough Therapy Designation (BTD) for petosemtamab for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) whose disease has progressed following treatment with platinum based chemotherapy and an anti-programmed cell death receptor-1 (PD-1) or anti-programmed death ligand 1 (PD-L1) antibody. This designation follows receipt of Fast Track Designation for petosemtamab for the treatment of patients with recurrent or metastatic HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-programmed cell death protein 1 (anti-PD-1) antibody announced in August 2023.

BTD is supported by data from the ongoing phase 1/2 open-label, multicenter trial evaluating petosemtamab monotherapy in patients with advanced solid tumors, including previously treated (recurrent or metastatic) HNSCC (NCT03526835). Merus plans to provide updated efficacy, durability and safety data from this cohort in the second half of 2024.

BTD is intended to expedite the development and review of a medicine to treat a serious or life-threatening condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on clinically significant endpoints over available therapies. BTD allows for more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, and eligibility for rolling review and priority review. With this BTD, Merus plans to engage in these discussions with the FDA in an expedited manner as we move toward our goal of a potential Biologics License Application (BLA) submission.

“We are excited and encouraged to receive BTD for petosemtamab which further validates its potential to become a new standard of care for patients with previously treated HNSCC,” said Ashley Pereira, Pharm.D. SVP of Regulatory Affairs at Merus. “We look forward to continued constructive conversations with the FDA as we move forward in our plan to initiate a phase 3 trial in previously treated HNSCC mid-2024 and prepare for a potential phase 3 trial evaluating the combination of petosemtamab and pembrolizumab in previously untreated patients.”

About Head and Neck Cancer
Head and neck squamous cell carcinoma (HNSCC) describes a group of cancers that develop in the squamous cells that line the mucosal surfaces of the mouth, throat, and larynx. These cancers begin when healthy cells change and grow in an unchecked manner, ultimately forming tumors. HNSCC is generally associated with tobacco consumption, alcohol use and/or HPV infections, depending on where they develop geographically. HNSCC is the sixth most common cancer worldwide and it is estimated that there were more than 930,000 new cases and over 465,000 deaths from HNSCC globally in 2020.[1] The incidence of HNSCC continues to rise and is anticipated to increase by 30% to more than 1 million new cases annually by 2030.[2] HNSCC is a serious and life-threatening disease with poor prognosis despite currently available standard of care therapies.

[1] Sung et al. CA Cancer J Clin, 71:209-49, 2021; [2] Johnson, D.E., Burtness, B., Leemans, C.R. et al. Head and neck squamous cell carcinoma. Nat Rev Dis Primers 6, 92 (2020)

About Petosemtamab
Petosemtamab, or MCLA-158, is a Biclonics® low-fucose human full-length IgG1 antibody targeting the epidermal growth factor receptor (EGFR) and the leucine-rich repeat containing G-protein-coupled receptor 5 (LGR5). Petosemtamab is designed to exhibit three independent mechanisms of action including inhibition of EGFR-dependent signaling, LGR5 binding leading to EGFR internalization and degradation in cancer cells, and enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) activity.

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 , Twitter 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, the potential benefits of Breakthrough designation for petosemtamab's development for the treatment of patients diagnosed with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) whose disease has progressed following treatment with platinum based chemotherapy and an anti-programmed cell death receptor-1 (PD-1) or anti-programmed death ligand 1 (PD-L1) antibody; Merus' belief that BTD may expedite the development and review of petosemtamab, and that it may allow for more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, and eligibility for rolling review and priority review; Merus' plans to engage in these discussions with the FDA in an expedited manner, and then provide a further update on the path and timeline as the Company moves towards its goal of a potential Biologics License Application (BLA) submission; Merus' belief that receipt of BTD further validates the potential of petosemtamab to become a new standard of care for patients with previously

treated HNSCC; Merus' looking forward to productive conversations with the FDA as the Company plans to initiate a phase 3 trial in 2L+ HNSCC mid-2024 and prepare for a potential phase 3 trial evaluating the combination of petosemtamab and pembrolizumab in previously untreated patients . These forward-looking statements are based on management's current expectations. 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 March 31, 2024, filed with the Securities and Exchange Commission, or SEC, on May 8, 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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