Merus Announces First Patient Dosed in LiGeR-HN2, a Phase 3 Trial Evaluating Petosemtamab in 2/3L r/m HNSCC

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Petosemtamab 1500 mg Q2W confirmed for both 2/3L phase 3 trial (LiGeR-HN2) and 1L trial (LiGeR-HN1) in r/m HNSCC following FDA feedback

UTRECHT, The Netherlands and CAMBRIDGE, Mass., July 24, 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 first patient has been dosed in the Company's phase 3 trial evaluating the efficacy and safety of petosemtamab, a Biclonics ® targeting EGFR and LGR5, compared to investigator's choice of single agent chemotherapy or cetuximab in previously treated (2/3L) patients with recurrent/metastatic head and neck squamous cell carcinoma (r/m HNSCC) referred to as the LiGeR-HN2 trial.

Merus has confirmed through feedback with the U.S. Food and Drug Administration (FDA) that petosemtamab 1500 mg every two weeks is appropriate for further development in HNSCC as monotherapy, and in combination with pembrolizumab.

"With petosemtamab's strong clinical data in HNSCC and alignment with the FDA on dose, we are excited to have treated our first patient in the 2/3L phase 3 trial," said Fabian Zohren, M.D., Ph.D., Chief Medical Officer of Merus. "We believe petosemtamab has the potential to become the new standard of care across r/m HNSCC."

More details of the trial can be found at clinicaltrials.gov.

About LiGeR-HN2
LiGeR-HN2, a phase 3 trial, will evaluate the safety and efficacy of petosemtamab compared to investigator's choice of methotrexate, docetaxel, or cetuximab in 2/3L r/m HNSCC patients. The trial is open to adult patients that have progressed on or after anti-PD-1 therapy and platinum-containing therapy. The primary endpoints are overall response rate as assessed by BICR based on RECIST v1.1 and overall survival. Secondary endpoints are duration of response and progression free survival. Merus plans to enroll approximately 500 patients in the trial.

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 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 Merus
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 evaluation of petosemtamab in patients with HNSCC in monotherapy and in combination with pembrolizumab, our belief, through feedback with the U.S. FDA, that petosemtamab 1500 mg every two weeks is appropriate for further development in HNSCC as monotherapy, and in combination with pembrolizumab; and our belief in alignment with the FDA on dose, our excitement to having treated our first patient in the 2/3L phase 3 trial; and belief that petosemtamab has the potential to become a new standard of care treatment for r/m HNSCC; and that the incidence of HNSCC continues to rise and is anticipated to increase by 30% to more than 1 million new cases annually by 2030. 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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