Merus Announces Abstract Accepted for Presentation at the ESMO Asia Congress 2024

September 17, 2024 at 9:00 AM EDT

Petosemtamab in 2L+ HNSCC interim clinical data selected for rapid oral presentation

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Sept. 17, 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 the acceptance of an abstract on petosemtamab, a Biclonics® targeting EGFR and LGR5, in previously treated (2L+) patients with recurrent/metastatic head and neck squamous cell carcinoma (r/m HNSCC) for presentation at the European Society for Medical Oncology (ESMO®) Asia Congress 2024 taking place in Singapore December 6-8, 2024.

Rapid oral presentation:
Title: Petosemtamab (MCLA-158) monotherapy in previously treated (2L+) recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 trial
Abstract #: 411MO
Session Title: Mini Oral session: Head and Neck cancers
Session Date and Time: December 7, 2024; 3:25-3:30 p.m. SGT
Location Hall: 404

The abstract will be available on the ESMO® Asia Congress website on Sunday, Dec. 1, 2024 at 11:05 a.m. ET. The full presentation will be available on the Merus website at the start of each session.

Merus provided an interim clinical update on petosemtamab monotherapy in 2L+ HNSCC at the American Association of Cancer Research® (AACR®) Annual Meeting 2023, demonstrating a 37% response rate among 43 evaluable patients. The presentation at ESMO® Asia will include updated efficacy, durability and safety data from that initial 2L+ HNSCC cohort along with interim data from the dose optimization cohort evaluating petosemtamab monotherapy 1500 or 1100 mg dose levels in 2L+ HNSCC.

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.

Merus is currently enrolling LiGeR-HN2, a phase 3 trial evaluating the efficacy and safety of petosemtamab compared to investigator's choice of single agent chemotherapy or cetuximab in previously treated (2/3L) patients with r/m HNSCC and plans to initiate LiGeR-HN1, a phase 3 trial evaluating petosemtamab in combination with pembrolizumab in frontline (1L) HNSCC by year end 2024.

About Petosemtamab
Petosemtamab, or MCLA-158, is a bispecific 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 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 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 clinical development of our clinical candidates, including petosemtamab, future clinical trial results or interim data, clinical activity and safety profile, and development plans in the on-going trials and described in forthcoming posters or presentations. 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-Q for the quarter ended June 30, 2024 filed with the Securities and Exchange Commission, or SEC, on August 1, 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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