# Merus Announces Publication of an Abstract on Petosemtamab as 2L+ treatment of r/m HNSCC at the ESMO Asia Congress 2024

December 1, 2024

*– Petosemtamab 1500 mg monotherapy phase 2 interim data continues to demonstrate clinically meaningful activity in 2L+ HNSCC*

*– Conference call on Saturday, Dec. 7 at 9:00 a.m. ET to discuss full data set*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Dec. 01, 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 publication of an abstract regarding petosemtamab, a Biclonics® targeting EGFR and LGR5, in previously treated (2L+) patients (pts) with recurrent/metastatic head and neck squamous cell carcinoma (r/m HNSCC) on the European Society for Medical Oncology (ESMO®) Asia Congress website. The abstract presents updated clinical data on petosemtamab from the initial expansion cohort (1500 mg) and a new dose-comparison cohort (1100 mg vs. 1500 mg) in 2L+ HNSCC for presentation at the ESMO® Asia Congress 2024 taking place in Singapore, Dec. 6-8, 2024.

The presentation will be discussed on a conference call on Saturday, December 7, at 9:00 a.m. ET. The presentation will include interim data from a later data cutoff date with additional patients evaluable for response and more mature duration of treatment information.

“Petosemtamab 1500 mg monotherapy continues to demonstrate consistent, durable, and clinically meaningful efficacy in 2L+ r/m HNSCC, underscoring its potential to become a new standard of care,” said Fabian Zohren, M.D., Ph.D., Chief Medical Officer of Merus. “We are looking forward to our upcoming presentation which will include new information with updated efficacy and safety of the larger, combined 2L+ dataset.”

**Presentation title:** Petosemtamab (MCLA-158) monotherapy in previously treated (2L+) recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 trial

Observations in the abstract include:

- As of a November 6, 2023 data cutoff date 54 pts were treated with 1500 mg Q2W in the expansion cohort reported initially at AACR® 2023
  - 47* pts were evaluable for response (≥4 months follow up prior to data cutoff date and ≥1 post baseline scan, or early progressive disease (PD)) and overall response rate was 40.4% (19/47 and 1 unconfirmed partial response (PR) that confirmed post cutoff, 20/47) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment
  - 7.2 months median duration of response
  - 5.1 months median progression free survival
  - 12.5 months median overall survival
- As of a March 6, 2024 data cutoff date, 42 pts were randomized to the 1500 mg vs. 1100 mg dose comparison cohort
  - At 1500 mg, 12 pts were evaluable for response, 5 responses were observed including 1 complete response, 3 PRs, and 1 unconfirmed PR (confirmed post cutoff)
  - At 1100 mg, 10 pts were evaluable for response with 1 confirmed PR observed
- Petosemtamab was well tolerated at both dose levels; no new safety signals observed
  - No grade 5 treatment emergent adverse events were reported

*6 pts were excluded per protocol (as previously presented at AACR® 2023): 5 pts withdrew due to infusion related reactions on Day 1; 1 pt had exclusion criteria deviation; 1 pt had <4 months follow up at the data cutoff

**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; 14:30 - 16:10 p.m. SGT
**Location Hall:** 404

As the full presentation becomes available at the ESMO® Asia Congress 2024, it will contemporaneously be available on the Merus website.

**Company Conference Call and Webcast Information**
Merus will hold a conference call and webcast for investors on December 7, 2024 at 9:00 a.m. ET. A replay will be available after the completion of the call in the Investors and Media section of our website for a limited time.

**Date & Time:** Dec. 07, 2024 at 9:00 a.m. ET
**Webcast link:** Available on our website
**Dial-in:** Toll Free: **1 (800) 715-9871**/ International: **1 (646) 307-1963**
**Conference ID: 1978503**

**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 , 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; and our belief that petosemtamab has the potential to become a new standard of care. 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 September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on October 31, 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.



Investor and Media Inquiries:
Sherri Spear
Merus N.V.
SVP Investor Relations and Strategic Communications
617-821-3246
s.spear@merus.nl

Kathleen Farren
Merus N.V.
Assoc. Director IR/Corp Comms
617-230-4165
k.farren@merus.nl

Source: Merus N.V.