Merus' Petosemtamab with Pembrolizumab Interim Data Demonstrates Robust Efficacy and Durability in 1L PD-L1+ r/m HNSCC

May 22, 2025

- 63% response rate observed among 43 evaluable patients

- 79% overall survival rate at 12-months; 9 months median progression-free survival

- Conference Call on Thursday, May 22 at 5:30 p.m. ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 22, 2025 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (Merus, the Company, we, or our), an oncology company developing innovative, full-length multispecific antibodies and antibody drug conjugates (Biclonics®, Triclonics® and ADClonics®), today announced interim clinical data as of a February 27, 2025 data cutoff from the ongoing phase 2 trial of the bispecific antibody petosemtamab in combination with pembrolizumab. These data will be presented by Dr. Carla M. L. van Herpen M.D. Ph.D., Radboud University Medical Center, Nijmegen, Netherlands at the 2025 American Society of Clinical Oncology® (ASCO®) Annual Meeting on Monday, June 2 at 9 a.m. - 12:00 p.m. CT.

"By essentially every metric, we believe these interim data are significantly better than pembrolizumab monotherapy, the control arm of our ongoing phase 3 trial, and underscores the opportunity petosemtamab holds to become a new standard of care, if approved, in head and neck cancer," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "Additionally, we believe our execution is outstanding with rapid site initiation. We are looking forward to potentially sharing top line interim readout of one or both of our phase 3 trials in 2026."

"Head and neck squamous cell carcinoma is associated with a poor prognosis and high mortality rate, and there remains a need for new treatment options for patients," added Dr. van Herpen. "In my clinic, I have witnessed firsthand profound tumor shrinkage with petosemtamab administration, and the efficacy results petosemtamab has shown thus far in combination with the current standard of care, pembrolizumab. I'm excited by the impressive ORR and durability of those responses, and what these results, if replicated more broadly could mean for the future of our practice in head and neck cancer."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors

Presentation title: Petosemtamab (MCLA-158) with pembrolizumab as first-line (1L) treatment of PD-L1+ recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 trial

Observations in the presentation include as of a February 27, 2025 data cutoff date:

- 45 patients (pts) were treated
  - The efficacy evaluable population consisted of 43 patients who were treated (with one or more doses) as of the data cutoff date and either ≥1 post-baseline tumor assessment, or discontinued early due to disease progression or death
  - Median follow up of 14.3 months for the 45 patients
- In 43 evaluable patients:
  - Confirmed overall response rate: 63% (27/43, 95% CI: 49-75), including 6 complete responses, 21 partial responses by Response Evaluation Criteria in Solid Tumors v1.1. per investigator assessment, including:
    - 4 of 8 patients with HPV associated cancer responded
    - Responses observed across PD-L1 levels (CPS 1-19: 47% [8/17]; CPS > 20: 73% [19/26])
  - Median progression-free survival was 9 months (95% CI: 5.2-12.9)
  - Median duration of response and median overall survival (OS) were not reached
  - 79% overall survival rate at 12-months (30/43 censored)
- At the time of data cutoff, 14 patients, each of whom are responders, remained on treatment
- In 45 patients the combination was generally well tolerated and no significant overlapping toxicities with pembrolizumab were observed
  - Treatment-emergent adverse events (TEAEs) were reported in 45 pts
  - G≥3 TEAEs occurred in 27 (60%) patients, including 20 (44%) patients who experienced treatment-related TEAEs
  - Infusion-related reactions (composite term) were reported in 38% of patients (all Gs) and 7% (G3), no G4 or 5, mainly occurred during the first infusion and were resolved

Abstract #: 6024
Poster Board: 432
Session Title: Head and Neck Cancer
Session Date and Time: June 2, 2025, 9:00-12:00 CT

As full presentations become available at the 2025 ASCO® Annual Meeting, they will contemporaneously be available on the Merus website.

An analysis of the confirmed responses observed from administration of petosemtamab across the first line combination (as of the February 27, 2025 data cutoff date) and second-line plus monotherapy phase 2 cohorts (as of the July 5, 2024 data cutoff date), demonstrated that two-thirds of these responses with petosemtamab in HPV-associated p16+ oropharyngeal cancer occurred in never-smokers.

Company Conference Call and Webcast Information
Merus will hold a conference call and webcast for investors on Thursday, May 22, 2025 at 5:30 p.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: May 22, 2025 at 5:30 p.m. ET
Webcast link: Available on our website
Dial-in: Toll Free: (800) 715-9871 **/** International: (646) 307-1963
Conference ID: 7517301 or Merus NV call

About Merus N.V.

Merus is an 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 , LinkedIn and Bluesky.

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 presentation; our belief that in this interim dataset, petosemtamab in combination with pembrolizumab are significantly better than the standard of care by essentially every metric; our belief that these data underscore the incredible opportunity petosemtamab holds to become a new standard of care in head and neck cancer; our statements regarding our future execution, including the rapidity of site initiation. 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 quarter ended March 31, 2025 filed with the Securities and Exchange Commission, or SEC, on May 7, 2025, 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.
Director Investor Relations and Corporate Communications
617-230-4165
k.farren@merus.nl

Source: Merus N.V.