Merus' Petosemtamab in Combination with Pembrolizumab Interim Data Demonstrates Robust Response Rate and Favorable Safety Profile in 1L r/m HNSCC

May 28, 2024 at 7:00 AM EDT

67% response rate observed among 24 evaluable patients

Conference Call on Tuesday, May 28th at 8 a.m. ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 28, 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 interim clinical data as of a March 6, 2024 data cutoff from the ongoing phase 1/2 trial of the bispecific antibody petosemtamab in combination with pembrolizumab. These data will be presented by Dr. Jerome Fayette M.D. Ph.D., Centre Léon Bérard, Lyon, France at the 2024 American Society of Clinical Oncology® (ASCO®) Annual Meeting on Monday, June 3 at 8 a.m. CT.

"In this interim dataset, petosemtamab in combination with pembrolizumab has demonstrated clinically meaningful activity in first line head and neck cancer, with a 67% response rate overall, observed across tumor PD-L1 expression levels and HPV status and with encouraging safety," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "I'm excited to announce plans to initiate a phase 3 registration trial of petosemtamab in combination with pembrolizumab, regardless of HPV status, in first line, PD-L1 expressing, head and neck cancer, which we expect will start by year end 2024."

"Despite recent advancements, head and neck squamous cell carcinoma remains a deadly disease with limited treatment options," added Dr. Fayette. "Based on these data, I'm optimistic petosemtamab, in combination with pembrolizumab, has the potential to become a new standard of care for patients with previously untreated head and neck cancer."

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

Rapid oral presentation title: Petosemtamab (MCLA-158) with pembrolizumab as first-line (1L) treatment of recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 study
Observations in the presentation include:

- As of a March 6, 2024 data cutoff date, 45 patients (pts) were treated
  - 26 patients were enrolled as of the abstract cutoff date
    - The efficacy population consisted of 24 patients who had the opportunity for 4 or more months follow up, with ≥2 treatment cycles and ≥1 post-baseline tumor assessment; or who discontinued early due to disease progression or death
    - Two patients were not included: One patient withdrew consent prior to first tumor assessment and the other patient discontinued due to toxicity with less than 2 cycles of treatment
  - Response rates overall (N=24): 67%, including 1 confirmed complete response, 12 confirmed partial responses (PRs) and 3 unconfirmed PRs (all of whom confirmed after the data cutoff) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment, including
    - 3 of 4 patients with HPV associated cancer responded
    - Responses observed across PD-L1 levels (CPS 1-19: 60% [6/10]; CPS ≥ 20: 71% [10/14])
  - At the time of data cutoff, 32 patients of the 45 enrolled, remained on treatment, including 14 of 16 responders and 18 of the initial 26 patients enrolled
  - Median follow up of 3.6 months for the 45 patients
- In 45 patients the combination was well tolerated and no significant overlapping toxicities with pembrolizumab were observed
- Treatment-emergent adverse events (AEs) were reported in 45 pts
  - Most were Grade (G) 1 or 2 in severity (no G4–5 were observed)
  - Infusion-related reactions (composite term) were reported in 38% (all Gs) and 7% (G3) of pts, most occurred during the first infusion and resolved

Presentation Details:
Abstract #: 6014
Session Title: Head and Neck Cancer
Session Date and Time: June 3, 2024, 8:00-9:30 a.m. CT

As full presentations become available at the 2024 ASCO® Annual Meeting, they 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 Tuesday, May 28, 2024 at 8:00 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: May 28, 2024 at 8:00 a.m. ET
Webcast link: Available on our website
Dial-in: Toll Free: 1 (800) **715-9871**/ International: **1 (646) 307-1963**
Conference ID: 4160163

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, https://www.merus.nl and https://twitter.com/MerusNV.

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 has demonstrated clinically meaningful activity in first line head and neck cancer with encouraging safety; our plans to initiate a phase 3 registration trial of petosemtamab in combination with pembrolizumab, regardless of HPV status, in first line, PD-L1 expressing, head and neck cancer, which we expect will start by year end 2024; and the potential for petosemtamab in combination with pembrolizumab to become a new standard of care in 1L head and neck cancer. 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 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 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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