Merus' Petosemtamab Interim Data Demonstrates Clinically Meaningful Activity in Previously Treated Head and Neck Squamous Cell Carcinoma (HNSCC)

April 17, 2023

- 37% overall response rate (ORR) observed in 43 evaluable patients
- 6 months median duration of response as of Feb. 1, 2023 data cutoff date
- End-of-phase meeting with U.S. Food & Drug Administration provides clarity to potential registration path in HNSCC
- Investor call on April 17, 2023 at 6:30 p.m. ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., April 17, 2023 (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 February 1, 2023 data cutoff, from the ongoing phase 1/2 trial of the bispecific antibody petosemtamab in previously treated head and neck squamous cell carcinoma (HNSCC). The Plenary Session presentation by Dr. Ezra EW Cohen, Moores Cancer Center, UC San Diego Health, will occur today at the American Association of Cancer Research (AACR) Annual Meeting 2023, taking place in Orlando, Florida.

Petosemtamab, or MCLA-158, is a human IgG1 Biclonics® designed to bind to cancer cells expressing epidermal growth factor receptor (EGFR) and leucine-rich repeat-containing G protein-coupled receptor 5 (LGR5).

"I am excited by this interim dataset that demonstrates the consistent and clinically meaningful activity of petosemtamab in patients with previously treated head and neck squamous cell carcinoma," said Dr. Andrew Joe, Chief Medical Officer at Merus. "This is clinical validation of a first of its kind EGFR and LGR5 targeting agent."

"There is significant unmet medical need in head and neck squamous cell carcinoma," added Dr. Cohen. "Petosemtamab has the potential to be a meaningful medicine and new standard of care for patients with head and neck cancer."

Updated information and observations from plenary presentation of the ongoing phase 1/2 trial include:

- As of the February 1, 2023 data cutoff date, 49 previously treated HNSCC patients (pts) were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous every two weeks
- Patient population:
  - Median age was 63 (range of 31-77); 78% were male
  - Median prior lines of systemic therapy was 2 (range 1-4); including PD-(L)1 inhibitor in 96% of pts, chemotherapy in 94% and platinum-based chemotherapy in 92% of pts; 2 pts received prior cetuximab
  - Most frequent primary tumor locations were oropharynx (35%), oral cavity (31%), and larynx (16%)
- 43 pts were evaluable for efficacy, receiving ≥2 treatment cycles (≥8 weeks) with ≥1 post-baseline tumor assessment or experiencing early progressive disease:
  - Antitumor activity among 43 pts:
    - Overall responses rate (ORR) was 37.2% (16/43; 95% CI 23%-53.3%) by RECIST 1.1. per investigator assessment, including 15 confirmed partial responses (PR) and 1 confirmed complete response (CR) (ongoing after 20 months)
    - Disease control rate (CR + PR + stable disease) was 72.1% (31/43; 95% CI 56.3%-84.7%)
    - Median time to response was 1.8 months (range 0.8-3.5)
    - Median duration of response was 6.0 months (95% CI 3.7-NC), with 10 of 16 (62.5%) responders ongoing, and 12 of 43 (27.9%) patients overall ongoing at the time of the data cutoff
    - Median progression free survival was 5.3 months (95% CI 3.7-6.8); with 29 of 43 pts progressing and 14 of 43 pts censored
    - Median overall survival was 11.5 months (95% CI 7.2-20.6); with 29 of 49 pts still alive at the data cutoff date
- Petosemtamab continued to demonstrate a manageable safety profile:
  - 80 pts were treated with 1500 mg petosemtamab every two weeks across dose escalation and expansion cohorts of the study
  - Gastrointestinal and skin toxicities were mostly mild to moderate
  - No treatment-related Grade 5 AEs:
    - Most frequent related AEs were signs and symptoms of infusion-related reactions (IRRs)
    - 74% Grade 1-4, 21% Grade 3-4 (as grouped term)
    - Mainly occurred during first infusion
    - 6 of 80 pts discontinued on Day 1 due to a Grade 3-4 IRR
    - For all patients rechallenged after an IRR, rechallenge was successful

- IRRs were manageable with prophylaxis/ prolonged infusion (necessary on Day 1 only)

The presentation is now available on the Merus website.

Company Conference Call and Webcast Information
Merus will hold a conference call and webcast for investors on April 17, 2023 at 6:30 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: April 17, 2023 at 6:30 p.m. ET
Webcast link: Available on our website
Dial-in: Toll Free: 1 (800) 715-9871 / International: 1 (646) 307-19631
Conference ID: 4032258

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 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 petosemtamab, future clinical trial progress, enrollment, results, clinical activity and safety profile of petosemtamab in the ongoing phase 1/2 trial; the potential of petosemtamab to be a meaningful medicine and new standard of care for patients with head and neck cancer; and our belief that petosemtamab interim data demonstrates clinically meaningful activity in previously treated head and neck squamous cell carcinoma and is clinical validation of an EGFRxLGR5 targeting agent. 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 COVID-19 pandemic; 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-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on February 28, 2023, 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.
VP Investor Relations and Corporate Communications
617-821-3246
s.spear@merus.nl

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