Merus Announces Publication of an Abstract on Petosemtamab Monotherapy in Previously Treated Head and Neck Squamous Cell Carcinoma for Plenary Session Oral Presentation at the AACR Annual Meeting 2023 and Provides a Program and Regulatory Update

April 14, 2023

- Robust 36% overall response rate (ORR) in 42 evaluable patients

- 6 months median duration of response with 17 patients still on treatment as of Nov. 28, 2022 data cutoff

- 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

ET UTRECHT, The Netherlands and CAMBRIDGE, Mass., April 14, 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 the publication of an abstract for a plenary session oral presentation of interim clinical data on the bispecific antibody petosemtamab in previously treated head and neck squamous cell carcinoma (HNSCC) at the American Association for Cancer Research (AACR) Annual Meeting 2023 taking place in Orlando, Florida April 14-19, 2023.

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).

"We are excited by these data demonstrating clinically meaningful efficacy and durability of petosemtamab in previously treated head and neck cancer. We are looking forward to sharing additional details at the AACR clinical trials plenary session and on our upcoming investor call," said Dr. Andrew Joe, Chief Medical Officer at Merus.

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
Enrollment continues in dose expansion in the phase 1/2 trial, including in combination with Keytruda (pembrolizumab)

Petosemtamab is in clinical development in the expansion part of a phase 1/2 open-label, multicenter trial in advanced solid tumors, including previously treated head and neck squamous cell carcinoma (HNSCC). The Company also initiated a cohort investigating petosemtamab in combination with Keytruda in patients with untreated HNSCC, designed to evaluate safety and clinical activity in this population.

Plenary Session Oral Presentation: Clinical activity of MCLA-158 (petosemtamab), an IgG1 bispecific antibody targeting EGFR and LGR5, in advanced head and neck squamous cell cancer (HNSCC)

The oral presentation will include updated interim data from the ongoing phase 1/2 clinical trial and will be presented by the Principal Investigator, Dr. Ezra EW Cohen, Moores Cancer Center, UC San Diego Health.

The abstract provides information and observations from the ongoing phase 1/2 trial, including:

- As of a November 28, 2022 data cutoff date, 49 previously treated HNSCC patients (pts) were treated with petosemtamab 1500 mg IV 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 anti-PD-1/PD-L1 in 96% of pts, 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%)
- 42 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 the 42 pts:
    - Overall responses rate (ORR) was 35.7% (15/42), by RECIST 1.1 per investigator assessment including 1 complete response (ongoing after 18 months), 12 partial responses (PRs), and 2 unconfirmed PRs with treatment ongoing at the data cutoff
    - Median duration of response (DOR) was 6.0 months (95%CI=3.3-not calculable) and median progression-free survival was 5.0 months (95%CI=3.2-6.8) with 17 pts continuing on therapy at the data cutoff

- Petosemtamab continued to demonstrate a manageable safety profile:
  - Of 78 pts treated at the recommended phase 2 dose of 1500 mg every two weeks (escalation and all expansion cohorts), the most frequent AEs regardless of causality (all grades/G3-4) were rash (33%/0%), hypotension (26%/6%), dyspnea (26%/4%), nausea (26%/1%), dermatitis acneiform (24%/1%), blood magnesium decreased (19%/5%), erythema (19%/0%), diarrhea (19%/0%); IRRs (composite term) were reported in 74%/21% of pts, mostly at the first infusion, and all resolved. 5 pts (6%) discontinued treatment due to IRRs on Day 1.

Presentation Details:
Title: Clinical activity of MCLA-158 (petosemtamab), an IgG1 bispecific antibody targeting EGFR and LGR5, in advanced head and neck squamous cell cancer (HNSCC)
Session Category: Clinical Trials Plenary Session
Session: Promising Novel Antitumor Strategies in Early Phase Clinical Trials
Date: Monday, April 17, 2023
Time: 10:15 a.m. – 12:15 p.m. ET
Presentation #: CT012

Regulatory Update

Merus met with the U.S. Food and Drug Administration (FDA) in an end-of-phase meeting to discuss interim results from the previously treated HNSCC cohort of the petosemtamab phase 1/2 trial. The FDA recognized recurrent or metastatic HNSCC represents an area of unmet medical need, and provided clear recommendations for the path to potential registration.

Based on the strong clinical data and discussions with the FDA, Merus believes a randomized clinical trial in previously treated (2L/3L) or untreated (front-line) HNSCC may support a possible registration. Additionally, Merus believes a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval. The Company plans to continue to acquire data to confirm a suitable dose for future randomized clinical trials.

“Based on our end-of-phase meeting with the FDA, we believe we have optionality in our development path for petosemtamab in head and neck squamous cell carcinoma and are excited to continue investigation of this important new potential therapy for patients,” said Bill Lundberg, M.D., President, Chief Executive Officer at Merus. “I’m proud of the progress we are making towards our ambition to become a fully integrated US product company.”

The abstract can be found on the conference 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 in monotherapy and in combination with pembrolizumab in pretreated and untreated HNSCC patients, enrollment, results, clinical activity and safety profile of petosemtamab in the ongoing phase 1/2 trial; the potential petosemtamab holds to offer a meaningful improvement in the lives of patients with head and neck cancer; Merus’ belief in the importance of petosemtamab as a new potential future therapy for patients in need; the promising data in the clinic of Merus' clinical candidates and potential of Merus' proprietary Biclonics ® technology; the sharing of additional details at the AACR clinical trials plenary session and on our upcoming investor call; Merus’ regulatory interactions with the FDA and Merus’ beliefs concerning potential randomized clinical trials in previously treated (2L/3L) or untreated (front-line) HNSCC that may support a possible registration, potential for accelerated approval and plans to continue to acquire data to confirm a suitable dose for future randomized clinical trials; and progress Merus is making towards our ambition to become a fully integrated US product company. 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.

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