Merus Announces Business Update Conference Call

October 15, 2023 at 7:58 PM EDT

- *Zeno interim clinical data continues to show robust efficacy in NRG1+ NSCLC and PDAC: Sufficient clinical data expected in 1H24 to support potential BLA submissions*
- *Petosemtamab 2L+ HNSCC phase 3 trial design supported by INTERLINK-1 control arm*
- *Clinical data update on petosemtamab monotherapy in 2L+ HNSCC planned 2024*
- *MCLA-129 abstracts accepted at ESMO Asia*
- *Investor call on Monday, October 16 at 7:30 a.m. ET*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Oct. 15, 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 that it will host a conference call to discuss a business update on Monday, October 16, 2023 at 7:30 a.m. ET.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion (NRG1+) cancer and other solid tumors

Today two abstracts were published on the European Society for Medical Oncology Congress (ESMO) 2023 website. The abstracts highlight updated interim clinical data from the ongoing phase 1/2 eNRGy trial and Early Access Program (EAP) of the bispecific antibody zenocutuzumab (Zeno) in patients with neuregulin 1 fusion (NRG1+) cancer. The Principal Investigator of the eNRGy trial, Dr. Alison Schram of Memorial Sloan-Kettering Cancer Center will present a mini oral session on NRG1+ NSCLC. The ESMO Congress 2023 will take place in Madrid, Spain October 20-24, 2023.

”Zeno continues to show remarkably consistent efficacy over time, with robust and durable responses in these difficult-to-treat indications,” said Dr. Andrew Joe, Chief Medical Officer at Merus. “We recently met with the FDA in the context of our two breakthrough therapy designations and based on these productive and collaborative discussions, we believe we will have sufficient data for both NRG1+ NSCLC and NRG1+ PDAC in the first half of 2024 to support biologics license application submissions.”

Interim data included in the abstracts are from the phase 1/2 eNRGy trial and EAP which are assessing the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer. Updated data will be provided in the presentations to include additional patients as well as follow-up on safety and efficacy for the patients presented in the abstracts:

Mini Oral Presentation Title: Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced *NRG1* fusion-positive (NRG1+) non-small cell lung cancer (NSCLC)

- Observations in the abstract include:
  - As of a February 1, 2023 data cutoff date, 85 patients (pts) with NRG1+ NSCLC were enrolled. 64 pts with measurable disease were treated as of August 1, 2022 allowing for the potential for ≥ 6 months follow up and were evaluable for response
    - 34% overall response rate (ORR) (95% CI, 23-47) by RECIST v1.1. per investigator assessment
    - 78% of pts had target lesion reduction
    - 12.9 months median duration of response (DOR), with responses ongoing in 50% of pts
    - Among the 85 pts enrolled, Grade ≥ 3 adverse events (AEs) irrespective of causality occurred in < 4% pts

Presentation Details:
Session Category: Mini oral session 1
Session: NSCLC, metastatic
Date: Saturday, October 21, 2023
Time: 9:35-9:40 CEST
Presentation #: 1315MO

Poster Presentation Title: Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced *NRG1* fusion-positive (NRG1+) pancreatic ductal adenocarcinoma (PDAC)

- Observations in the abstract include:
  - As of a February 1, 2023 data cutoff date, 38 pts with NRG1+ PDAC were enrolled. 27 pts with measurable disease were treated as of August 1, 2022 allowing for the potential for ≥ 6 months follow-up and were evaluable for response
    - 44% ORR (95% CI, 26-65) by RECIST v1.1. per investigator assessment; including 1 complete response

- 81% of pts had target lesion reduction and 84% of pts had CA 19-9 decline of ≥ 50% from baseline
- 9.1 months median DOR, with responses ongoing in 33% of pts
- Among the 38 pts enrolled, Grade ≥ 3 AEs irrespective of causality occurred in < 5% pts

Presentation Details:
Session: Poster Session
Date: Monday, October 23, 2023
Time: 9:00-17:00 CEST
Presentation #: 1618P

As full presentations become available at the ESMO Congress 2023, they will contemporaneously be available on the Merus website.

Merus is also evaluating Zeno in combination with androgen deprivation therapy (enzalutamide or abiraterone) in men with castration resistant prostate cancer, irrespective of NRG1+ status. Merus plans to provide initial clinical data in the second half of 2023.

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

Merus plans to initiate the phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in previously treated recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). Earlier this year in a presentation at the American Association of Cancer Research Annual Meeting, interim clinical data in this indication, having a data cutoff date of February 1, 2023, demonstrated the high and durable efficacy of petosemtamab with a well-tolerated and manageable safety profile.

“We’re very excited to start enrolling the randomized phase 3 trial as we believe we have an opportunity to significantly improve the outcomes of patients with head and neck cancer,” said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. “Additionally, we are encouraged to report that among the initial patients dosed in the front-line combination of petosemtamab with Keytruda®, the safety profile has been observed to be generally favorable with no dose limiting toxicities reported to date.”

In the planned phase 3 trial, patients will be randomized to petosemtamab monotherapy or to investigators choice of single agent chemotherapy or cetuximab. Data regarding the INTERLINK-1 trial was released today ahead of the ESMO Congress 2023. Merus believes the clinical activity of cetuximab monotherapy in patients with recurrent or metastatic squamous cell carcinoma of the head and neck who received prior platinum-based chemotherapy and a PD-1/PD-L1 inhibitor, further supports the planned design of our phase 3 clinical trial.

Merus continues to enroll approximately 40 patients with previously treated HNSCC with petosemtamab monotherapy at the 1100 or 1500 mg dose levels to confirm a suitable dose for future potential randomized trials. Merus plans to share the clinical data from this cohort in 2024.

Merus also continues to enroll patients with previously untreated advanced PD-L1+ HNSCC with petosemtamab 1500 mg in combination with Keytruda®. Initial safety data from this single arm cohort may support the initiation of a first-line registration trial with this combination. Merus plans to report initial interim safety and efficacy data from this cohort in the first half of 2024.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors

Abstracts on the bispecific antibody MCLA-129 in NSCLC and in previously treated HNSCC were selected for presentation at the ESMO Asia Congress 2023 taking place in Singapore December 1-3, 2023.

Title: Efficacy and safety of MCLA-129, an EGFR x c-MET bispecific antibody, combined with osimertinib, as first-line therapy or after progression on osimertinib in non-small cell lung cancer (NSCLC)

Title: Efficacy and safety of MCLA-129, an anti-EGFR/c-MET bispecific antibody, in head and neck squamous cell cancer (HNSCC)

Merus is discontinuing the NSCLC with EGFR exon20 mutation cohort due to the competition in this niche market.

Company Conference Call and Webcast Information

Merus will hold a conference call and webcast for investors on **October 16, 2023 at 7:30 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 and Time: October 16, 2023 at 7:30 a.m. ET
Webcast link: Available on our website
Dial-in: Toll-Free: 1 (800) 715-9871 / International: 1 (646) 307-1963
Conference ID: 6064075

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://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 content and timing of clinical trials, data readouts and clinical updates for our product candidates, our belief on the impact of breakthrough therapy designations and FDA interactions on future events for zenocutuzumab; the treatment potential of our product candidates, their mechanism of action, future clinical trial developments or interim analyses, or statements about any future impact from evidence of clinical activity, including of zenocutuzumab in NRG1+ cancer, NRG1+ NSCLC or NRG1+ PDAC, and our belief that we will have sufficient data for both NRG1+ NSCLC and NRG1+ PDAC in the first half of 2024 to support biologics license application submissions; plans to initiate the phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in previously treated recurrent or metastatic HNSCC; the future potential safety and efficacy of zenocutuzumab or petosemtamab alone or in combination with Keytruda; the potential opportunity that petosemtamab may have to significantly improve the outcomes of patients with head and neck cancer; our belief that data from INTERLINK-1 trial further supports a planned phase 3 trial; and updates planned for petosemtamab in 2024 and beyond. 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 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 Quarterly Report on Form 10-Q for the period ended June 30, 2023 filed with the Securities and Exchange Commission, or SEC, on August 3, 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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