Merus' Zeno Interim Data Continues to Demonstrate Robust and Durable Responses in NRG1+ Cancer

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- 37% ORR and 14.9 months median DOR in 78 evaluable NRG1+ NSCLC patients

- 42% ORR and 9.1 months median DOR in 33 evaluable NRG1+ PDAC patients

- Sufficient clinical data expected in 1H24 to support potential BLA submissions

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Oct. 23, 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 July 31, 2023 data cutoff date, from the phase 1/2 eNRGy trial and Early Access Program (EAP) of the bispecific antibody zenocutuzumab (Zeno) in patients with neuregulin 1 fusion (NRG1+) cancer presented by Principal Investigator, Dr. Alison Schram* of Memorial Sloan Kettering Cancer Center at the European Society for Medical Oncology (ESMO) Congress 2023.

"I've been impressed by the consistency of the Zeno clinical data and am convinced Zeno has the potential to be both a first and best in class treatment for NRG1+ cancer," said Dr. Andrew Joe, Chief Medical Officer at Merus. "I expect we will have the dataset in the first half of 2024 to support potential BLA submissions in both NRG1+ NSCLC and PDAC."

Dr. Schram added, "Currently, there are no approved therapies specifically for the treatment of NRG1+ cancer, resulting in patients being treated with standard of care by tumor type despite data suggesting NRG1+ cancers may respond poorly to chemoimmunotherapy. With Zeno's durable efficacy and excellent safety profile reported at ESMO, I believe Zeno could be an important, new standard of care for patients with NRG1+ cancer."

The reported data 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.

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 presentation include:

- As of July 31, 2023 data cutoff date, 105 patients with NRG1+ NSCLC were treated with Zeno. 78 patients with measurable disease were treated by February 13, 2023, allowing for the potential for ≥ 24 week follow-up, and who met the criteria for the primary analysis population.
    - 37.2% (29/78; 95% CI: 26.5-48.9) overall response rate (ORR) per RECIST v1.1 by investigator assessment
    - 61.5% (95% CI: 49.8 - 72.3) clinical benefit rate
    - 14.9 months median duration of response (DOR) and 20 of patients were continuing treatment as of the data cutoff

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

Observations in the presentation include:

- As of July 31, 2023 data cutoff date, 44 patients with NRG1+ PDAC were treated with Zeno. 33 patients with measurable disease were treated by February 13, 2023, allowing for the potential for ≥ 24 weeks follow-up, and who met the criteria for the primary analysis population.
    - 42.4% (95% CI, 25.5–60.8) ORR per RECIST v1.1 by investigator assessment; 1 (3%) patient achieved a complete response, and 13 (39%) patients achieved a partial response
    - 72.7% (95% CI, 54-87) clinical benefit rate
    - 82% experienced tumor reduction
    - Of 21 patients evaluable for CA 19-9 levels, 78% showed a ≥ 50% decrease in CA 19-9 values from baseline
    - 9.1 months (95% CI, 5.5–12.0) median DOR; and 6 patients were continuing treatment as of the data cutoff

Safety findings from both presentations: Zeno demonstrated a well-tolerated safety profile among the 189 NRG1+ cancer patients who were treated with 750 mg Q2W monotherapy, with only 6% of patients experiencing related grade 3-4 toxicities.

The full presentations are available on the Publications page of our website.

**Dr. Schram has financial interests related to Merus.*

About the eNRGy Clinical Trial
Merus is currently enrolling patients in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer. The eNRGy trial

consists of three cohorts: NRG1+ pancreatic cancer; NRG1+ non-small cell lung cancer; and NRG1+ cancer. Further details, including current trial sites, can be found at www.ClinicalTrials.gov and Merus' trial website at www.nrg1.com or by calling 1-833-NRG-1234.

About Zeno

Zeno is an antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® that utilizes the Merus Dock & Block® mechanism to inhibit the neuregulin/HER3 tumor-signaling pathway in solid tumors with NRG1 gene fusions (NRG1+ cancer). Through its unique mechanism of binding to HER2 and potently blocking the interaction of HER3 with its ligand NRG1 or NRG1-fusion proteins, Zeno has the potential to be particularly effective against NRG1+ cancer. In preclinical studies, Zeno also potently inhibits HER2/HER3 heterodimer formation and tumor growth in models harboring NRG1 fusions.

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, http://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 Zeno, future clinical trial progress, enrollment, results, clinical activity and safety profile of Zeno in the on-going eNRGy trial and EAP; the potential for Zeno to be a first in class and best in class for patients with NRG1+ cancer and potential of Zeno to offer an important, potential new standard of care; our expectation that we will have a dataset to support potential BLA submissions in both NRG1+ NSCLC and PDAC in the first half of 2024; and the impact of Zeno's durable efficacy and excellent safety profile reported at ESMO on any future results, including future regulatory interactions or otherwise. 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 clinical development efforts for marketable drugs; potential delays in enrollment of patients, and our reliance on third parties to conduct our clinical trials, manufacturing and accompanying activities for clinical drug development and potential approval and the potential for those third parties to not perform satisfactorily, which could affect the receipt of necessary regulatory approvals; impacts of the COVID-19 pandemic and global instability; 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 7, 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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