

Merus

Merus Presents Clinical Data on Zenocutuzumab (Zeno) in NRG1-fusion (NRG1+) Cancer at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting (Oral Abstract)

June 5, 2022

- 34% overall response rate in 79 evaluable patients with measurable disease
- 9.1 months median duration of response
- Tumor reduction in 70% of patients
- Zeno observed to be very well-tolerated
- Potential new standard of care for patients with NRG1+ cancer
- Investor call to discuss clinical results on Sunday, June 5 at 6:00 p.m. CT

UTRECHT, The Netherlands and CAMBRIDGE, Mass., June 05, 2022 (GLOBE NEWSWIRE) -- [Merus N.V.](#) (Nasdaq: MRUS) ("Merus", "the Company", "we", or "our"), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclronics® and Triclronics®), today announced interim efficacy data as of an April 12, 2022 data cutoff date, from the phase 1/2 eNRGy trial and Early Access Program (EAP) of the bispecific antibody Zeno in patients with NRG1+ cancer presented virtually by Lead Author, Dr. Alison Schram of Memorial Sloan Kettering Cancer Center (MSKCC) at the 2022 ASCO Annual meeting.

"We have made significant progress with enrollment in the eNRGy trial over the past year," said Dr. Andrew Joe, Chief Medical Officer at Merus. "And Zeno continues to demonstrate consistent efficacy in patients with multiple types of NRG1+ cancer. We believe Zeno has the potential to be both first in class and best in class as a tumor agnostic treatment for patients with NRG1+ cancer."

Dr. Schram added, "Zeno has led to durable responses in previously treated NRG1 fusion-positive cancer, with a median duration of response greater than 9 months and more than 25% of those responding continuing at 12 months. Additionally, Zeno has an extremely well tolerated safety profile. There are currently no approved therapies targeting NRG1 fusion-positive cancer and Zeno offers an important, potential new standard of care."

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.

Key findings of the presentation include:

- As of April 12, 2022, 110 patients were treated with Zeno
- Efficacy was assessed in 79 evaluable patients with measurable disease having the opportunity for 6 months or more follow-up and who met the criteria for the primary analysis population
- Median age was 59 years (range of 22-84); 59% were female
- Median number of prior lines of systemic therapy was 2, (range of 0-8)
- Qualifying NRG1 fusions included 26 distinct fusion partners
- ORR per RECIST criteria as assessed by investigator was 34% (95% CI; 24%-46%) across multiple tumor types
 - PDAC ORR 42% (8/19)
 - NSCLC ORR 35% (16/46)
- Tumor shrinkage was observed in 70% of patients
- Median time to response was 1.8 months, and median duration of exposure was 6.3 months
- Median duration of response was 9.1 months, and 20/83 patients were continuing treatment as of the cutoff date
- Strong safety profile with a low incidence of Grade 3 or higher treatment-related adverse events, including low rates of severe gastrointestinal and dermatologic toxicity, without clinically significant cardiotoxicity

The full presentation is available on the [Publications page](#) of our website.

Company Conference Call and Webcast Information

Merus will hold a conference call and webcast for investors on Sunday, June 5, 2022 at 6:00 p.m. CT to discuss the Zeno clinical data and provide a program update. 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: Sunday, June 5, 6:00 p.m. CT

Webcast link: [available on our website](#)

Dial-in: Toll-free: 18772601463/ International: 17066435907

Conference ID: 7194538

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 Biclomics® 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 potentially 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 potentially 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 Multiclomics®. Multiclomics® 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 zenocutuzumab, 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 as a tumor agnostic treatment for patients with NRG1+ cancer and potential of Zeno to offer an important, potential new standard of care. 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 Biclomics®, Triclomics® 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; we may not identify suitable Biclomics® 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; and risks related to our ceasing to qualify as an emerging growth company and a smaller reporting company after December 31, 2021.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended March 31, 2022 filed with the Securities and Exchange Commission, or SEC, on May 9, 2022, 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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The Merus logo consists of the word "Merus" in a bold, blue, sans-serif font. The letter "M" is significantly larger and more prominent than the other letters, which are of a standard size and spaced evenly.