Merus Presents Updated Analysis of Zenocutuzumab, Trastuzumab, and Vinorelbine in Patients with HER2+ Metastatic Breast Cancer at the San Antonio Breast Cancer Symposium

December 10, 2021

- The primary endpoint of Clinical Benefit Rate at 24 weeks with the triplet combination was met

- The triplet combination showed clinically meaningful activity after 3 lines of anti-HER2 therapies including T-DM1

- Validates the potential of zenocutuzumab in additional indications outside NRG1 fusions

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Dec. 10, 2021 (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®), presented clinical data on zenocutuzumab (Zeno) in combination with trastuzumab and vinorelbine in patients (pts) with HER2 positive/amplified (HER2+) metastatic breast cancer (MBC) who had progressed on anti-HER2 antibody drug conjugates (ADC), at the San Antonio Breast Cancer Symposium in San Antonio, Texas.

Andrew Joe, Chief Medical Officer at Merus, said, "We are pleased to present the final analysis of the triplet Zeno combination which has demonstrated clinically meaningful activity in heavily pretreated patients with HER2+/amplified MBC. We are encouraged by Zeno's potential to be active in indications outside NRG1 fusion cancers, opening opportunities for potential collaborations in these areas."

The reported data are from the completed phase 2 study, designed to explore the efficacy of a triplet combination of Zeno plus trastuzumab and vinorelbine in MBC patients (NCT03321981). Preliminary results for patients treated with the triplet regimen were presented at the American Society of Clinical Oncology 2020 Annual Meeting. The combination was observed to be well-tolerated in the run-in cohort and the cohort was expanded. The primary endpoint of the study was clinical benefit rate (CBR) at 24 weeks of 45%. Updated results from the cohort expansion are presented here:

- At the efficacy data cut-off, March 31, 2021, 39 patients, with a median age of 57 and with a median number of five prior therapies, had received the Zeno-based triplet combination, 4 of whom were ongoing. All patients had completed at least 6 months of treatment or discontinued
- 37 patients with locally confirmed HER2 overexpression (IHC 3+ or IHC 2+/FISH-positive) were evaluable for antitumor activity
- The clinical benefit rate (CBR: complete response + partial response + stable disease ≥24 weeks) per investigator assessment was 49% (18/37 patients; 90% CI 34 - 63)
- Confirmed responses (per investigator) were reported in 10 patients, including 2 patients with complete response (CR)
- Median duration of response was 4.2 months (90% CI 2.8 - 12.4), including 2 patients with CR lasting 4.2 and 7.2+ months, and 8 patients with partial responses (PR) lasting from 2.6 to 12.4 months
- Median progression-free survival was 5.5 months (90% CI 4.1 - 5.6); 7 patients (19%) were censored. Estimated overall survival rates at 12 and 24 months were 73% and 61%, respectively
- The combination was observed to be well tolerated, with AEs primarily related to chemotherapy

As previously reported, with completion of this phase 2 trial, Merus does not have plans to advance into a phase 3 clinical trial in metastatic breast cancer in the absence of a partner. The company continues to focus on the eNRGy trial to potentially support a BLA submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers.

The full poster is available on our website.

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+). 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+ cancers. 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, the design and treatment

potential of our bispecific antibody candidates, including Zeno; the potential for Zeno and its mechanism of action to be particularly effective against NRG1+ cancers; the potential of Zeno in additional indications outside NRG1 fusions; opportunities for potential collaborations in these areas; Merus' plans to only advance development in metastatic breast cancer with a partner and focus on the eNRGy trial of Zeno in NRG1 fusion cancers to potentially support a BLA submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers.

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 September 30, 2021 filed with the Securities and Exchange Commission, or SEC, on November 2, 2021, 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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