

Merus

Merus Presents Early Clinical Data on MCLA-158 and Preclinical Data on Zenocutuzumab at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics

October 7, 2021

- Tumor shrinkage and partial responses observed in patients with advanced head and neck squamous cell carcinoma (HNSCC) treated with MCLA-158
 - In preclinical studies, Zeno observed to block cell growth 100 fold more potently than anti-HER3 antibody alone

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Oct. 07, 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 (Biclronics® and Triclronics®), today presented clinical data on MCLA-158, including clinical responses observed in advanced head and neck squamous cell carcinoma (HNSCC) and preclinical data on zenocutuzumab (Zeno) at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

Dr. Andrew Joe, Chief Medical Officer at Merus, said, "We are encouraged by the early evidence of clinical activity of MCLA-158 in patients with advanced, previously treated HNSCC, further validating the potential of our Biclronics® platform. With Zeno, our preclinical research continues to reinforce the mechanisms by which Zeno is capable of potently inhibiting the growth of NRG1 fusion cancers."

MCLA-158 (petosemtamab)

The reported data are from the ongoing phase 1 dose expansion cohort that is investigating the safety, tolerability, and anti-tumor activity of MCLA-158 monotherapy in advanced HNSCC.

Observations in the presentation include:

- Enrollment of 10 patients with advanced HNSCC, as of the safety and efficacy data cutoff date of August 9, 2021, with median age of 65 (range 50-77) years, and who were treated with a median of 2 lines of prior therapy.
- Seven patients were evaluable for an interim efficacy analysis by investigator assessment (three patients were enrolled <8 weeks from the cutoff date).
- Three of seven patients achieved partial responses, with one achieving complete response after the data cutoff date. Tumor reduction was observed in all seven patients.
- The safety profile of MCLA-158 was based on 29 patients with advanced solid tumors who were treated at 1500 mg every two weeks across the phase 1 trial.
 - The most frequent adverse events (AEs) were infusion related reactions; 72% any grade, 7% grade ≥ 3.
 - Mild to moderate skin toxicity (3% grade ≥3).

The Company is planning its next update on the MCLA-158 trial in 2022.

Zeno

Observations in the preclinical presentation include:

- The bispecific HER2/HER3 antibody Zeno blocked cell growth 100 fold more potently than the bivalent HER3 antibody derived from Zeno, in an NRG1 driven growth assay.
- Zeno potently blocked NRG1-fusion mediated downstream signaling and growth *in vitro* and *in vivo*.
- Zeno induced both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) mediated killing of cancer cells in a dose-dependent manner.
- As of September 1, 2021 more than 80 patients with NRG1 fusion cancers have been treated with Zeno monotherapy in our phase 1/2 eNRGy trial and Early Access Program. (www.nrg1.com).

About MCLA-158

[MCLA-158](#), or petosemtamab, is an ADCC-enhanced human IgG1 Biclronics® designed to bind to cancer stem cells (CSCs) expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor receptor (EGFR). In preclinical models, MCLA-158 binding triggers EGFR degradation in LGR5+ CSCs and is designed to have two different mechanisms of action. The first entails blocking of growth and survival pathways in cancer initiating cells. The second exploits the recruitment and enhancement of immune effector cells to directly kill cancer initiating cells that persist in solid tumors and can cause relapse and

metastasis.

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+). 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+ cancers. 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 content and timing of clinical trials, data readouts and clinical updates for our product candidates, the treatment potential of our product candidates, their mechanism of action, future clinical trial developments or interim analyses, or statements about early evidence of clinical activity impact on the potential of our Biclomics[®] platform. 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 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.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2020 filed with the Securities and Exchange Commission, or SEC, on March 16 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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The logo for Merus, featuring the word "Merus" in a bold, blue, sans-serif font.