

# Merus

## Merus Announces the Acceptance of Six Abstracts at Upcoming Medical Conferences and Provides Program Updates

May 14, 2020

- MCLA-128, zenocutuzumab, independent epidemiology analysis reaffirms significant clinical and commercial potential in NRG1 fusion cancers –
- MCLA-117 demonstrates limited clinical activity in Phase 1 trial –
- Extensive panel of novel CD3 bispecific antibodies provides important insights and avenues to maximize T-cell engager biology –

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 14, 2020 (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 the acceptance of six abstracts at upcoming cancer medical meetings. Four abstracts regarding zenocutuzumab ("Zeno"), including results from an independent epidemiology study of the prevalence of NRG1 gene fusion-positive ("NRG1+") cancers, will be presented at the American Society for Clinical Oncology ASCO20 Virtual Scientific Program (ASCO), May 29-31, 2020. Abstracts detailing interim data from the Phase 1 MCLA-117 acute myeloid leukemia (AML) trial and an analysis of an extensive, proprietary panel of CD3 bispecific antibodies will be presented at the 25<sup>th</sup> European Hematology Association (EHA) Annual Congress Virtual Edition, June 11-14, 2020.

"We look forward to sharing data at ASCO and EHA for two of our clinical candidates, Zeno and MCLA-117. As a highlight for Zeno, our presentations include an important epidemiology analysis of the prevalence of NRG1 fusions that we believe helps to highlight the patient need and commercial opportunity for Zeno in patients with NRG1 fusion cancers, particularly as molecular testing becomes more commonplace across different types of cancer," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "For MCLA-117, the interim data from the Phase 1 trial demonstrated some evidence of activity in patients with AML, but insufficient clinical responses have been observed to continue enrollment in the planned dose expansion cohorts in the trial. Importantly, the findings from the MCLA-117 trial – coupled with new data from an extensive panel of novel, proprietary CD3 T-cell binding antibodies – provide powerful insights to further inform and optimize the development of our T-cell engager platform."

### **Zenocutuzumab (MCLA-128: HER3 x HER2 Biclonics®)**

#### *NRG1+ Cancers*

Merus provided an update in October 2019 on the eNRGy trial and reported encouraging early clinical activity from the administration of Zeno (monotherapy) in several patients with pancreatic or non-small cell lung cancer (NSCLC) harboring NRG1 gene fusions (NRG1+) including tumor shrinkage, symptomatic improvement and durability up to the then most recent clinical assessments.

The NRG1 gene fusion is a rare, powerful driver of cancer cell growth found in lung, pancreatic and other solid tumor types. Zeno, through its unique mechanism of binding to HER2 and blocking NRG1 fusion protein interaction with HER3, has the potential to be particularly effective against NRG1+ cancers.

Merus continues to enroll patients on the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. The eNRGy trial consists of three cohorts: NRG1+ pancreatic cancer, NRG1+ non-small cell lung cancer, and NRG1+ other solid tumors. The majority of global clinical trial sites for are now open and enrolling patients. Details, including current trial sites, can be found at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and Merus' trial website at [www.nrg1.com](http://www.nrg1.com), or by calling 1-833-NRG-1234.

The Company expects to present updated data from the Phase 1/2 eNRGy trial at a medical conference by the end of 2020.

At the upcoming American Society of Clinical Oncology (ASCO) ASCO20 Virtual Scientific Program, the following Merus abstracts and poster presentations will be reported:

- **NRG1 Fusion-Drive Cancers: A Systemic Literature Review and Meta-Analysis. Abstract # e15605**

A robust epidemiologic methodology based on a meta-analysis of literature by an independent organization engaged by Merus found the prevalence of NRG1 fusion cancers to be 3.3% in pancreatic ductal adenocarcinoma (95% confidence intervals (CI): 0.3-28.7%) and 9.8% in the invasive mucinous adenocarcinoma subtype of NSCLC (95% CI: 4.7-19.6%), reaffirming the clinical and commercial potential of Zeno in this patient population.

- **A phase 2 basket study of MCLA-128, a bispecific antibody targeting the HER3 pathway, in NRG1 fusion-positive advanced solid tumors. Abstract # TPS3654**

A Trials in Progress abstract describes the ongoing eNRGy clinical trial for zenocutuzumab in NRG1 fusion cancers.

#### *Metastatic Breast Cancer*

Merus has now completed enrollment in two Phase 2 trials of Zeno in metastatic breast cancer. The consistent safety results across both trials strongly supports the excellent safety profile of Zeno for patients with cancer. The Phase 2 results show that Zeno in combination with trastuzumab and vinorelbine is active in heavily pretreated HER2+ metastatic breast cancer patients who have progressed on multiple lines of anti-HER2 therapies. Following from the Phase 2 interim analysis reported in October 2019, Merus has previously disclosed that it plans to only advance development in metastatic breast cancer with a partner and intends to focus efforts on the eNRGy trial of Zeno in NRG1 fusion cancers.

At the upcoming American Society of Clinical Oncology (ASCO) ASCO20 Virtual Scientific Program, the following Merus abstracts and poster presentations will be

reported:

**- Clinical activity of MCLA-128 (zenocutuzumab), trastuzumab and vinorelbine in HER2 amplified metastatic breast cancer (MBC) patients who had progressed on anti-HER2 ADCs. Abstract # 3093**

The triplet Zeno combination is active in heavily pretreated patients with HER2+/amplified MBC and is safe and well tolerated. Twenty-eight patients with a median of 3 prior lines of anti-HER2 therapy in the metastatic setting received a median of 5 Zeno treatment cycles. Of 26 evaluable patients, the disease control rate was 77% with 1 confirmed CR and 4 unconfirmed partial responses. Data on primary endpoint, clinical benefit rate at 24 weeks overall response rate and pharmacokinetics (PK) will be presented.

**- Clinical activity of MCLA-128 (zenocutuzumab) in combination with endocrine therapy (ET) in ER+/HER2-low, non-amplified metastatic breast cancer (MBC) patients with ER-resistant disease who had progressed on a CDK4/6 inhibitor. Abstract # 1037**

The addition of Zeno to the last line of endocrine therapy showed clinical activity and a favorable safety profile. Forty-eight patients with a median of 2 prior lines of endocrine therapy and 1 prior line of chemotherapy, had all previously progressed on a CDK4/6i. Of 42 evaluable patients, the disease control rate was 45% with 2 unconfirmed partial responses. Data on primary endpoint, clinical benefit rate at 24 weeks, overall response rate and (PK) will be presented.

**MCLA-117 (CLEC12A x CD3 Biclomics®): Acute Myeloid Leukemia (AML)**

**MCLA-117 Phase 1 interim data**

MCLA-117 is a bispecific (Biclomics®) T-cell engager antibody that is designed to engage CD3 on T-cells and to bind to and kill AML blasts via the CLEC12A antigen. It is currently being evaluated in a Phase 1 trial in a single-arm, open-label, global study to assess the safety, tolerability and anti-tumor activity of MCLA-117 currently enrolling patients with relapsed/refractory AML.

MCLA-117 demonstrated clinical activity in terms of T-cell activation, mild to moderate cytokine release syndrome and blast count reductions in some patients and at some dose cohorts. However, given the limited clinical activity and the evolving treatment landscape in AML, Merus will not continue enrollment into the planned dose expansion cohorts in the trial. Insights from this trial are planned to be used to inform and maximize development of our CD3 T-cell engager platform, which includes a panel of >175 novel and diverse T-cell CD3 Fab ("fragment antigen-binding") binders across a wide range of affinities and attributes.

At the upcoming European Hematology Association Annual Virtual Meeting in June, the following Merus abstracts will be presented:

**- Update from the ongoing Phase 1 multinational study of MCLA-117, a bispecific CLEC12A x CD3 engager, in patients with acute myelogenous leukemia (AML). Abstract # EP538**

The abstract contains interim data from the Phase 1 trial, a single-arm, open-label, global study of MCLA-117 in relapsed/refractory AML patients. As of November 30, 2019, of the 50 patients treated, 26 are evaluable with a follow up bone marrow assessment and, 4 patients showed greater than 50% blast reduction. No dose limiting toxicity was observed.

**T-Cell engaging bispecific antibodies generated from a novel, large and diverse CD3 panel. Abstract #EP1482**

The poster features the results from Merus' generation of a large and diverse panel of over 175 unique CD3 binders across 8 superclusters, with binding affinities ranging from the low picomolar to high nanomolar range. Unique variants are identified with substantial T-cell activation and cell killing but reduced cytokine release. This functional analysis revealed that an optimal balance of T-cell activation, cytokine release and tumor cell killing may not be predicted by CD3 affinity alone, and instead may be achieved by empirical evaluation of diverse CD3 panels and tumor targeting Fab arms, and high through-put screening of these binding arms in multispecific antibody formats—features of Merus' distinctive CD3 panel and common light chain approach to multispecific antibody research and development.

**About Merus N.V.**

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclomics®. Biclomics® 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, [www.merus.nl](http://www.merus.nl) and <https://twitter.com/MerusNV>.

**Forward Looking Statement**

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 content and timing of potential milestones described in this press release, the planned poster presentations, timing of updates, clinical trials and data readouts for our product candidates including the expectation to present updated data from the Phase 1/2 eNRGy trial at a medical conference by the end of 2020, the design and treatment potential of our bispecific antibody candidates, including the potential for Zeno and its mechanism of action to be particularly effective against NRG1+ cancers, clinical study designs, statements regarding the significant clinical and commercial potential for Zeno in patients with NRG1 fusion cancers, molecular testing becoming more commonplace across different types of cancer, the insights from the MCLA-117 trial planned to be used to inform and maximize development of Merus' CD3 T-cell engager platform and avenues to maximize T cell engager biology provided by the Merus' extensive panel of novel CD3 bispecific antibodies, the majority of global clinical trial sites for the eNRGy trial enrolling patients, the prevalence of NRG1 fusion cancers, 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, the estimated disease control rate and clinical benefit rate to be presented in the Phase 2 studies of Zeno in MBC, that Merus will not continue enrollment into the planned dose expansion cohorts in the trial for MCLA-117, the interim data from the Phase 1 trial, a single-arm, open-label, global study of MCLA-117 in relapsed/refractory AML patients to be presented, the ability to achieve an optimal balance of T-cell activation, cytokine release and tumor cell killing by empirical evaluation of diverse CD3 panels and tumor targeting Fab arms, and high through-put screening of Merus' CD3 binding arms in multispecific antibody formats, and Merus' distinctive CD3 panel and common light chain approach to multispecific antibody research and development. 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® and bispecific 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the Securities and Exchange Commission, or SEC, on May 11, 2020, 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.