

# Merus

## Merus Announces Publication of Abstracts on MCLA-129 for Presentation at ESMO Asia Congress 2023

November 26, 2023 at 11:05 AM EST

- Oral presentation on MCLA-129 in combination with osimertinib as first line therapy, and in previously treated, NSCLC on Sunday, December 3 at 9:40 a.m. SGT
- Poster presentation on MCLA-129 in previously treated HNSCC on Saturday, December 2 at 17:50 p.m. SGT
- Investor call on Monday, November 27, 2023 8:00 a.m. ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 26, 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 the publication of two abstracts regarding MCLA-129 on the European Society for Medical Oncology (ESMO) Asia Congress [website](#). The abstracts highlight updated interim clinical data from expansion cohorts in non-small cell lung cancer (NSCLC) and in previously treated head and neck squamous cell carcinoma (HNSCC) for presentation at the ESMO Asia Congress 2023 taking place in Singapore December 1-3, 2023.

"MCLA-129 is now the third asset, together with our other clinical assets petosemtamab and zenocutuzumab, developed from the Merus proprietary Biclonics® platform to demonstrate strong clinical activity," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "As we continue the development of MCLA-129, we are planning to take a disciplined capital allocation approach, making focused investments in the program to identify areas of potential differentiation. We remain open to potential business development opportunities as a means to leverage added resources, infrastructure and expertise of a potential partner to more fully evaluate and develop MCLA-129."

### **MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors**

Interim data included in the abstracts describe data from three expansion cohorts in the open label trial evaluating MCLA-129 in combination with osimertinib, a third generation EGFR TKI, in treatment-naïve EGFR mutant (m) NSCLC and in EGFRm NSCLC that has progressed on osimertinib, as well as MCLA-129 monotherapy in previously treated HNSCC.

Updated clinical data, with additional patients and a later data cutoff date, will be included in the mini-oral presentation on NSCLC and the poster on HNSCC at ESMO Asia next week.

**Mini-oral presentation title:** Efficacy and safety of MCLA-129, an EGFR x c-MET bispecific antibody, combined with osimertinib, as first-line therapy or after progression on osimertinib in non-small cell lung cancer (NSCLC)

Observations in the abstract include:

- As of a May 10, 2023 data cutoff date, 48 patients (pts) with advanced/metastatic EGFRm NSCLC were treated (14/1L, 34/2L+)
  - In the 1L setting, 14 pts were treated, with 10 pts evaluable for response
    - 2 confirmed partial responses (PRs) and 6 unconfirmed PRs were observed (8/10, 80%; 95% CI 44-98) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment; all responses were ongoing as of the data cutoff date
    - 90% disease control rate (DCR) (95% CI 56-100)
    - 10 weeks (range 2-26) median duration of exposure with 93% continuing treatment
  - In the 2L+ setting, 34 pts were treated, with 22 pts evaluable for response
    - All received prior osimertinib in 1L/2L setting, 71% as the most recent therapy; 24% received prior chemotherapy
    - 6 confirmed PRs and 5 unconfirmed PRs were observed (11/22, 50%; 95% CI 28-72) by RECIST v1.1. per investigator assessment; 9 responses were ongoing as of the data cutoff date, including 4 of the unconfirmed PRs
    - 82% DCR (95% CI 60-95)
    - 10 weeks (range 2-38) median duration of exposure with 68% continuing treatment
- Early safety assessment in 48 NSCLC pts treated with MCLA-129 plus osimertinib included
  - Most common adverse events (AEs) regardless of causality were infusion related reactions (IRRs; composite term) in 85% (6% ≥ grade(G) 3)
  - Skin toxicity (composite term) in 75% (4% G3)
  - Treatment related interstitial lung disease (ILD)/pneumonitis in five patients (10%), two were G2, two were G3, and one was G5 and one progressed to G5 after the data cutoff date
  - Venous thromboembolic (VTE) events in 15%; 4% treatment related

### **Presentation Details:**

**Session:** Thoracic Cancer

**Date:** Sunday, December 3, 2023

**Time:** 9:40 -9:45 a.m. SGT

**Presentation #:** 516MO

**Poster presentation title:** Efficacy and safety of MCLA-129, an anti-EGFR/c-MET bispecific antibody, in head and neck squamous cell cancer (HNSCC)  
Observations in the abstract include:

- As of a May 10, 2023 data cutoff date, 18 pts with previously treated HNSCC were treated
  - Pts received median of two lines prior therapy, 89% prior chemotherapy, 78% prior anti-PD-(L)1, 28% prior cetuximab
  - 12 pts were evaluable for response
    - 2 unconfirmed PRs were observed (2/12, 17%) by RECIST v1.1. per investigator assessment; one response was ongoing as of the data cutoff date
    - 67% DCR (95% CI 35-90%)
    - 8 weeks (range 2-17) median duration of exposure with 50% continuing on treatment
- Early safety assessment in 18 HNSCC pts treated with MCLA-129 monotherapy included
  - Most common AEs regardless of causality were IRRs (composite term) in 72% (28% ≥ G3), all on cycle 1 day 1, that led to treatment discontinuation in two pts
  - Skin toxicity in 61% (11% G3)
  - No ILD or VTE events were reported

**Presentation details:**

**Session Category:** Poster session

**Date:** Saturday, December 2, 2023

**Time:** 17:50-18:45 p.m. SGT

**Presentation #:** 362P

**MCLA-129 Development Strategy**

In EGFRm NSCLC, with the strong clinical activity for MCLA-129 shown in the interim data presented today, we are encouraged by the potential for MCLA-129 in the treatment of lung cancer and beyond. We have identified focused investment opportunities. We continue to follow patients with EGFRm NSCLC treated with MCLA-129 in combination with osimertinib, to evaluate potential for biomarkers as a means to maximize efficacy, while proactively addressing safety signals seen to date.

We plan to start a cohort of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in the first quarter of next year.

Additionally, we remain interested and are continuing investigation of cohort B evaluating MCLA-129 in patients with MET exon14 skipping NSCLC. We also remain interested in exploring partnering MCLA-129 with other companies to sufficiently resource the development of MCLA-129 and potential benefit it may have for patients.

In HNSCC, based on the interim data, we observed clinical activity with MCLA-129. However, we view the clinical activity with MCLA-129 monotherapy as of the cutoff date as modest, with 2 unconfirmed partial responses or 17%. The safety profile was manageable, and there were no reported ILD or VTE events. Our assessment of this cohort is that the clinical activity of MCLA-129 in second line head and neck cancer appears substantially inferior to that of our lead asset petosemtamab, and only on par with other EGFR or cetuximab-based monoclonal or bispecific antibodies as monotherapy in a similar setting. We believe this efficacy is insufficient to warrant further development in head and neck cancer.

**Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclomics®): NRG1 fusion (NRG1+) cancer and other solid tumors**

An abstract for an encore of a recent ESMO Congress 2023 presentation on zenocutuzumab interim clinical data from the eNRGy trial and Early Access Program in patients with NRG1 fusion (NRG1+) NSCLC has also been accepted for presentation at ESMO Asia.

**Presentation details:**

**Title:** Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) non-small cell lung cancer (NSCLC)

**Session Category:** Poster session

**Date:** Saturday, December 2, 2023

**Time:** 17:50-18:45 p.m. SGT

**Presentation #:** 595P

As full presentations become available at the ESMO Asia Congress 2023, they will contemporaneously be available on the Merus [website](#).

**Company Conference Call and Webcast Information**

Merus will hold a conference call and webcast for investors on **November 27, 2023 at 8:00 a.m. ET**. 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 and Time:** November 27, 2023 at 8:00 a.m. ET

**Webcast link:** Available on our website

**Dial-in:** Toll-Free: 1 (800) 715-9871 / International: 1 (646) 307-1963

**Conference ID:** 2833671

**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 MCLA-129, future clinical trial progress, enrollment, results, clinical activity and safety profile of MCLA-129; our belief in MCLA-129 exhibiting strong clinical activity; our plans to take a disciplined capital allocation approach, making focused investments in the program to identify areas of potential differentiation; our openness to potential business development opportunities as a means to leverage added resources, infrastructure and expertise of a potential partner to more fully evaluate and develop MCLA-129; our development plans and strategy for MCLA-129 including continuing to follow patients with EGFR mutant non-small cell lung cancer treated with MCLA-129 in combination with osimertinib, to evaluate potential for biomarkers as a means to maximize efficacy, while proactively addressing safety signals seen to date; our plan to start a cohort of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in the first quarter of next year; our continuing investigation of cohort B evaluating MCLA-129 in pts with MET exon14 skipping NSCLC; our interest in exploring partnering MCLA-129 with other companies to sufficiently resource the development of MCLA-129 and the potential benefit it may have for patients; the safety profile of MCLA-129 and implications for future safety; and our belief that MCLA-129's activity in 2L+ HNSCC is insufficient to warrant further development in head and neck cancer. 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 and global instability; 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 period ended September 30, 2023 filed with the Securities and Exchange Commission, or SEC, on November 2, 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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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.