Merus Presents Interim Data on MCLA-129 at ESMO Asia Congress 2023

December 2, 2023 at 8:40 PM EST

MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC planned to initiate 1Q24

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Dec. 02, 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 updated interim clinical data on MCLA-129 from ongoing expansion cohorts in non-small cell lung cancer (NSCLC) and in previously treated head and neck squamous cell carcinoma (HNSCC) were presented at the European Society for Medical Oncology (ESMO) Asia Congress 2023.

"MCLA-129 is a very active drug in EGFRm NSCLC and we're planning a focused investment to evaluate MCLA-129 in combination with chemotherapy, which we expect to start early in 2024," said Bill Lundberg M.D., President, Chief Executive Officer of Merus. "We are in a fortunate position to have a strong balance sheet. We also recognize the importance of being responsible with our resources to maintain financial strength, as we plan to initiate a phase 3 trial of petosemtamab in 2L+ HNSCC by mid-2024."

The reported data are 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 (1L) and in EGFRm NSCLC that has progressed on osimertinib (2L+), as well as MCLA-129 monotherapy in previously treated HNSCC.

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 presentation include:

- As of an August 10, 2023 data cutoff date, 60 patients (pts) with advanced/metastatic EGFRm NSCLC were treated (16/1L, 44/2L+)
  - In the 1L setting, 16 pts were treated, with all pts evaluable for response
    - All 16 pts experienced tumor shrinkage
    - 9 confirmed partial responses (PRs) and 3 unconfirmed PRs were observed (12/16, 75%; 95% CI 48-93) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment; 11 responses were ongoing, including the 3 unconfirmed PRs
    - 94% disease control rate (DCR) (95% CI 70-100)
    - 5.1 months (range 0.5-8.5) median duration of exposure with 81% continuing treatment
  - In the 2L+ setting, 44 pts were treated, with 34 pts evaluable for response
    - All received prior osimertinib in the 1L/2L setting, 50% as only prior therapy; 36% received prior chemotherapy
    - 11 confirmed PRs and 1 unconfirmed PR were observed (12/34, 35%; 95% CI 20-54) by RECIST v1.1. per investigator assessment, 9 responses were ongoing as of the data cutoff date, including the 1 unconfirmed PR
    - 74% DCR (95% CI 56-87)
    - 2.8 months (range: 0.3-11.5) median duration of exposure with 39% continuing treatment
- Early safety assessment in 60 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 87% (12% ≥ grade(G) 3)
  - Treatment emergent adverse events (TEAEs) led to discontinuations in 14 (23%) pts
  - Treatment related interstitial lung disease (ILD)/pneumonitis in 13 pts (22%), four were G1, two were G2, four were G3, and three were G5
  - Venous thromboembolic (VTE) events in 23%; 5% treatment related

Efficacy and safety of MCLA-129, an anti-EGFR/c-MET bispecific antibody, in head and neck squamous cell cancer (HNSCC)

Observations in the presentation include:

- As of an August 10, 2023 data cutoff date, 22 pts with previously treated HNSCC were treated
  - 20 pts were evaluable for response
  - Pts received a median of 3 lines of prior therapy, 22% prior chemotherapy, 20% prior anti-PD-(L) 1, 36% prior cetuximab
  - 1 confirmed and 1 unconfirmed PR were observed (2/20, 10%, 95% CI 1–32) by RECIST v1.1. per investigator assessment
    - The confirmed response was ongoing with a duration of response of 3.4+ months at data cutoff date
    - The unconfirmed PR was confirmed after the data cutoff date with treatment still ongoing at the time of presentation
  - 60% DCR (95% CI 36–81)
  - 2.2 months (range 0.5–6) median duration of exposure
- Early safety assessment in 22 HNSCC pts treated with MCLA-129 monotherapy included
  - IRRs (composite term) in 73% (14% ≥ G3) all on cycle 1 day 1
  - Skin toxicity (composite term) in 86% (14% ≥ G3)
  - No ILD or VTE events were reported
  - No G5 TEAEs were reported

The full presentations are available on the Publications page of our website.

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, https://www.merus.nl and https://twitter.com/MerusNV.

About MCLA-129
MCLA-129 is an antibody-dependent cellular cytotoxicity-enhanced Biclonics® that is designed to inhibit the EGFR and c-MET signaling pathways in solid tumors. Preclinical data have shown that MCLA-129 can effectively treat TKI-resistant NSCLC in xenograft models of cancer. MCLA-129 is designed to have two complementary mechanisms of action: blocking growth and survival pathways to stop tumor expansion and recruitment and enhancement of immune effector cells to eliminate the tumor.

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 that MCLA-129 is a very active drug in EGFRm NSCLC; our plans to make a focused investment to evaluate MCLA-129 in combination with chemotherapy, which we expect to start early in 2024; our balance sheet and impact on future activities; our plan to initiate a phase 3 trial of petosemtamab in 2L+ HNSCC by mid-2024; and our development plans and strategy for MCLA-129. 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 Biclonics®, Triclonics® 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 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, 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.

Investor and Media Inquiries:
Sherri Spear
Merus N.V.
VP Investor Relations and Corporate Communications
617-821-3246
s.spear@merus.nl

Kathleen Farren
Merus N.V.
IR/Corp Comms
617-230-4165
k.farren@merus.nl

Merus