Merus Announces Publication of Abstract on MCLA-129 at the 34th EORTC/NCI/AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics

October 12, 2022

– MCLA-129 observed to be well tolerated with preliminary evidence of anti-tumor activity during dose escalation phase

– Initial recommended phase two dose set at 1500 mg with dose expansion ongoing

– Poster presentation with additional data at ENA available on October 26 at 9am CET/3am ET, and presented on October 28, 2022, 10:00-15:00 CET

– Investor call to discuss a MCLA-129 program update on October 26 at 13:30 CET/7:30am ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Oct. 12, 2022 (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 the abstract highlighting interim data from the ongoing phase 1/2 trial of the bispecific antibody MCLA-129 on the 34th EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA Symposium) website. MCLA-129 is a fully human IgG1 Biclonics® bispecific antibody that binds to EGFR and c-MET and is being investigated in patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. This phase 1/2 study has completed the dose escalation phase and is on-going in the dose expansion phase.

The poster will be presented at the 34th ENA Symposium in Barcelona, Spain on Friday, October 28, 2022, 10:00-15:00 CET, and will be available online Wednesday, October 26, 2022. The poster presentation will include additional interim clinical data from this dose escalation cohort.

"We are encouraged by the promising initial clinical data for MCLA-129 presented in the abstract and are looking forward to providing additional clinical data from the dose escalation cohort in the poster presentation at the ENA Symposium," said Dr. Andrew Joe, Chief Medical Officer at Merus. "We also intend to share a MCLA-129 program update on our upcoming conference call."

The reported interim data in the abstract are from the phase 1/2 trial of MCLA-129 in patients with advanced NSCLC and other solid tumors.

Information and observations in the abstract include:

- As of the May 8, 2022 cutoff date, 20 patients were treated with MCLA-129 across doses of 100, 300, 600, 1000, and 1500 mg every two weeks
- Median age of patients was 65 years (range 43-79)
- Tumor types enrolled included:
  - 14 patients with EGFR mutant (mt) NSCLC (4 L858R, 8 Del19, 1 exon 20 insertion, 1 other)
  - 2 patients with c-MET exon 14 mt NSCLC
  - 1 patient with c-MET amplified gastric adenocarcinoma
  - 1 patient with squamous cell esophageal cancer
  - 2 patients with head and neck squamous cell carcinoma
- 13 patients were evaluable for response with preliminary signs of anti-tumor activity observed:
  - Two partial responses (one confirmed) in EGFR mt NSCLC
  - Four confirmed stable disease
- Median duration of treatment was 8 weeks (range 3.4- 29.3) with 11 patients still on treatment at the cutoff date
- Safety:
  - No dose limiting toxicity was observed and maximum tolerated dose was not reached
  - The most frequently reported adverse event (AE) was infusion related reaction (IRR)
    - 18 of 20 pts (90%) reported IRR after first dose, all but one were mild or moderate (grade 1-2)
    - All but one infusion were completed on the same day

- No treatment discontinuations due to AE
- No interstitial lung disease was observed

- Recommended initial phase 2 dose for expansion is 1500 mg every two weeks. The expansion cohorts are enrolling.
  - Dose-dependent depletion of soluble EGFR and c-MET was observed
  - In doses ranging from 600-1500 mg every two weeks, MCLA-129 demonstrated linear pharmacokinetics
  - Mean serum concentrations at 1500 mg every two weeks dose are modeled to be above that required for >95% target engagement of cell-bound EGFR and c-MET throughout the dosing period

Presentation Details:

Title: MCLA-129, a human anti-EGFR and anti-c-MET bispecific antibody, in patients with advanced NSCLC and other solid tumors: an ongoing phase 1/2 study
First author: Prof. Sai-Hong Ignatius Ou, Department of Medicine, Division of Hematology Oncology, University of California Irvine School of Medicine, US
Session: New Therapies in Immuno Oncology
Date: Friday, October 28, 2022
Time: 10:00-15:00 CET
Abstract #: 341
Poster #: PB121

The poster will be available at the start of the conference on October 26, 2022 and on-demand throughout the conference on the conference website. The poster will also be available on the Merus website contemporaneously.

Company Conference Call and Webcast Information

Merus will hold a conference call and webcast for investors on Wednesday, October 26, 2022 at 13:30 CET/7:30am ET to discuss the MCLA-129 initial clinical data and provide a program update. 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: October 26, 2022
Webcast link: available on our website
Dial-in: Toll-free: 1 (800) 715-9871 / International: 1 (646) 307-1963
Conference ID: 1694377

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 non-small cell lung cancer (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.

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 statements regarding MCLA-129's mechanisms of action; the impact of observations concerning any interim clinical data, including on future results or development plans; any planned clinical or program updates; and potential of the MCLA-129 Biclonics® in preclinical or clinical development to treat 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 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 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 June 30, 2022 filed with the Securities and Exchange Commission, or SEC, on August 8, 2022, 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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