Merus Presents First in Human Data on MCLA-129 at the 34th EORTC/NCI/AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics

October 26, 2022

- MCLA-129 observed to be well tolerated with a favorable safety profile

- Antitumor activity was observed among heavily pretreated patients, across multiple tumor types and dose levels

- Initial recommended phase 2 dose 1500 mg every two weeks; expansion cohorts enrolling

- 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. 26, 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 interim data as of an August 15, 2022 data cutoff, 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 ADCC enhanced 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 is now available on the Merus website and will be presented at the 34th ENA Symposium in Barcelona, Spain on Friday, October 28, 2022, 10:00-15:00 CET.

"These initial data provide encouraging clinical evidence that MCLA-129 has the potential to be meaningful in patients with solid tumors including NSCLC," said Dr. Andrew Joe, Chief Medical Officer at Merus. "We look forward to continuing the dose expansion portion of this trial to further evaluate the efficacy and safety of MCLA-129 both as monotherapy and in combination with a third generation EGFR TKI."

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. These patients were followed for safety and efficacy through a data cutoff of August 15, 2022, with 18 evaluable for efficacy, with two discontinuing before the second infusion (1 patient due to investigator decision, clinical progression; and 1 patient passing away due to an unrelated AE).

As of the August 15, 2022 cutoff date:

- Median age of patients was 65.5 years (range 43-79)
- Tumor types enrolled included:
  - 14 patients with EGFR mutant (mt) NSCLC (8 Del19, 4 L858R, 1 exon 20 insertion [EGFRex20], 1 other)
  - 2 patients with c-MET exon 14 mt (MetEx14) NSCLC
  - 1 patient with c-MET amplified gastric adenocarcinoma
  - 1 patient with esophageal squamous cell cancer
  - 2 patients with head and neck squamous cell carcinoma (HNSCC)
- Antitumor activity observed by investigator review, include:
  - 2 confirmed partial responses observed
  - 4 additional patients had >20% tumor shrinkage
- Time on treatment:
  - Median duration of exposure was 12.6 weeks (range: 3-43 weeks)
  - Six of the 20 patients remained on-going as of the data cutoff date
- MCLA-129 was observed to be well tolerated based on 20 patients who received one or more doses of MCLA-129 across all dose levels tested:
  - No dose limiting toxicities (DLTs) were reported
  - Most frequent AEs were infusion-related reactions (IRR)
  - 90% of patients experienced IRR AEs of any grade, one patient (5%) experienced a grade 3, no grade 4 or 5 AEs were observed
  - The majority of AEs occurred during the first infusion
  - No treatment-related grade 4 or 5 AEs reported
  - No patients discontinued MCLA-129 treatment due to drug-related toxicity
  - No interstitial lung disease reported
- Based on pharmacokinetic and pharmacodynamic data, and the safety profile an initial recommend phase 2 dose was selected at 1500 mg every two weeks.

As October 2022, 33 patients have been enrolled in the dose escalation and dose expansion phases of the trial. The additional 13 patients enrolled did not yet have an opportunity to be evaluated for response as of the August 15, 2022 data cutoff. The MCLA-129 trial is ongoing in the dose expansion phase, treating patients with MCLA-129 monotherapy in MetEx14 NSCLC, EGFRex20 NSCLC, HNSCC, as well as in combination with a third generation EGFR tyrosine kinase inhibitor (TKI) in treatment naïve EGFRmt NSCLC and in patients with EGFRmt NSCLC that have progressed on Tagrisso (osimertinib).

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 is now available on-demand throughout the conference on the conference website and on the Publications page of our website.

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 potential to be meaningful in patients with solid tumors including NSCLC; continuing the dose expansion portion of this trial to further evaluate the efficacy and safety of MCLA-129 both as monotherapy and in combination with a third generation EGFR TKI; MCLA-129's mechanisms of action; the impact of observations concerning any interim clinical data, including observed safety and efficacy, the determination of the initial RP2D and the potential impact 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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