Merus Presents Interim Data on MCLA-145 Monotherapy and in Combination with Pembrolizumab at the 2024 ASCO® Annual Meeting

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UTRECHT, The Netherlands and CAMBRIDGE, Mass., June 02, 2024 (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-145 monotherapy and in combination with pembrolizumab were presented at the 2024 American Society of Clinical Oncology® (ASCO®) Annual Meeting taking place in Chicago May 31-June 4, 2024.

“MCLA-145 as monotherapy or with pembrolizumab appears to have a manageable safety profile and early clinical activity in these difficult to treat cancers. Our biomarker data suggest that both dose and less frequent administration may be important determinants of clinical activity, and we are encouraged by the progress we are making with MCLA-145,” said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. “As our company is now increasingly focused on our lead asset petosemtamab and plan to initiate phase 3 trials in head and neck cancer later this year, we aim to advance clinical development of MCLA-145 in the context of a potential collaboration.”

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Interim data included in the presentation describe data from patients (pts) with advanced/metastatic solid tumors who received MCLA-145 Q2W in 28 day cycles or every three weeks (Q3W) in 21 day cycles. Pts treated with the combination of MCLA-145 and pembrolizumab had cancers that either relapsed after PD-(L)1 therapies or were immunotherapy (IO) naïve.

Rapid oral presentation title: Phase I study of MCLA-145, a bispecific antibody targeting CD137 and PD-L1, in solid tumors, as monotherapy or in combination with pembrolizumab
Observations in the presentation include:

- As of a January 3, 2024 data cutoff date, 72 pts with multiple cancer types were treated; 25% of pts had non-small cell lung cancer (NSCLC)
  - All patients were heavily pre-treated with a median of 3 prior therapies; prior IO in 49% of the monotherapy pts and 100% of the combination pts
- In monotherapy, 52 pts with a variety of tumor types and treated at different dose levels were evaluable for response
  - 5 partial responses (PRs) were observed at different dose levels in glioblastoma (ongoing as of the cutoff date for >3 years), sarcoma (pretreated with pazopanib and gemcitabine/docetaxel), cervical, anal, and gastric cancer by Response Evaluation Criteria in Solid Tumors v1.1. per investigator assessment
  - 2 of 6 pts PRs (33%) were observed for pts treated at the recommended dose for expansion (RDE), 40 mg Q3W
  - 3 of 6 PRs (50%) were observed for pts with evaluable baseline tumor CD8 T-cell density of ≥ 250 cells/mm2 responded
- In combination with pembrolizumab, 19 pts with a variety of tumor types and treated at different dose levels were evaluable for response
  - 1 PR in Merkel cell carcinoma was observed at 25 mg Q3W
  - 1 complete response was observed in PD-L1+ NSCLC at the RDE 40 mg Q3W
  - 3 pts were continuing combination therapy at cutoff date
- MCLA-145 monotherapy or in combination with pembrolizumab had a well-tolerated and manageable safety profile at the RDE, 40mg Q3W
  - Shifting from Q2W to Q3W resulted in a 50% reduction of Grade (G) ≥3 treatment-emergent adverse events in both monotherapy and combination therapy
  - Liver toxicity, a common CD137 related adverse event, was controlled with no G4 events observed at Q3W

The full presentation is available on the Merus website.

About Merus
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 , X and LinkedIn.

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 our clinical candidates, including MCLA-145, future clinical trial results or interim data, clinical activity and safety profile, and development plans

in the on-going trials and described in forthcoming posters or presentations; the ability of our Mutliclonics®; our belief that for MCLA-145, biomarker data suggest that both dose and less frequent administration may be important determinants of clinical activity; our statements concerning the progress we are making with MCLA-145; our increasingly focus on our lead asset petosemtamab and plan to initiate phase 3 trials in head and neck cancer later this year; and our aim to advance clinical development of MCLA-145 in the context of a potential collaboration. These forward-looking statements are based on management's current expectations. 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 market volatility; 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 Annual Report on Form 10-Q for the quarter ended March 31, 2024 filed with the Securities and Exchange Commission, or SEC, on May 8, 2024, 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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