Merus' Petosemtamab Monotherapy Interim Data Continues to Demonstrate Clinically Meaningful Activity in 2L+ r/m HNSCC

December 7, 2024

Petosemtamab in combination with pembrolizumab in 1L r/m PD-L1 expressing HNSCC ongoing with clinical data update planned for 2025

Petosemtamab in mCRC evaluation expanded to include 1L and 3L+; initial clinical data planned for 2025

– Conference Call on Saturday, December 7th at 9:00 a.m. ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Dec. 07, 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 interim clinical data as of a July 5, 2024 data cutoff from the ongoing phase 1/2 trial of petosemtamab, a Biclonics® targeting EGFR and LGR5, in previously treated (2L+) patients (pts) with recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC). These data were presented by Christophe Le Tourneau MD, Ph.D., Institut Curie, Paris, France at the European Society for Medical Oncology (ESMO®) Asia Congress on Saturday, Dec. 7 in Singapore.

"Petosemtamab clinical data in r/m HNSCC continues to demonstrate potentially practice changing efficacy and safety, both as monotherapy in 2L+ and in combination with pembrolizumab in 1L PD-L1 expressing HNSCC," said Fabian Zohren, M.D., Ph.D., Chief Medical Officer of Merus. "Further, the monotherapy durability of petosemtamab thus far compares favorably to current standard of care, which we believe is another positive indicator for the likelihood of success of our phase 3 investigation of petosemtamab and pembrolizumab in 1L PD-L1 expressing HNSCC."

"Head and neck squamous cell carcinoma remains a deadly disease with limited treatment options," added Dr. Le Tourneau. "With its strong clinical outcomes across a large dataset of patients, regardless of HPV status and EGFR expression, petosemtamab has the potential to become a new standard of care for patients with recurrent/metastatic head and neck cancer."

Presentation title: Petosemtamab (MCLA-158) monotherapy in previously treated (2L+) recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 trial
Observations in the presentation include:

- As of a July 5, 2024 data cutoff date, 82 pts were treated with petosemtamab 1500 mg Q2W
  - The efficacy population consists of 75 pts who had the opportunity for 4 or more months follow up and ≥1 post-baseline tumor assessment; or who discontinued early due to disease progression or death
  - Seven pts were not efficacy evaluable: 6 pts were previously described at AACR 2023 and one additional patient withdrew due to infusion related reaction (IRRs) on Day 1
  - Confirmed overall response rate (ORR): 36% (90% CI: 27–46; 27/75) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment, including 4 complete responses (CRs), with one CR continuing on treatment for more than 3 years as of the data cutoff; and 13% (2/15) ORR in HPV associated cancer with another 5 patients achieving stable disease
  - At the time of data cutoff, 10 pts remain on treatment including 8 responders and 2 pts with stable disease
  - Median duration of response (DOR), progression free survival (PFS) and overall survival (OS) were 6.2, 4.9 and 11.4 months
  - For the most mature data set, the single arm cohort previously presented at AACR 2023, as of a July 5, 2024 data cutoff, for all 54 patients, the median DOR, PFS and OS were 6.7, 5.1, and 12.0 months, respectively; among the 48 treatment evaluable subset, they were 6.7, 5.2, and 12.5 months, respectively
- Petosemtamab 1500 mg Q2W continues to be well tolerated with a manageable safety profile with no new safety signals observed (82 pts)
- Infusion related reactions (IRRs) were predominantly seen on day 1 of cycle 1; a clinically meaningful reduction in the incidence and severity of IRR was observed with an updated administration regimen
- As of a July 5, 2024 data cutoff date, 28 pts were treated with petosemtamab 1100 mg Q2W
  - The efficacy population consists of 27 pts who had the opportunity for 4 or more months follow up and ≥1 post-baseline tumor assessment; or who discontinued early due to disease progression or death
  - One pt was not evaluable for efficacy due to withdrawing consent with <2 months treatment
  - ORR: 19% (90% CI: 8–35; 5/27), including 2 CRs, by RECIST v1.1. per investigator assessment

The full presentation is available on the Merus website.

Petosemtamab Clinical Development
r/m HNSCC: LiGeR-HN1 phase 3 trial in 1L and LiGeR-HN2 phase 3 trial in 2/3L enrolling; phase 2 trial of petosemtamab in combination with pembrolizumab in PD-L1+ 1L HNSCC ongoing with a clinical data update planned for 2025

mCRC: Phase 2 trial of petosemtamab in combination with standard chemotherapy in 2L metastatic colorectal cancer (mCRC) enrolling; phase 2 trial

in 1L mCRC in combination with standard chemotherapy planned to initiate in 2025, and phase 2 trial in 3L+ monotherapy planned to initiate in 2025; mCRC initial clinical data planned for 2025

Company Conference Call and Webcast Information
Merus will hold a conference call and webcast for investors on December 7, 2024 at 9:00 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 & Time: Dec. 07, 2024 at 9:00 a.m. ET
Webcast link: Available on our website
Dial-in: Toll Free: 1 (800) 715-9871/ International: 1 (646) 307-1963
Conference ID: 1978503

About Head and Neck Cancer
Head and neck squamous cell carcinoma (HNSCC) describes a group of cancers that develop in the squamous cells that line the mucosal surfaces of the mouth, throat, and larynx. These cancers begin when healthy cells change and grow in an unchecked manner, ultimately forming tumors. HNSCC is generally associated with tobacco consumption, alcohol use and/or HPV infections, depending on where they develop geographically. HNSCC is the sixth most common cancer worldwide and it is estimated that there were more than 930,000 new cases and over 465,000 deaths from HNSCC globally in 2020.1 The incidence of HNSCC continues to rise and is anticipated to increase by 30% to more than 1 million new cases annually by 2030.2 HNSCC is a serious and life-threatening disease with poor prognosis despite currently available standard of care therapies.

[1] Sung et al. CA Cancer J Clin, 71:209-49, 2021; [2] Johnson, D.E., Burtness, B., Leemans, C.R. et al. Head and neck squamous cell carcinoma. Nat Rev Dis Primers 6, 92 (2020)

About Petosemtamab
Petosemtamab, or MCLA-158, is a Biclonics® low-fucose human full-length IgG1 antibody targeting the epidermal growth factor receptor (EGFR) and the leucine-rich repeat containing G-protein-coupled receptor 5 (LGR5). Petosemtamab is designed to exhibit three independent mechanisms of action including inhibition of EGFR-dependent signaling, LGR5 binding leading to EGFR internalization and degradation in cancer cells, and enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) activity.

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 , 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 petosemtamab, future clinical trial results, interim data, clinical activity and safety profile, and development plans in the on-going trials, future clinical and regulatory milestones; and our belief that petosemtamab clinical data in r/m HNSCC continues to demonstrate potentially practice changing efficacy and safety both as monotherapy in 2L+ and in combination with pembrolizumab in 1L PD-L1 expressing HNSCC; our belief that the monotherapy durability of petosemtamab thus far compares favorably to current standard of care, which we believe is another positive indicator for the likelihood of success of our phase 3 investigation of petosemtamab and pembrolizumab in 1L PD-L1 expressing HNSCC; and planned updates in 2025 for initial clinical data for the phase 2 trial investigating petosemtamab in mCRC, and of the phase 2 trial investigating petosemtamab in combination with pembrolizumab in PD-L1+ 1L HNSCC. 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 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 volatility in the global economy, including global instability, including the ongoing conflicts in Europe and the Middle East; 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, 2024, filed with the Securities and Exchange Commission, or SEC, on October 31, 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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