

Merus

Merus Announces Publication of an Abstract on Petosemtamab in Advanced Gastric/Esophageal Adenocarcinoma for Presentation at the AACR Annual Meeting 2023

April 14, 2023

UTRECHT, The Netherlands and CAMBRIDGE, Mass., April 14, 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 the publication of an abstract for a poster presentation of early clinical data on the bispecific antibody petosemtamab in advanced gastric/esophageal adenocarcinoma (GEA) at the American Association for Cancer Research (AACR) Annual Meeting 2023 taking place in Orlando, Florida April 14-19, 2023.

Petosemtamab, or MCLA-158, is a human IgG1 Biclonics® designed to bind to cancer cells expressing epidermal growth factor receptor (EGFR) and leucine-rich repeat-containing G protein-coupled receptor 5 (LGR5).

Petosemtamab is in clinical development in the expansion part of a phase 1/2 open-label, multicenter trial in advanced solid tumors, including advanced GEA.

Although petosemtamab has demonstrated promising clinical activity among pretreated gastric/esophageal adenocarcinoma (GEA) patients having EGFR gene amplification and/or overexpression, the Company has decided to pause further clinical exploration of the GEA cancer cohort at this time. The Company plans to prioritize investigating petosemtamab in head and neck squamous cell carcinoma, in view of the strong clinical activity observed in this cohort.

Information and observations from the cohort of GEA patients treated in the phase 1/2 trial include:

- As of an October 24, 2022 data cutoff date, 14 previously treated GEA patients (pts) were treated with petosemtamab 1500 mg (IV) every two weeks
- Patient Population:
 - Median age was 63 (range of 40-80); 79% were male
 - Median prior lines of systemic therapy was 3 (range 1-4); including platinum-based chemotherapy (36% of pts) and checkpoint inhibitors (14%)
- 14 pts were evaluable for efficacy, receiving ≥ 2 treatment cycles (≥ 8 weeks) with ≥ 1 post-baseline tumor assessment or experiencing early progressive disease
 - Antitumor activity among the 14 pts:
 - 1 pt with tumor EGFR protein overexpression and gene copy number amplification (CNA) showed a confirmed sustained partial response (67% tumor reduction; response ongoing after 24 cycles);
 - 3 pts had stable disease (1 with EGFR overexpression and gene CNA; 2 not evaluable for IHC), with tumor reductions of 2%, 17%, and 40%.
- Petosemtamab continues to demonstrate a manageable safety profile:
 - Of 78 pts treated at the recommended phase 2 dose of 1500 mg every two weeks (escalation and all expansion cohorts), the most frequent AEs regardless of causality (all grades/G3-4) were rash (33%/0%), hypotension (26%/6%), dyspnea (26%/4%), nausea (26%/1%), dermatitis acneiform (24%/1%), blood magnesium decreased (19%/5%), erythema (19%/0%), diarrhea (19%/0%); IRRs (composite term) were reported in 74%/21% of pts, mostly at the first infusion, and all resolved. 5 pts (6%) discontinued treatment due to IRRs on Day 1.

Presentation Details:

Title: MCLA-158 (petosemtamab), an IgG1 bispecific antibody targeting EGFR and LGR5, in advanced gastric/esophageal adenocarcinoma (GEA)

Session: Phase II Clinical Trials 1

Date: Monday, April 17, 2023

Time: 1:30 - 5:30 p.m. ET

Poster #: 18

Abstract #: CT156

The abstract can be found on the conference [website](#).

About Petosemtamab

Petosemtamab, or MCLA-158, is a bispecific 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 [Multiclronics®](#). Multiclronics® 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>.

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 petosemtamab, future clinical trial; the Company's decision to prioritize investigating petosemtamab in HNSCC patients; the promising clinical activity in pretreated gastric/esophageal adenocarcinoma (GEA) patients having EGFR gene amplification and/or overexpression, and decision to pause further exploration of the GEA cancer cohort at this time. 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 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on February 28, 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.

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