

# Merus

## **CORRECTING and REPLACING --Merus Provides 2023 Outlook**

January 9, 2023

- *As of year-end 2022, more than 150 patients with NRG1 gene fusion positive (“NRG1+”) cancer have been treated with zenocutuzumab (“Zeno”) monotherapy*
  - *Petosemtamab clinical update planned for first half of 2023*
  - *MCLA-129 clinical update planned for second half of 2023*
- *Based on the Company’s current operating plan, existing cash, cash equivalents and marketable securities, expected to fund Merus’ operations into second half 2025*

In a release issued January 8, 2023 by Merus N.V. (Nasdaq:MRUS) with the same headline, an error was made stating Merus plans to provide a regulatory path and program update on petosemtamab in the second half of 2023, which has been corrected to indicate this update is planned for the first half of 2023. Further, an error was made stating Merus has initiated a cohort evaluating Zeno in monotherapy in castration resistant prostate cancer, this has been corrected to indicate this is not in monotherapy, but in addition to Enzalutamide or Abiraterone acetate. The corrected release further discloses that Merus plans to provide an update on the potential registrational path and timeline of Zeno in NRG1+ cancer in the first half of 2023. The corrected release follows:

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Jan. 09, 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 provided its 2023 outlook.

“2023 looks to be another productive year for Merus with multiple value-creating clinical updates throughout the year. We continue to advance numerous programs which have demonstrated important clinical activity in patients,” said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. “I am proud of our team, having created the Merus Multiclonics® proprietary platforms, which has led to the generation of these important potential medicines being developed internally here at Merus and with our collaborators and licensees.”

### **Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclonics®): NRG1+ cancer and other solid tumors**

*Enrollment continues in the eNRGy trial of Zeno monotherapy in NRG1+ cancer; with a cohort investigating Zeno in castration resistant prostate cancer (CRPC) initiated in December 2022*

In October, Merus met with the U.S. Food and Drug Administration (FDA) regarding a potential Biologics License Application (BLA) filing for Zeno in NRG1 fusion (NRG1+) cancer. Based on the FDA feedback, Merus believes multiple registrational paths remain viable, and has decided the optimal approach is to sequence its development plan by first seeking a potential application for NRG1+ lung and/or pancreatic cancer, which could then be followed by a potential tumor agnostic filing. The Company believes Zeno has the potential to be both first in class and best in class, and a new standard of care for the treatment of NRG1+ cancer.

Enrollment continues in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer. As of year-end, over 150 patients have been treated in the eNRGy trial and Early Access Program (EAP).

Merus plans to provide an update on the potential registrational path and timeline in NRG1+ cancer in the first half of 2023 and a clinical update on Zeno in NRG1+ cancer at a major medical conference in 2023.

Details of the eNRGy trial can be found at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and Merus’ trial website at [www.nrg1.com](http://www.nrg1.com), or by calling 1-833-NRG-1234.

Further, Merus has initiated a cohort evaluating Zeno in addition to Enzalutamide or Abiraterone acetate in CRPC, and plans to initiate a cohort exploring the combination of Zeno with afatinib for patients with NRG1+ non-small cell lung cancer (NSCLC). The Company is also continuing to explore the ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers.

Merus plans to provide an initial clinical data update on Zeno in CRPC in the second half of 2023.

### **Petosemtamab (MCLA-158: Lgr5 x EGFR Biclonics®): Solid Tumors**

*Enrollment continues in dose expansion in the phase 1 trial; clinical update planned for 1H23*

Petosemtamab is in clinical development in advanced solid tumors, including previously treated head and neck squamous cell carcinoma (HNSCC), in the expansion part of a phase 1 open-label, multicenter study.

Merus plans to provide a clinical update for petosemtamab at a medical conference in the first half of 2023. The planned presentation will provide the opportunity to present a robust update across the program, including approximately 40 patients with HNSCC with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy.

Merus further plans to provide a regulatory path and program update on petosemtamab in the first half of 2023.

### **MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors**

*Enrollment continues in the expansion cohorts in the phase 1/2 trial; clinical update planned for 2H23*

MCLA-129 is in clinical development in a phase 1/2, open-label clinical trial evaluating patients with MCLA-129 monotherapy in EGFRex20 NSCLC, MetEx14 NSCLC, and in HNSCC, as well as in combination with a third generation EGFR TKI in treatment naïve EGFR mutant (m) NSCLC and in patients with EGFR m NSCLC that have progressed on Tagrisso (osimertinib).

MCLA-129 is also subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to exclusively develop MCLA-129 in China, while Merus retains global rights outside of China.

Merus plans to provide an initial clinical data update from the expansion cohorts, and a further clinical development strategy update in the second half of 2023.

#### **MCLA-145 (CD137 x PD-L1 Biclomics®): Solid Tumors**

*Enrollment continues in the phase 1 trial including in combination with a PD1 inhibitor*

MCLA-145 is in clinical development in a global, phase 1, open-label, clinical trial evaluating MCLA-145 in patients with solid tumors. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. Merus is also evaluating the combination of MCLA-145 with a PD-1 blocking antibody, with enrollment on-going.

#### **Collaborations**

##### **Incyte Corporation (“Incyte”)**

Since 2017, Merus has been working together with Incyte Corporation under a global collaboration and license agreement focused on the research, discovery and development of bispecific antibodies utilizing Merus' proprietary Biclomics® technology platform. The agreement grants Incyte certain exclusive rights for up to ten bispecific and monospecific antibody programs. The collaboration is progressing, with multiple programs in various stages of preclinical development. Further, Incyte announced, in 2022, that it plans to start a clinical study of INCA32459, a novel Lag3xPD-1 bispecific antibody developed through the collaboration. For each program under the collaboration, Merus receives reimbursement for research activities and is eligible to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved.

##### **Loxo Oncology at Lilly**

In January 2021 Merus and Loxo Oncology at Lilly, a research and development group of Eli Lilly and Company (Lilly) announced a research collaboration and exclusive license agreement to develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies utilizing Merus' Biclomics® platform and proprietary CD3 panel along with the scientific and rational drug design expertise of Loxo Oncology at Lilly. The collaboration is progressing with multiple active research programs underway.

#### **Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into second half 2025**

As of September 30, 2022, Merus had \$372.9 million cash and cash equivalents. After undergoing the Company's 2023 budgeting process and based on the Company's current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into second half 2025.

#### **Corporate Update**

On January 6, Merus announced the promotion of Peter B. Silverman as Chief Operating Officer. Mr. Silverman adds this title to his role as Executive Vice President, General Counsel. Mr. Silverman is an accomplished healthcare leader, with demonstrated success in progressing Merus across multiple business functions during his tenure at the company. Since Mr. Silverman joined Merus in 2017, he has made significant contributions to enhance the company's platform technology, intellectual property portfolio, advance our strategic collaborations, and has overseen the company's general and administrative functions, which have been instrumental in fostering the company's growth. We congratulate him on his well-deserved promotion and believe it will strengthen the organizational structure that will allow us to better maximize the exciting opportunities that lie ahead.

#### **About Merus N.V.**

Merus is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as Multiclomics®. Multiclomics® 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, [www.merus.nl](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 the content and timing of clinical trials, data readouts and clinical, regulatory, strategy and development updates for our product candidates, including with respect to enrollment and timing of data in our eNRGY trial and EAP, the treatment potential of Zeno and to be potentially first and best in class for NRG1 fusion cancer; our belief in the potential registrational path in NRG1+ cancer tumor agnostic indication or separate applications for lung and pancreatic cancer, which could then be followed by a subsequent potential tumor agnostic filing; our understanding of the recent FDA draft guidance; our potential filing of a BLA for Zeno in NRG1+ cancer under either a tumor agnostic or tumor specific approach; the continuation of enrollment of patients in the eNRGY trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers; future use and potential benefit of Zeno in combination with other cancer therapies; our planned clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC; the advancement of the clinical trial investigating Zeno as a treatment for CRPC; our exploring the ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into the second half of 2025; the advancement of the Phase 1 trial of MCLA-145, as monotherapy and in combination with a PD-1 blocking antibody; the advancement of the phase 1 trial for MCLA-158 and the planned update at a medical conference in the first half of 2023 and opportunity to present a robust update across the program, including approximately 40 patients with head and neck squamous cell carcinoma with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy and planned regulatory interactions; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in MetEx14 NSCLC, EGFRex20 NSCLC, and in HNSCC, as well as in combination with a third generation EGFR TKI in treatment naïve EGFRmt NSCLC and in patients with EGFRmt NSCLC that have progressed on Tagrisso (osimertinib); the selection of the initial recommended phase 2 dose on the MCLA-129 study; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; the benefits of the collaboration between Loxo Oncology at Lilly and Merus, its potential for future value generation, including whether and when Merus will receive any future payment under the collaboration, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; Merus' and Lilly's activities under the agreement; our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to ten bispecific and monospecific antibodies from our Biclomics® platform and Incyte's plans to start a clinical study of INCA32459 developed in collaboration with us; our collaboration and license agreement with Betta, which permits Betta to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights, and any developments that may arise from these agreements; and Mr. Silverman's anticipated contribution to the organizational structure and ability to better maximize the exciting opportunities that lie ahead. 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 COVID-19 pandemic; we may not identify suitable Biclomics<sup>®</sup> 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; our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks; and risks related to our ceasing to qualify as an emerging growth company and a smaller reporting company after December 31, 2021.

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, 2022, filed with the Securities and Exchange Commission, or SEC, on November 3, 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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The Merus logo consists of the word "Merus" in a bold, blue, sans-serif font. The letter "M" is significantly larger than the other letters, and the "e" and "s" are also larger than the "r" and "u".