Zenocutuzumab (Zeno) granted Breakthrough Therapy Designation by the U.S. Food & Drug Administration for the treatment of NRG1+ pancreatic cancer

June 29, 2023

UTRECHT, The Netherlands and CAMBRIDGE, Mass., June 29, 2023 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®) for cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for zenocutuzumab (Zeno) for the treatment of patients with advanced unresectable or metastatic NRG1 fusion (NRG1+) pancreatic cancer following progression with prior systemic therapy or who have no satisfactory alternative treatment options. This designation for Zeno follows a Fast Track Designation for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions (NRG1+ cancer) that have progressed on standard of care therapy on January 7, 2021 and Orphan Drug Designation for the treatment of patients with pancreatic cancer on July 27, 2020.

BTD is supported by data from the ongoing phase 1/2 eNRGy trial and Early Access Program (EAP) which are assessing the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer (Phase 1/2: NCT02912949, EAP: NCT04100694). Data from the eNRGy trial and EAP were featured as oral presentations during the 2021 and 2022 American Society of Clinical Oncology Annual Meetings (Abstract #3003, #105 respectively). As of June 1, 2023, more than 175 patients with NRG1+ cancer have been treated with Zeno monotherapy.

BTD is intended to expedite the development and review of a medicine to treat a serious or life-threatening condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on clinically significant endpoints over available therapies. BTD allows for more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, and eligibility for rolling review and priority review. With this BTD, Merus plans to engage in these discussions with the FDA in an expedited manner, and then provide a further update on the path and timeline to a potential Biologics License Application (BLA) submission.

Merus believes that obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved.

“We believe the compelling clinical data for Zeno in NRG1+ cancer, and Breakthrough Therapy Designation, provide the opportunity to further engage with the FDA to expedite the review of a potential BLA submission,” said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. “Additionally, our intention to partner Zeno is a reflection of our strategy to carefully balance value creation with capital allocation requirements across our portfolio.”

Merus plans to provide a clinical update on Zeno in NRG1+ cancer at a major medical conference in 2023.

Further, Merus is evaluating Zeno in combination with androgen deprivation therapy (enzalutamide or abiraterone) in castration resistant prostate cancer (CRPC), irrespective of NRG1+ status. Merus plans to provide initial clinical data on Zeno in CRPC in the second half of 2023. Merus is also evaluating Zeno in combination with afatinib in patients with NRG1+ NSCLC.

About the eNRGy Clinical Trial

Merus is currently enrolling patients in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer. The eNRGy trial consists of three cohorts: NRG1+ pancreatic cancer; NRG1+ non-small cell lung cancer; and other NRG1+ cancer. Further details, including current trial sites, can be found at www.ClinicalTrials.gov and Merus’ trial website at www.nrg1.com or by calling 1-833-NRG-1234.

About Zeno

Zeno is an antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® that utilizes the Merus Dock & Block® mechanism to inhibit the neuregulin/HER3 tumor-signaling pathway in solid tumors with NRG1 fusions (NRG1+ cancer). Through its unique mechanism of binding to HER2 and potently blocking the interaction of HER3 with its ligand NRG1 or NRG1-fusion proteins, Zeno has the potential to be particularly effective against NRG1+ cancer. In preclinical studies, Zeno potently inhibits HER2/HER3 heterodimer formation thereby inhibiting oncogenic signaling pathways, leading to inhibition of tumor cell proliferation and blocking tumor cell survival.

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 , Twitter 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, the potential benefits of Breakthrough designation for Zeno’s development for the treatment of patients diagnosed with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard of care therapy or who have no satisfactory alternative treatment options; Merus’ belief that a obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved; Merus’ belief that clinical data for Zeno in NRG1+ cancer, and Breakthrough Therapy Designation, provide the opportunity to further engage with the FDA to expedite the review of a potential BLA filing; Merus’ intention to partner Zeno and strategy to carefully balance value creation with capital allocation requirements across our portfolio; the Zeno clinical study design, the enrollment of the eNRGy trial, any planned updates on Zeno and NRG1+ cancer, and Zeno in combination with an ADT for the potential treatment of CRPC. 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 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; 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 Annual Report on Form 10-Q for the period ended March 31, 2023, filed with the Securities and Exchange Commission, or SEC, on May 4, 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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