

Merus

Merus announces FDA Orphan Drug Designation of Zenocutuzumab for the Treatment of Pancreatic Cancer

July 27, 2020

UTRECHT, The Netherlands and CAMBRIDGE, Mass., July 27, 2020 (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 Orphan Drug Designation to Zenocutuzumab (Zeno) for the treatment of patients with pancreatic cancer.

Zeno is a first in class bispecific antibody that potently binds to the HER2 and HER3 receptors, to potently block the interaction of HER3 with its ligand, neuregulin 1 (NRG1). Zeno has demonstrated promising early clinical responses in patients with previously treated pancreatic cancer harboring NRG1 gene fusions, as presented at the AACR/NCI/EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2019. The NRG1 gene fusion is a rare, powerful driver of cancer cell growth found in pancreatic, lung and other types of solid tumors. Zeno is now being evaluated in a global phase 1/2 clinical trial called the [eNRGy trial](#).

"Receiving Orphan Drug Designation for Zeno is another important milestone for our lead program, and it validates the significant unmet need in patients with pancreatic cancer," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "We are pleased with the progress we are making in our ongoing global clinical trial, and believe that Zeno has the potential to play a significant role in shifting the treatment paradigm for NRG1 fusion cancers from conventional chemotherapy to a personalized medicine approach."

The FDA grants Orphan Drug Designation to drugs that are intended to treat rare diseases that affect fewer than 200,000 people in the U.S. Orphan Drug Designation may provide Merus certain benefits, such as grant funding towards clinical trial costs, tax advantages and eligibility for seven-year market exclusivity.

Pancreatic cancer is estimated to occur in approximately 57,000 patients annually in the United States, according to the NCI SEER database. Pancreatic ductal adenocarcinoma (PDAC), the most common subtype of pancreatic cancer, is one of the most aggressive solid tumor cancers and the fourth leading cause of cancer related deaths.

About the eNRGy Clinical Trial

Merus is currently enrolling patients on the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. The eNRGy trial consists of three cohorts: NRG1+ pancreatic cancer; NRG1+ non-small cell lung cancer; and NRG1+ other solid tumors. 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 NRG1 Fusions

The NRG1 gene encodes for neuregulin 1 (also known as heregulin), the ligand for HER3. Fusions between NRG1 and partner genes are rare genetic events occurring in patients with certain lung, pancreatic and other solid tumors, associated with activation of HER2/HER3 signaling and growth of cancer cells. NRG1 fusions are estimated to occur at a rate of approximately 0.5% - 1.5% in PDAC, based on the limited available published data.

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. 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+ cancers. In preclinical studies, Zeno also potently inhibits HER2/HER3 heterodimer formation and tumor growth in models harboring NRG1 fusions.

Learn more about Zeno Dock & Block® at <https://merus.nl/technology/>.

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, 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, the potential of Zeno to play a significant role in shifting the treatment paradigm for NRG1 fusion cancers from conventional chemotherapy to a personalized medicine approach; the progress of the eNRGy trial; and the potential benefits of the orphan drug designation of Zeno, such as grant funding towards clinical trial costs, tax advantages and eligibility for seven-year market exclusivity. 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the Securities and Exchange Commission, or SEC, on May 11, 2020, 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". The logo is positioned in the upper left quadrant of the page.