Merus Presents Clinical Data on Zenocutuzumab in NRG1-fusion (NRG1+) Cancers at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting (Oral Abstract)

June 4, 2021

- 61 patients with NRG1+ cancer have been enrolled, including 45 patients evaluable for response as of the April 13, 2021 data cutoff date
- Encouraging early clinical activity observed, with confirmed responses in 5 of 12 patients with pancreatic cancer (42%) and in 13 of 45 patients across several NRG1+ tumor types (29%)
- Zenocutuzumab continues to be well tolerated with a favorable safety profile
- Company to host investor call to discuss interim clinical results and provide a program update on Sunday, June 6 at 6:00 PM ET

UTRECHT, The Netherlands and CAMBRIDGE, Mass., June 04, 2021 (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 efficacy data, as of an April 13, 2021 cutoff date, from the phase 1/2 eNRGy trial and Early Access Program (EAP) of bispecific antibody zenocutuzumab (Zeno) in patients with NRG1+ cancers, presented virtually by Lead Author, Dr. Alison Schram of Memorial Sloan Kettering Cancer Center (MSKCC) at the 2021 ASCO Annual Meeting.

Dr. Andrew Joe, Chief Medical Officer at Merus said, "With confirmed partial responses observed in 42% of pancreatic cancer patients, and partial responses across several NRG1+ tumor types, we remain encouraged that Zeno has the potential to become a new treatment for patients with NRG1 fusion positive cancers. The data, including durability, continue to mature with 40% of evaluable patients remaining on therapy as of the data cutoff date."

Dr. Alison Schram said, "It is very exciting to witness the emergence of a potential new treatment for patients with NRG1 fusion-positive cancers, a population with unmet need. The data presented today are the first to clinically validate NRG1 fusions as drivers of cancer and show that Zeno is capable of blocking tumor growth in patients harboring these fusions."

The reported data are from the ongoing phase 1/2 eNRGy trial and EAP which are investigating 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 (NSCLC); and NRG1+ other solid tumors.

Key findings in the presentation include:

- Enrollment of 61 patients with NRG1+ pancreatic, NSCLC, and other cancers.
- 47 patients were evaluable for primary analysis , with a median age of 56 (range 22-84), previously treated with a median of 2 lines of prior therapy.
- 45 patients were evaluable for response by local review with measurable disease and the opportunity for ≥ 1 post-baseline tumor assessment (two patients with non-measurable disease are included in the primary analysis of 47 patients, but not included in the 45 evaluable for response).
- Partial responses (PRs) achieved across four different NRG1+ tumor types and multiple different fusion partners
    - Across NRG1+ tumor types, 29% overall response rate (ORR) with 13 of 45 achieving PRs, one additional unconfirmed PR was confirmed after the April 13, 2021 data cutoff date (14 of 45, 31%); median duration of exposure is 5.5 months, with 40% of evaluable patients continuing on treatment; the duration of response ranges from 1+ to approximately 12 months.
    - 34 of 45 (76%) patients had tumor reduction
- 42% ORR with 5 of 12 PRs in pretreated NRG1+ pancreatic cancer
    - Median duration of exposure as of the April 13, 2021 data cut-off is 5.7 months, with 7 of 12 patients continuing on treatment.
- In NSCLC, 25% ORR, with 6 of 24 PRs; one additional unconfirmed PR was confirmed after the data cutoff date (7 of 24, 29%).
- Among all other solid tumors, 22% ORR with 2 of 9 PRs.
- Zeno was observed to have a favorable and tolerable safety profile (across 157 patients treated with Zeno monotherapy as of the Jan 12, 2021 safety data cutoff date).
    - The majority of adverse events were mild or moderate (Grade 1 or 2) in severity.
    - Absence of severe gastrointestinal and skin toxicities and clinical cardiotoxicity.
    - Low incidence (7%) of infusion reactions

- First prospective clinical validation of NRG1 fusions as actionable oncogenic drivers that may be amenable to targeted therapy with Zeno.

Merus plans the next program and clinical update for Zeno at a major medical conference by the first half of 2022.

Company Conference Call and Webcast Information

Merus will hold a conference call and webcast for investors on Sunday, June 6, 2021 at 6:00 PM ET to discuss the Zeno clinical data. A replay will be available after the completion of the call in the Investors and Media section of our website.

Date: Sunday, June 6 at 6:00 pm ET
Webcast link: available on our website
Dial-in: Toll-Free: 1-877-260-1463 / International: 1-706-643-5907
Conference ID: 9678617

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+ 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 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 gene fusions (NRG1+). 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.

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, 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 clinical development of zenocutuzumab, the next planned program and clinical update, future clinical trial results, clinical activity, durability and safety profile of Zeno in the on-going eNRGy trial and EAP, including in previously treated pancreatic cancer, and each cohort of the eNRGy trial, Zeno's potential to become a new treatment for patients with NRG1+ cancer and prospective clinical validation of NRG1 fusions as actionable oncogenic drivers that may be amenable to targeted therapy with Zeno. 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 period ended March 31, 2021 filed with the Securities and Exchange Commission, or SEC, on May 6, 2021, 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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