

Merus

Merus and Caris Life Sciences Announce Collaboration to Detect NRG1 Fusions in Cancer Patients

July 13, 2020

Caris to provide DNA and RNA molecular testing to support patient identification and enrollment for Merus' Zenocutuzumab Phase 1/2 eNRGy trial

UTRECHT, The Netherlands and CAMBRIDGE, Mass. and IRVING, Texas, July 13, 2020 (GLOBE NEWSWIRE) -- [Merus N.V.](#) (Nasdaq: MRUS), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics™) and Caris Life Sciences®, a leading innovator in molecular science focused on fulfilling the promise of precision medicine, today announced a collaboration to detect neuregulin 1 (NRG1) fusions in cancer patients. Under the agreement, Caris has agreed to perform whole exome sequencing of DNA and whole transcriptome sequencing of RNA for certain cancer patients, focusing on pancreatic cancer, to identify the presence of NRG1 fusions and to increase awareness of and potential enrollment in Merus' bispecific antibody Zenocutuzumab ("Zeno") Phase 1/2 eNRGy trial.

"We are pleased to collaborate with Merus and to identify patients with NRG1 fusions," said David Spetzler, M.S., Ph.D., MBA, President and Chief Scientific Officer of Caris Life Sciences. "Our molecular profiling tools provide critical information physicians and patients need to make informed treatment decisions. We look forward to providing this important molecular information to clinicians, and Merus, to evaluate patient eligibility for the eNRGy trial with Zeno."

The NRG1 gene fusion is a rare, powerful driver of cancer cell growth found in lung, pancreatic and other solid tumor types. Zeno, through its unique mechanism of blocking the interaction of the NRG1 fusion protein with its receptor HER3, has the potential to be particularly effective against NRG1+ cancers.

"We look forward to working with Caris to identify patients who may benefit from Zeno," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "While genomic sequencing is more commonly being used in the healthcare setting, it is not sufficiently employed in the diagnosis and management of pancreatic and other cancers where treatment options have been limited. We believe our collaboration with Caris will help to raise awareness of the value of molecular profiling in pancreatic and other cancers, and potentially enhance enrollment in our Zeno eNRGy trial and Early Access Program."

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 (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. Overall projections for NRG1 fusions occurrence are based on limited published information at present. Based on the current literature available, Merus estimates NRG1 fusions occur at a rate of approximately 0.3% – 3.0% in non-small cell lung cancer (NSCLC), 0.5% - 1.5% in pancreatic ductal adenocarcinoma (PDAC), and less than 1% in all other tumor types.

In preclinical studies, the mechanism by which the NRG1 fusion protein stimulates tumor growth has been observed to be especially sensitive to inhibition by the Zeno Dock & Block® mechanism of binding (docking) to HER2 and blocking the interaction of HER3 with its ligand neuregulin or with the NRG1 fusion protein. In preclinical studies, Merus has observed that Zeno is capable of potent inhibition of neuregulin-driven HER2/HER3 heterodimer formation and tumor growth in models harboring NRG1 fusions.

About Zeno

Zeno is an antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® that utilizes Merus Dock & Block® mechanism and inhibits the neuregulin/HER3 tumor-signaling pathway in solid tumors. Zeno is believed to target the HER3 signaling pathway and to overcome the resistance of tumor cells to HER2-targeted therapies using two mechanisms: blocking growth and survival pathways to stop tumor expansion and recruitment and enhancement of immune effector cells to eliminate the tumor. 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 antibody therapeutics, referred to as Biclonics®. Biclonics® 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>.

About Caris Life Sciences

Caris Life Sciences® is a leading innovator in molecular science focused on fulfilling the promise of precision medicine through quality and innovation. The company's suite of market-leading molecular profiling offerings assesses DNA, RNA and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. MI Exome™ whole exome sequencing with 22,000 DNA genes, and MI Transcriptome™ whole transcriptome sequencing with 22,000 RNA genes along with cancer-related pathogens, bacteria, viruses and fungi analysis run on every patient provides the most comprehensive and clinically relevant DNA and RNA profiling available on the market.

Caris is also advancing precision medicine with Caris MAI™ (Molecular Artificial Intelligence) that combines its innovative service offerings, Caris Molecular Intelligence® with its proprietary artificial intelligence analytics engine, DEAN™, to analyze the whole exome, whole transcriptome and complete cancer proteome. This information, coupled with mature clinical outcomes on thousands of patients, provides unmatched molecular solutions for patients, physicians, payers and

biopharmaceutical organizations.

Caris Pharmatech is changing the paradigm and streamlines the clinical trial process by assisting biopharma companies with accessing research-ready oncology sites for clinical trials. With over 200 research sites within the Caris Pharmatech JIT Oncology Network, biopharma companies can identify and enroll more patients, faster. Caris Pharmatech Just-In-Time Clinical Trial Solutions focus on rapid site activation and patient enrollment to streamline the drug development process. By implementing a Just-In-Time (JIT) Research System, site activation and patient enrollment is achievable within 14 days for pre-registered locations with pre-qualified patients.

Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Asia and other international markets. To learn more, please visit www.CarisLifeSciences.com or follow us on Twitter ([@CarisLS](https://twitter.com/CarisLS)).

Forward Looking Statement

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, Caris' agreement to perform whole exome sequencing of DNA and whole transcriptome sequencing of RNA of certain cancer patients, focusing on pancreatic cancer, to identify the presence of NRG1 fusions; increase awareness of and potential enrollment in Merus' bispecific antibody Zeno Phase 1/2 eNRGy trial; the design and treatment potential for Zeno and its mechanism of action to be particularly effective against NRG1+ cancers; the ability of the collaboration with Caris to identify patients with NRG1 fusions; the ability of Caris' molecular profiling tools to provide the knowledge physicians and patients need to make informed treatment decisions and for clinicians, and Merus, to evaluate patient eligibility for the eNRGy trial with Zeno; the collaboration' ability to help to raise awareness of the value of genetic diagnosis in pancreatic and other cancers, and potentially enhance enrollment in the Zeno eNRGy trial and Early Access Program; the Zeno clinical study design, the occurrence of NRG1 fusion cancers. 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 Biclomics® 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 Biclomics® 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.

Merus Investor and Media Inquiries:

Jillian Connell
Merus N.V.
Investor Relations and Corporate Communications
617-955-4716
j.connell@merus.nl

Caris Life Sciences Media & Company Contact:

Lindsey Bailys
GCI Health
lindsey.bailys@gcihealth.com
+1-212-798-9884

The Merus logo consists of the word "Merus" in a bold, blue, sans-serif font. The letter "M" is significantly larger and more prominent than the other letters, which are of a standard size and spaced evenly.