Merus Announces First Patient Dosed in Phase 1 Clinical Trial of MCLA-158 in Patients with Solid Tumors

May 24, 2018

- IND Accepted in April by the U.S. FDA for MCLA-158 -

UTRECHT, The Netherlands, May 24, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced that the first patient has been dosed in a Phase 1, first-in human clinical trial of MCLA-158 in patients with solid tumors with an initial focus on metastatic colorectal cancer. The trial will be conducted in Europe, where several Clinical Trial Applications (CTAs) have been approved to date. The Company also announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for MCLA-158, which was accepted by the FDA in April 2018. With this acceptance, Merus plans to open additional sites for this trial in the United States.

MCLA-158 is designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor receptors (EGFR). MCLA-158 was identified from a large library of bispecific antibodies targeting molecules belonging to the Wnt and receptor tyrosine kinase signaling pathways as part of work performed by the suppresSTEM consortium, a project that was funded by the European Union. Functional evaluation of patient-derived colorectal tumors, including those harboring RAS and/or PI3K mutations, demonstrated that MCLA-158 was more effective at inhibiting tumor growth and promoting apoptosis than an approved targeted therapy comparator for metastatic colorectal cancer, cetuximab. In preclinical studies, Merus also observed that the growth inhibitory activity of MCLA-158 was greater for colon tumors compared to normal colon tissue, consistent with its good safety profile in non-human primates.

“The commencement of our Phase 1 clinical trial of MCLA-158 is an important milestone for the advancement of our pipeline of bispecific antibodies obtained from our Biclonics® technology platform,” said Ton Logtenberg, Ph.D., Chief Executive Officer. “We believe MCLA-158 has the potential to address features that limit currently approved colorectal cancer-targeted therapies, including issues with off-target toxicity and inability to target tumor stem cells, and thus, potentially treat a broader population of patients more effectively.”

The Phase 1, open-label, multicenter clinical trial of MCLA-158 consists of two parts, a dose escalation and a dose expansion. The dose escalation part is intended to determine the appropriate dose of MCLA-158. The dose expansion part will evaluate the safety and tolerability of the defined dose of MCLA-158 in patients with solid tumors. The dose escalation and expansion parts of the trial will also examine the preliminary antitumor activity of single-agent MCLA-158.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclonics®. Biclonics®, which are based on the full-length IgG format, 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. Merus' most advanced bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 2 combination trial in two metastatic breast cancer populations. MCLA-128 is also being evaluated in a Phase 1/2 clinical trial in gastric, ovarian, endometrial and non-small cell lung cancers. Additional pipeline programs include MCLA-117, which is currently being studied in a Phase 1 clinical trial in patients with acute myeloid leukemia, and MCLA-158, a Biclonics® being studied in a Phase 1 clinical trial in patients with solid tumors with an initial focus on metastatic colorectal cancer. Through its collaboration with Incyte Corporation, Merus is also developing a preclinical bispecific antibody designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. For additional information, please visit Merus' website, www.merus.nl.

About suppresSTEM

The suppresSTEM consortium consisted of Merus N.V. as coordinator, The Hubrecht Institute (The Netherlands), OcellO B.V. (The Netherlands), Institute for Research in Biomedicine (IRB, Barcelona Spain), and The Wellcome Trust Sanger Institute (UK). The research leading to the results described here received funding from the European Union Seventh Framework Programme FP7/2007-2013 under grant agreement n° 601876. In May 2013 the consortium was granted a total of about €6 million to develop novel antibody-based therapeutics targeting cancer stem cells for the treatment of colorectal cancer as well as patient-derived organoid-based screening tools to aid drug discovery as a European Union's FP7 program. Specifically, the consortium was focused on addressing mechanisms that lead to the development of treatment resistance and tumor escape in colon cancer, a problem that has hampered the development of efficient therapeutics in the past. Furthermore, it pioneered the application of patient-derived tissue in drug discovery to address the high clinical failure rate in cancer drug research.

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 statements regarding the potential or promise of Merus' platform for generating bispecific antibodies and their development, the design, treatment potential, clinical development and clinical development plans for Merus' bispecific antibody therapeutic candidates, the advancement of the Phase I clinical trial in Europe for MCLA-158, the plan to open sites for a Phase 1 MCLA-158 trial in the United States, the treatment potential of MCLA-158 compared to other approved targeted therapies such as cetuximab in humans, the design of our Phase 1, open-label, multicenter clinical trial of MCLA-158 to determine the appropriate dose of MCLA-158, the planned expansion phase to evaluate the safety and tolerability of the defined dose of MCLA-158 in patients with solid tumors, the plan to examine the preliminary antitumor activity of single-agent MCLA-158, and the suppresSTEM consortium's ability to address mechanisms that lead to the development of treatment resistance and tumor escape in colon cancer, and ability to use patient-derived tissue in drug discovery to address the clinical failure rate in cancer drug research.

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® and bispecific 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; we may not identify suitable Biclonics® or bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; 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 existing and 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 30, 2018, 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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