Merus Announces Financial Results for the First Quarter 2019 and Provides Business Update

May 30, 2019

UTRECHT, The Netherlands, May 30, 2019 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", "we", "our" or the "Company"), a clinical-stage immuno-oncology company developing Biclonics®, innovative full-length human bispecific antibody therapeutics, today announced financial results for the first quarter ended March 31, 2019 and provided a business update.

"We had continued momentum in the first quarter following an active 2018," said Ton Logtenberg, Ph.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "This past month we announced the first patient treated in our fourth clinical program, MCLA-145, and presented promising pre-clinical data for the program at AACR. Merus is rapidly maturing; we are now a team of over 100 employees globally, committed to the execution of our clinical trials and the expansion of our technology. We remain on track to meet our expected milestones, and anticipate news across multiple programs by the end of 2019."

Clinical Programs and Business Update:

MCLA-128 (HER3 x HER2 Biclonics®): Phase 2 metastatic breast cancer cohort update planned for 2H 2019

The Phase 2 clinical trial evaluating MCLA-128 in combination treatments in two metastatic breast cancer ("MBC") populations continues to enroll patients in the U.S. and Europe. The Phase 2 study was initiated following data from a Phase 1/2 study in patients with MBC, where MCLA-128 was observed to be well tolerated and evidence of single-agent, antitumor activity in heavily pretreated patients was seen. Merus plans to provide an update on the Phase 2 MBC trial in the second half of 2019.

The single agent Phase 1/2 trial in solid tumors is ongoing in the non-small-cell lung cancer ("NSCLC") and gastric cancer and gastroesophageal junction cancer ("GC/GEJ") cohorts, with the GC/GEJ cohort enrollment completed. In the NSCLC cohort, an update is expected in the second half of 2019. In the gastric cancer patient population, as a next step Merus intends to explore collaboration options for potential trials in rational therapeutic combinations.

MCLA-128 is an antibody-dependent cell-mediated cytotoxicity ("ADCC") -enhanced Biclonics® that inhibits the heregulin/HER3 tumor-signaling pathway in solid tumors. MCLA-128 is believed to work with HER2-targeted therapies and to overcome the resistance of tumor cells using two mechanisms: blocking growth and survival pathways to stop tumor expansion and recruitment and enhancement of immune effector cells to eliminate the tumor.

MCLA-117 (CLEC12A x CD3 Biclonics®): Initial data from Phase 1 trial expected 2H 2019

The Phase 1 clinical trial for MCLA-117 is progressing and preliminary anti-tumor activity has been observed. Dose escalation continues steadily and carefully in order to establish the optimal therapeutic window. Merus anticipates initial data for the Phase 1 trial in the second half of 2019 and plans to provide further guidance on the program upon announcement of the maximum tolerated dose.

MCLA-117 is a Biclonics® that binds with relative low affinity to CD3, a component of the T cell receptor present on all T cells, and relative high affinity to CLEC12A, a cell surface molecule present on acute myeloid leukemia ("AML") tumor cells and AML stem cells. MCLA-117 has been shown in preclinical studies to recruit and activate T-cells to kill CLEC12A-expressing malignant cells which may prevent recurrence of the tumor, while sparing hematopoietic stem cells. MCLA-117 has a full-length IgG format with a silenced constant region, which Merus believes may contribute to safety and attractive dosing schedules for patients.

MCLA-158 (Lgr5 x EGFR Biclonics®): Emerging data from Phase 1 trial expected at end of 2019

The dose escalation of the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is ongoing. Emerging data for the Phase 1 trial is expected at the end of 2019.

On March 12, 2019, Merus presented preclinical data on MCLA-158 at the 26thInternational Molecular Med Tri-Con Conference, showing arrested tumor organoid growth ex vivo, and inhibition of primary tumor formation and metastasis in vivo. Importantly, preclinical data showed MCLA-158 activity in >60% of patient tumor organoids (15/24) regardless of RAS mutational status, which indicates that MCLA-158 has the potential to be a leading targeted colorectal cancer ("CRC") treatment to block growth of tumors with RAS mutations (present in ~50% of all CRC patients). In preclinical models, MCLA-158 demonstrated the potential ability to block metastasis, an important mechanism of action for this patient population.

MCLA-158 is an ADCC-enhanced Biclonics® that binds to cancer initiating cells expressing Lgr5 and EGFR. MCLA-158 has two different mechanisms of action. The first entails blocking of growth and survival pathways in cancer initiating cells. The second exploits the recruitment and enhancement of immune effector cells to directly kill cancer initiating cells that persist in solid tumors and can cause relapse and metastasis.

MCLA-145 (CD137 x PD-L1 Biclonics®): **First patient treated in Phase 1 clinical trial**

On May 9, 2019, it was announced that the first patient had been treated in the Phase 1 trial evaluating safety, tolerability, and preliminary efficacy of MCLA-145 for the treatment of patients with advanced solid tumors. The Phase 1, open-label, single-agent clinical trial of MCLA-145 consists of dose escalation followed by dose expansion. Primary objectives of the Phase 1 trial are dose finding, evaluation of safety and tolerability of MCLA-145 in patients with advanced solid tumors. The Phase 1 trial will also examine potential preliminary antitumor activity and functional target engagement of single-agent MCLA-145.

On March 31, 2019, Merus and Incyte Corporation ("Incyte") presented two posters at the American Association for Cancer Research (AACR) Annual Meeting outlining

preclinical data on MCLA-145. Data presented showed a potent triple action, designed to recruit and activate T cells through CD137 and prevent their exhaustion through inhibition of the PD-1 checkpoint pathway for patients with solid tumors. Because the T cell activation was shown to be context-dependent, requiring PD-L1 expression in the tumor microenvironment, MCLA-145 has the potential to overcome known side effects of CD137 agonists currently in development.

Merus is developing MCLA-145 as part of a collaboration entered into with Incyte in December 2016 to potentially develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform. Under the terms of the collaboration, Merus retains all rights to develop and commercialize MCLA-145, if approved, in the United States, while Incyte has rights to develop and commercialize MCLA-145, if approved, outside the United States.

MCLA-145 is a Biclonics® T-cell agonist that has been observed to bind to human PD-L1 and CD137 in preclinical models. Discovered through an unbiased functional screening of multiple immunomodulatory target combinations, the differentiated profile of MCLA-145 derives from its potential to attract T cells into solid tumors, potently activate immune effector cells in the context of the tumor microenvironment and simultaneously block inhibitory signals in the same immune cell population.

Expanding Merus platform technology and next generation capabilities

The Company continues to explore and identify potential novel target combinations and cutting edge technologies to advance its next generation of multi-specific antibodies. Adding to existing capabilities, Merus has developed its new proprietary Triclonics ™ technology. Triclonics ™ employ a common light chain for unforced, natural pairing with three distinct V_H regions, and is capable of simultaneously binding three different targets or epitopes with the potential for generating new biology and modes of action.

Merus U.S. office opened

In May, Merus US, Inc. opened its new U.S. office located at 139 Main Street, Cambridge, MA. The new location will now serve as Merus' US Inc.'s base of operations, and can accommodate up to 50 employees. Merus made the decision to expand into a permanent U.S. location with the goal of deepening the Company's leadership in bispecific and multispecific antibodies. The move further represents a commitment to attracting and retaining top talent in biotech worldwide.

First Quarter 2019 Financial Results

Total revenue for the three months ended March 31, 2019 was €7.7 million compared to €9.9 million for the same period in 2018. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements and R&D cost reimbursements and milestone payments for performance of research and development or manufacturing services under its various collaboration agreements. The decrease in revenue for the three months ended March 31, 2019 was primarily attributable to a €1.4 million decrease in research milestone payments earned, a €0.6 million decrease in amortization of upfront license payments and a €0.1 million decrease in R&D cost reimbursements.

Research and development costs for the three months ended March 31, 2019 were €10.4 million compared to €10.3 million for the same period in 2018. The increase in research and development costs reflects additional spending in support of the Company's clinical and preclinical development programs.

Management and administration costs for the three months ended March 31, 2019 were €1.9 million compared to €2.9 million for the same period in 2018. The decrease relates primarily to lower share-based compensation expense.

Other expenses for the three months ended March 31, 2019 were €4.0 million compared to €2.7 million for the same period in 2018. The increase in other expenses was the result of higher consulting, accounting and professional fees as well as higher facilities-related expenses.

For the three months ended March 31, 2019, Merus reported a net loss of €6.2 million, or €0.26 net loss per share (basic and diluted), compared to a net loss of €8.4 million, or €0.40 net loss per share (basic and diluted), for the same period in 2018. The net loss for the three months ended March 31, 2019 includes €2.0 million of foreign currency gains as compared to €2.8 million of foreign currency losses in the same period in 2018.

Merus ended the first quarter of 2019 with cash, cash equivalents and investments of €195.3 million compared to €205.5 million at December 31, 2018. The decrease was primarily the result of cash used in operations and purchases of property, plant and equipment, partially offset by investment maturities and interest received.

Financial Outlook

Based on the Company's current operating plan, Merus expects that its existing cash, cash equivalents and investments will be sufficient to fund its operations into the second quarter of 2021.

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 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 is currently 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 MCLA-145, designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. For additional information, please visit Merus' website, www.merus.nl.

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 the sufficiency of our cash, cash equivalents and investments, our rapid maturation of the Company, the design and execution of our clinical trials and technology, the content and timing of potential milestones described in this press release, the timing of updates, guidance, information, clinical trials, their enrollment, and data readouts for our product candidates, the design and treatment potential of our bispecific antibody candidates, our exploration of collaboration options for potential combination trials in rational therapeutic combinations with MCLA-128 for gastric cancer, the potential contributions of MCLA-117's full length IgG format with a silenced constant region to safety and an attractive dosing schedule, preclinical data for MCLA-158, which indicates its potential to be a leading targeted CRC treatment to block growth of tumors with RAS mutations and to block metastasis, the characteristics and immunostimulatory profile of MCLA-145, and this profile having a potential of MCLA-145 to overcome known side effects of CD137 agonists, the continuing collaboration with Incyte on MCLA-145's global development, and potential to develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform, whether any of the programs under the collaboration will be successful, including for MCLA-145, our **exploration and identification of potential novel target combinations and cutting edge technologies to advance our next generation of multi-specific antibodies**, Triclonics™ technology's potential to identify new biology and modes of action and simultaneously bind three different targets or epitopes, the permanent nature of the U.S. location, the goal of deepening the Company's leadership in bispecific and multispecific antibodies, and our ability and commitment to attract and retain top talent in biotech worldwide. 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 or any of our other collaborators may fail to perform adequately under our collaborations with them; 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”), on April 3, 2019, 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.

Unaudited Condensed Consolidated Statement of Financial Position

	March 31, 2019	December 31, 2018
	(euros in thousands)	
Non-current assets		
Property, plant and equipment, net	2,512	2,420
Lease right-of-use assets	2,596	-
Intangible assets, net	2,398	2,445
Non-current investments	13,752	16,945
Other assets	649	1,075
	21,907	22,885
Current assets		
Taxes and social security assets	675	-
Trade and other receivables	8,282	7,032
Current investments	41,834	44,855
Cash and cash equivalents	139,705	143,747
	190,496	195,634
Total assets	212,403	218,519
Shareholders’ equity		
Issued and paid-in capital	2,104	2,102
Share premium account	264,877	264,854
Accumulated loss	(180,014)	(175,085)
Total shareholders’ equity	86,967	91,871
Non-current liabilities		
Deferred revenue, net of current portion	93,853	97,675
Other liabilities	1,799	-
	95,652	97,675
Current liabilities		
Trade payables	3,602	3,819
Taxes and social security liabilities	69	256
Deferred revenue	17,326	16,934
Other liabilities and accruals	8,787	7,964
	29,784	28,973
Total liabilities	125,436	126,648
Total shareholders’ equity and liabilities	212,403	218,519

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three-months ended March 31, 2019	2018
	(euros in thousands, except per share data)	
Revenue	7,702	9,921

Research and development costs	(10,371	)	(10,298	)
Management and administration costs	(1,936	)	(2,852	)
Other expenses	(4,004	)	(2,686	)
Total operating expenses	(16,311	)	(15,836	)
Operating result	(8,609	)	(5,915	)
Finance income	2,506		340	
Finance cost	(35	)	(2,806	)
Other income (expense)	2,471		(2,466	)
Result before taxation	(6,138	)	(8,381	)
Income tax expense	(66	)	(52	)
Result after taxation	(6,204	)	(8,433	)
Other comprehensive income				
Exchange differences from the translation of foreign operations	23		(15	)
Total other comprehensive income for the period	23		(15	)
Total comprehensive loss for the period	(6,181	)	(8,448	)
Loss per share - basic and diluted*	(0.26	)	(0.40	)
Weighted average shares outstanding - basic and diluted*	23,373,054		20,984,663	

* For the periods included in these financial statements, share options were excluded from the diluted loss per share calculation as the Company was in a loss position in each period presented above. As a result, basic and diluted loss per share are equal.

Investor and Media Inquiries:

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

Source: Merus N.V.