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

August 19, 2019

UTRECHT, The Netherlands, Aug. 19, 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 second quarter ended June 30, 2019 and provided a business update.

"We have made good progress with our clinical programs in the second quarter and have achieved further clarity with our clinical trial plans," said Ton Logtenberg, Ph.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "Patient enrollment for our MCLA-158 and MCLA-145 Phase 1 trials is on track. Importantly, we amended the MCLA-117 T-cell engager trial to allow us to explore higher doses, and we re-focused our MCLA-128 Phase 1/2 monotherapy trial on a subpopulation of patients with solid tumors harboring NRG1 gene fusions. We plan to report on our Phase 2 MCLA-128 MBC trial in the fourth quarter. Additionally, our collaborator Ono Pharmaceutical announced the submission of an IND for a bispecific CD3 x PD-1 antibody for autoimmune diseases."

Clinical Programs and Business Update:

MCLA-128 (HER3 x HER2 Biclonics®): Phase 2 metastatic breast cancer cohort update planned for 4Q 2019; Phase 1/2 single agent trial amended to focus on solid tumors harboring Neuregulin 1 (NRG1) gene fusions.

The Phase 2 clinical trial evaluating MCLA-128 in combination treatments in two metastatic breast cancer ("MBC") populations is ongoing. Merus will provide an update which will include data from both cohorts in the fourth quarter of 2019.

In August, Merus amended the single agent Phase 1/2 trial in solid tumors to focus solely on the exploration of MCLA-128 in solid tumors harboring NRG1 fusions. The amended global study will evaluate the activity of MCLA-128 in three cohorts, each aiming to treat patients harboring an NRG1 fusion: patients with non-small cell lung cancer (NSCLC), patients with pancreatic cancer and patients with any other solid tumor (basket cohort). The current amendment follows on an effort in the ongoing Phase 1/2 study which sought to identify a sub-population of patients with NSCLC harboring NRG1 fusions. More information will be provided by the end of 2019. Details of the trial can be found at ClinicalTrials.gov.

The NRG1 gene encodes for neuregulin (also known as heregulin), the ligand to HER3. Fusions between NRG1 and partner genes are rare, tumorigenic genomic events occurring in patients with certain lung and other cancers, associated with activation of HER2/HER3 heterodimers and growth of cancer cells. In preclinical studies, Merus has observed that MCLA-128 is capable of potent inhibition of heregulin-driven HER2/HER3 heterodimer formation, resulting in blocking of tumor cell growth in models harboring NRG1 fusions.

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®): Expect to present initial Phase 1 data at a medical conference 1H 2020.

Dose escalation for the Phase 1 clinical trial for MCLA-117 continues and preliminary anti-tumor activity has been observed. In July, Merus amended the MCLA-117 protocol to allow for the exploration of higher doses. The Phase 1 trial initiated at a low dose level based on the potent nature of T-cell engagers. Due to this amendment and continued dose escalation, Merus now plans to present initial data at a medical conference in the first half of 2020.

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, which will include safety and information around the recommended Phase 2 dose, is expected at the end of 2019. Merus plans to provide further guidance on the program in 2020.

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®): **Phase 1 clinical trial progressing as planned**

The Phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing and consists of dose escalation followed by dose expansion. Preclinical data has shown 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 demonstrated 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.

Milestone payment earned in collaboration with Ono Pharmaceutical

In July 2019, Merus earned a milestone payment from Ono Pharmaceutical Co., Ltd. ("Ono") under its research and license agreement with Ono on the development of human bispecific antibodies. The milestone was achieved upon Ono's submission of the Investigational New Drug ("j-IND") for ONO-4685, a PD-1 x CD3 bispecific antibody, to the Ministry of Health, Labour and Welfare in Japan. In April 2014, Merus and Ono entered into a research and license agreement to develop bispecific antibody therapies for autoimmune diseases. ONO-4685 is the clinical candidate that emerged from that agreement. In March 2018, Ono exercised its option for a research and license agreement for a second bispecific antibody program for autoimmune diseases.

Under the terms of the agreement with Ono, Merus is eligible to receive milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under the agreements, if any, Merus is also eligible to receive a mid-single digit royalty on net sales.

Second Quarter 2019 Financial Results

Total revenue for the three months ended June 30, 2019 was €5.6 million compared to €6.5 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 June 30, 2019 was primarily attributable to a €0.7 million decrease in R&D cost reimbursements and a €0.1 million decrease in research milestone payments earned.

Research and development costs for the three months ended June 30, 2019 were €10.0 million compared to €12.5 million for the same period in 2018. The decrease in research and development costs reflects a decrease in manufacturing costs and lower research and development-related costs.

Management and administration costs for the three months ended June 30, 2019 were €3.1 million compared to €2.6 million for the same period in 2018. The increase relates primarily to higher personnel-related expenses.

Other expenses for the three months ended June 30, 2019 were €3.7 million compared to €3.3 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 June 30, 2019, Merus reported a net loss of €12.0 million, or €0.51 net loss per share (basic and diluted), compared to a net loss of €4.6 million, or €0.20 net loss per share (basic and diluted), for the same period in 2018. The net loss for the three months ended June 30, 2019 includes €1.1 million of foreign currency losses as compared to €6.9 million of foreign currency gains in the same period in 2018.

Merus ended the second quarter of 2019 with cash, cash equivalents and investments of €179.9 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.

Unaudited Condensed Consolidated Statement of Financial Position

	June 30, 2019	December 31, 2018
	(euros in thousands)	
Non-current assets		
Property, plant and equipment, net	2,585	2,420
Lease right-of-use assets	6,069	-
Intangible assets, net	2,351	2,445
Non-current investments	12,319	16,945
Other assets	742	1,075
	24,066	22,885
Current assets		
Taxes and social security assets	978	-
Trade and other receivables	8,295	7,032
Current investments	35,560	44,855
Cash and cash equivalents	131,993	143,747
	176,826	195,634
Total assets	200,892	218,519
Shareholders' equity		
Issued and paid-in capital	2,105	2,102
Share premium account	264,878	264,854
Accumulated loss	(190,214)	(175,085)
Total shareholders' equity	76,769	91,871
Non-current liabilities		

Deferred revenue, net of current portion	89,666	97,675
Other liabilities	4,705	-
	94,371	97,675
Current liabilities		
Trade payables	2,666	3,819
Taxes and social security liabilities	128	256
Deferred revenue	17,208	16,934
Other liabilities and accruals	9,750	7,964
	29,752	28,973
Total liabilities	124,123	126,648
Total shareholders' equity and liabilities	200,892	218,519

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(euros in thousands, except per share data)			
Revenue	5,579	6,543	13,281	16,464
Research and development costs	(9,984)	(12,523)	(20,355)	(22,821)
Management and administration costs	(3,119)	(2,639)	(5,055)	(5,491)
Other expenses	(3,743)	(3,297)	(7,747)	(5,983)
Total operating expenses	(16,846)	(18,459)	(33,157)	(34,295)
Operating result	(11,267)	(11,916)	(19,876)	(17,831)
Finance income	476	7,411	1,899	4,945
Finance cost	(1,144)	(1)	(96)	(1)
Other income (expense)	(668)	7,410	1,803	4,944
Result before taxation	(11,935)	(4,506)	(18,073)	(12,887)
Income tax expense	(54)	(87)	(120)	(139)
Result after taxation	(11,989)	(4,593)	(18,193)	(13,026)
Other comprehensive income				
Exchange differences from the translation of foreign operations	(17)	36	6	21
Total other comprehensive income for the period	(17)	36	6	21
Total comprehensive loss for the period	(12,006)	(4,557)	(18,187)	(13,005)
Loss per share - basic and diluted*	(0.51)	(0.20)	(0.78)	(0.60)
Weighted average shares outstanding - basic and diluted*	23,387,841	22,628,611	23,380,488	21,809,950

* 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.

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. 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, the design, execution and progress of our clinical trials and technology, the content and timing of potential milestones described in this press release, the timing of updates, guidance and information of clinical trials, their future enrollment, and data readouts for our product candidates, the design and treatment potential of our bispecific antibody candidates, the enrollment of the amended study evaluating the activity of MCLA-128 in three cohorts: patients with NSCLC, patients with pancreatic cancer and patients with any other solid tumor (basket cohort), and the aim to treat such patients harboring an active NRG1 fusion, the capability of MCLA-128 to potently inhibit heregulin-driven HER2/HER3 heterodimer formation, resulting in blocking of tumor cell growth in patients harboring NRG1

fusions, the amendment and continued dose escalation of MCLA-117, its impact on Merus' plans to explore higher dosing and to present initial data at a medical conference in the 1H 2020, the full-length IgG format with a silenced constant region for MCLA-117 contributing to safety and attractive dosing for patients, Merus' plan to report at the end of 2019 emerging data for the Phase 1 trial, which will include safety and information around the recommended Phase 2 dose, Merus' plans to provide further guidance on the program in 2020, 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, the potential advancement of ONO-4685 post j-IND filing in clinical development, and Merus' eligibility to receive any further milestone payments from Ono upon achievement of future specified research and clinical development milestones and eligibility to receive a mid-single digit royalty on any potential future net sales. 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 any of our other collaborators, 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.

Biclonics® is a registered trademark of Merus N.V.

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