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

November 12, 2019

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", "we", "our" or the "Company"), a clinical-stage company developing innovative, full-length bispecific antibodies (Biclonics®), today announced financial results for the third quarter ended September 30, 2019 and provided a business update.

"We are very encouraged by the recently reported early responses in patients treated with MCLA-128 whose tumor cells harbor an NRG1 fusion, a rare oncogenic driver, and believe the data offer further clinical validation of our Biclonics® platform," said Ton Logtenberg, Ph.D., President and Chief Executive Officer of Merus. "We remain focused on our plans to identify and recruit patients who may be amenable to MCLA-128 therapy, and to execute on all of our pipeline programs. We expect to provide additional meaningful clinical program updates in 2020."

Clinical Programs and Business Update:

MCLA-128 (HER3 x HER2* Biclonics®*): Early clinical activity presented in patients with pancreatic and lung cancers harboring NRG1 fusions; more mature data expected to be presented at a medical conference by end of 2020

On October 27, 2019, investigators from the Memorial Sloan Kettering Cancer Center presented early clinical activity of MCLA-128 ("zenocutuzumab", "zeno") in three patients with cancers harboring NRG1 fusions; Merus also disclosed information on six additional patients with cancers harboring an NRG1 fusion treated with MCLA-128.

Of the aggregate nine NRG1 fusion patients who have been treated with MCLA-128 across the clinical trial and early access program, three were diagnosed with pancreatic ductal adenocarcinoma cancer (PDAC) and six with non-small cell lung cancer (NSCLC). All patients had previously progressed through standard of care and were identified through various diagnostic methods and investigator sites.

- Three patients (two PDAC, one NSCLC) treated with MCLA-128 with data presented by Memorial Sloan Kettering investigators responded with significant tumor shrinkage and symptomatic improvement and all currently remain on drug. As of October 27, 2019:
  - Two patients (one PDAC, one NSCLC) showed a partial response by RECIST 1.1 criteria.
  - One PDAC patient showed a stable disease by RECIST 1.1 criteria.
  - The two PDAC patients had been on treatment for greater than 7 months and the NSCLC patient for approximately 5 months; each remain on treatment.
- Six additional patients with NRG1 fusions (one PDAC and five NSCLC) treated with MCLA-128 included:
  - One NSCLC patient had a stable disease with duration of 7 months before discontinuing due to poor adherence to treatment protocol (unrelated any adverse event or lack of efficacy).
  - One PDAC patient with a very advanced stage of disease was treated while in hospice care. MCLA-128 treatment was used as a last resort. The drug could not be delivered as intended and the patient passed away due to severe complications of the underlying disease prior to a first tumor evaluation.
  - Two NSCLC patients were in an advanced, rapidly progressive disease stage entering into MCLA-128 treatment and rapidly progressed.
  - Two NSCLC patients were recently enrolled and are too early on MCLA-128 treatment to be evaluated.

Merus plans to report on interim data from patients whose cancer cells harbor NRG1 fusions at a medical conference by the end of 2020, when more mature data, better characterization of the patient population and activity of MCLA-128 in a larger set of patients are expected to be available. Details of the eNRGy trial evaluating MCLA-128 in patients with NRG1 fusions, including current trial sites, can be found at ClinicalTrials.gov and Merus' trial website at nrg1.com.

MCLA-128 (HER3 x HER2* Biclonics®*): Phase 2 Metastatic Breast Cancer interim analysis reported

In the Phase 2 Metastatic Breast Cancer trial, in patients enrolled as of August 31, 2019, Merus conducted an unplanned interim efficacy analysis with a data cut-off of October 23, 2019. The company expects to present mature results, including the primary endpoint of clinical benefit rate at 24 weeks for both cohorts at a medical conference in 2020. Following the planned completion of the Phase 2 Metastatic Breast Cancer Trial, Merus will only advance development in metastatic breast cancer or gastric cancer with a collaborator. Merus intends to focus MCLA-128 program efforts on the eNRGy trial going forward.

MCLA-117 (CLEC12A x CD3* Biclonics®*): Expect to present initial Phase 1 data at a medical conference 1H 2020

Merus remains on track to present initial data at a medical conference in the first half of 2020. In July 2019, 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. Preliminary anti-tumor activity was reported in December 2018 and dose escalation for the Phase 1 clinical trial for MCLA-117 continues.

MCLA-158 (Lgr5 x EGFR* Biclonics®*): Initial safety data from Phase 1 trial expected at end of 2019, further guidance in 2020

The dose escalation of the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is progressing as planned. 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-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 demonstrated that 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 with Incyte signed in December 2016 to potentially develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform.

MCLA-129 (EGFR x c-MET* Biclonics®*): Pre-clinical data presented at medical conference October 2019

On October 29, 2019, Merus presented pre-clinical data for the first time at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. MCLA-129 is an antibody-dependent cell-mediated cytotoxicity ("ADCC") -enhanced Biclonics® that inhibits the EGFR and c-MET signaling pathways in solid tumors. Preclinical data has shown that MCLA-129 reverses resistance to tyrosine kinase resistant non-small cell lung cancer (NSCLC) cell lines resulting in tumor growth inhibition in xenograft models of NSCLC. MCLA-129 is being developed in collaboration with Betta Pharmaceuticals ("Betta"), and is currently in IND-enabling studies. Under the collaboration entered into in December 2018, Merus granted an exclusive license to Betta to develop and commercialize MCLA-129 in China and Merus has retained all rights outside of China.

Third Quarter 2019 Financial Results

Total revenue for the three months ended September 30, 2019 was €8.1 million compared to €6.5 million for the same period in 2018. Revenue is comprised primarily of the amortization of upfront license payments, R&D cost reimbursements, milestone payments for performance of R&D, and manufacturing services under our various collaboration agreements. The €1.6 million increase in revenue for the three months ended September 30, 2019 was primarily attributable to milestone revenue related to our license agreement with Ono.

Research and development costs for the three months ended September 30, 2019 were €12.8 million compared to €11.9 million for the same period in 2018. The increase in research and development costs reflects an increase in personnel-related costs and higher preclinical research and development-related costs.

Management and administration costs for the three months ended September 30, 2019 were €2.9 million compared to €2.7 million for the same period in 2018. The increase relates primarily to higher personnel-related expenses.

Other expenses for the three months ended September 30, 2019 were €4.4 million compared to €3.9 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 September 30, 2019, Merus reported a net loss of €8.3 million, or €0.35 net loss per share (basic and diluted), compared to a net loss of €10.7 million, or €0.47 net loss per share (basic and diluted), for the same period in 2018. The net loss for the three months ended September 30, 2019 includes €3.1 million of foreign currency gains as compared to €0.9 million of foreign currency gains in the same period in 2018.

Merus ended the third quarter of 2019 with cash, cash equivalents and investments of €168.1 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, effects of exchange rate changes 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 2022. The Company's outlook has been updated given the recent equity financing in November 2019 which provided gross proceeds of $79.2 million.

Unaudited Condensed Consolidated Statement of Financial Position

	September 30, 2019	December 31, 2018
	(euros in thousands)	
Non-current assets		
Property, plant and equipment, net	**3,422**	2,420
Lease right-of-use assets	**5,843**	-
Intangible assets, net	**2,304**	2,445
Non-current investments	**10,609**	16,945
Other assets	**942**	1,075
	23,120	22,885
Current assets		
Trade and other receivables	**9,218**	7,032
Current investments	**34,045**	44,855
Cash and cash equivalents	**123,480**	143,747
	166,743	195,634
Total assets	**189,863**	218,519
Shareholders' equity		
Common share capital	**2,107**	2,102
Common share premium	**264,892**	264,854
Accumulated loss	**(196,624)**	(175,085)
Total shareholders' equity	**70,375**	91,871
Non-current liabilities		
Deferred revenue, net of current portion	**85,361**	97,675
Other liabilities	**4,463**	-

	89,824	97,675
Current liabilities		
Trade payables	**2,452**	3,819
Taxes and social security liabilities	**183**	256
Deferred revenue	**17,163**	16,934
Other liabilities and accruals	**9,866**	7,964
	29,664	28,973
Total liabilities	**119,488**	126,648
Total shareholders' equity and liabilities	**189,863**	218,519

Unaudited Condensed Consolidated Statement of Operations

	Three months ended September 30,		**Nine months ended September 30,**	
	2019	**2018**	**2019**	**2018**
	(euros in thousands, except per share data)			
Revenue	**8,115**	6,514	**21,396**	22,978
Research and development costs	**(12,814)**	(11,896)	**(33,169)**	(34,717)
Management and administration costs	**(2,852)**	(2,658)	**(7,907)**	(8,149)
Other expenses	**(4,360)**	(3,949)	**(12,107)**	(9,932)
Total operating expenses	**(20,026)**	(18,503)	**(53,183)**	(52,798)
Operating result	**(11,911)**	(11,989)	**(31,787)**	(29,820)
Finance income	**3,482**	1,369	**5,381**	6,314
Other income	**175**	-	**175**	-
Finance cost	**(71)**	(3)	**(167)**	(4)
Other income (expense)	**3,586**	1,366	**5,389**	6,310
Result before taxation	**(8,325)**	(10,623)	**(26,398)**	(23,510)
Income tax expense	**1**	(67)	**(119)**	(206)
Result after taxation	**(8,324)**	(10,690)	**(26,517)**	(23,716)
Other comprehensive income				
Exchange differences from the translation of foreign operations	**64**	5	**70**	26
Total other comprehensive income for the period	**64**	5	**70**	26
Total comprehensive loss for the period	**(8,260)**	(10,685)	**(26,447)**	(23,690)
Loss per share - basic and diluted *	**(0.35)**	(0.47)	**(1.13)**	(1.07)
Weighted average shares outstanding - basic and diluted *	**23,402,887**	22,687,034	**23,388,036**	22,105,524

*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® 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.

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 belief regarding the early clinical data and its impact on the clinical validation of our Biclonics® platform, our plans to identify and recruit patients who may be amenable to MCLA-128 therapy and to execute on all of our pipeline programs, our clinical development plans for MCLA-128 including plans to only advance development in metastatic breast cancer or gastric cancer with a collaborator, the intent to focus MCLA-128 program efforts on the eNRGy trial going forward, the timing of clinical trial results, 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, including future availability of more mature data, better characterization of the patient population and activity of MCLA-128 in a larger set of patients, the design and treatment potential of our bispecific antibody candidates, 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 first half of 2020, the dose escalation of the Phase 1 clinical trial of MCLA-158 and its progress as planned, Merus' plan to report at the end of 2019 emerging data for the Phase 1 trial, including 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 currently in development, 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 characteristics of MCLA-129, and potential to be developed in collaboration with Betta, its progress in IND-enabling studies, whether Betta will be successful in developing and commercializing MCLA-129 in China or by Merus outside of China. 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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