Merus Announces Financial Results for the Third Quarter 2018 and Provides Business Update

December 27, 2018

Clinical milestones for four lead Biclonics® programs expected in 2019
Cash expected to be sufficient to fund operations into the second quarter of 2021

UTRECHT, The Netherlands, Dec. 27, 2018 (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 third quarter ended September 30, 2018 and provided a business update.

"I am pleased to report progress on several fronts," said Ton Logtenberg, Ph.D., President and Chief Executive Officer of Merus. "We have continued to make advancements in each of our clinical programs and are moving closer to bringing novel treatments to oncology patients. Dose escalation in the MCLA-117 trial is progressing, and encouraging data from MCLA-128 has helped to form our long-term plans for the program. Ongoing work within our Biclonics® platform gives us confidence that we will continue to produce differentiated, best-in-class bispecific antibody programs. Looking ahead, 2019 will be an important year for Merus as we anticipate reaching several potential milestones and begin to unveil more details within our pipeline."

Clinical Programs and Business Update:

MCLA-128: *Antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® binding to HER2 and HER3-expressing tumor cells for the treatment of solid tumors*

Metastatic breast cancer: The Phase 2, open-label, multicenter international clinical trial evaluating MCLA-128 in combination treatments in two metastatic breast cancer (mBC) populations continues to enroll HER2-positive patients and hormone receptor positive/HER2-low patients at sites in the United States (U.S.) and Europe. Merus plans to provide an update on the trial in the second half of 2019.

MCLA-128 data presented at scientific conference: In October 2018, Merus presented a poster at the European Society for Medical Oncology (ESMO) Congressoutlining overall safety data as well as preliminary activity data in the gastric cancer (GC) patient cohort of the Phase 2 portion our Phase 1/2 study of MCLA-128. In the 97 patients treated with MCLA-128 across all indications explored in the study, MCLA-128 was well tolerated and showed a low risk of immunogenicity. The MCLA-128 poster can be accessed on the Merus website through the link here.

Gastric: In GC patients, evidence of activity of single agent MCLA-128 was shown in heavily pretreated HER2-positive metastatic GC/gastro-esophageal junction (GEJ) cancer patients progressing on 1 to 3 prior anti-HER2-targeted therapies. Based on this data, the company believes MCLA-128 warrants further evaluation in rational therapeutic combinations in the GC/GEJ cancer patient population. Merus is evaluating options and timing for potential combination trials in GC.

NSCLC, Endometrial and Ovarian: Enrollment in the non-small cell lung cancer (NSCLC) cohort is ongoing. In endometrial and ovarian patient populations, although activity has been observed, Merus has made a strategic decision to discontinue further development alone or in combination in order to dedicate resources to other programs.

MCLA-128 is an ADCC-enhanced Biclonics® designed to address HER3-expressing solid tumor cells. MCLA-128 employs a unique mechanism, DOCK & BLOCK®, to bind to HER2 and HER3-expressing solid tumor cells (DOCK) *for the selective and potent inhibition of the heregulin/HER3 tumor-signaling pathway (BLOCK). MCLA-128 is designed to overcome the inherent and acquired 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.*

MCLA-117*: Biclonics® binding to CD3 and CLEC12A for the treatment of Acute Myeloid Leukemia (AML)*

The Phase 1 clinical trial for MCLA-117 continues in Europe and the U.S., with several additional trial sites recently opened. The trial is progressing as planned and preliminary anti-tumor activity has been observed in the most recent cohort completed. Dose escalation continues steadily and carefully in order to establish the optimal therapeutic window. Merus plans to provide further guidance on the program upon announcement of the maximum tolerated dose (MTD) and anticipates data readouts for the Phase 1 trial in the second half of 2019.

The Phase 1 trial is a single-arm, open-label, global study to assess the safety, tolerability and anti-tumor activity of MCLA-117. The first phase of the MCLA-117 study is designed as a dose escalation study, followed by a second safety dose expansion phase. The initial dose of the trial was determined using minimal anticipated biological effect level (MABEL) dose escalation requirements, and careful dose escalation is being explored due to the inherent potent activity of T-cell engagers. The primary endpoint is safety and tolerability; secondary endpoints include pharmacokinetic measures, anti-tumor response and clinical benefit.

MCLA-117 is a Biclonics® that binds to CD3, a cell-surface molecule present on all T cells, and CLEC12A, a cell surface molecule present on AML tumor cells and AML stem cells. MCLA-117 is designed to recruit and activate T-cells to kill CLEC12A-expressing malignant cells which may prevent recurrence of the tumor. MCLA-117 has a full-length IgG format with a silenced constant region, which Merus believes may contribute to safety and more predictability during manufacturing and upon injection in patients.

MCLA-158*: An ADCC-enhanced Biclonics® binding to cancer initiating cells expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor (EGFR) for the treatment of solid tumors.*

The Phase 1, open-label, multicenter clinical trial in patients with solid tumors is ongoing and progressing as planned. The trial is being conducted in Europeand the U.S. The initial indication is in metastatic colorectal cancer with additional solid tumors under consideration. Emerging data for the Phase 1 trial is expected at the end of 2019.

MCLA-158 is an ADCC-enhanced Biclonics® that binds to cancer initiating cells expressing Lgr5 and EGFR. MCLA-158 is designed to use 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 cause relapse and metastasis.

***MCLA-145**: Biclonics® binding to PD-L1 and an undisclosed immunomodulatory target*

MCLA-145 continues to progress as planned in Investigational New Drug (IND)-enabling studies. MCLA-145 is the first of up to 11 bispecific antibody programs under the Merus and Incyte global research collaboration. MCLA-145 originated from the Merus platform prior to the agreement. Merus has full rights to develop and commercialize MCLA-145 in the U.S. Further information on MCLA-145 will be provided upon IND acceptance.

MCLA-145 is a Biclonics® that is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target.

Third Quarter 2018 Financial Results

Merus ended the third quarter of 2018 with cash, cash equivalents and investments of €209.9 million compared to €190.8 million at December 31, 2017. The increase was primarily the result of the closing of a $55.8 million (€44.8 million) private placement of approximately 3.1 million common shares completed in February 2018.

Total revenue for the three months ended September 30, 2018 was €6.5 million compared to €5.7 million for the same period in 2017. Revenue for the three months ended September 30, 2017 has been restated for the adoption of IFRS 15, a new accounting standard related to revenue recognition. Under IFRS 15, Merus reduced the period that it amortizes revenue for the upfront license payment received from Incyte from 21 years to 9 years, which resulted in €2.3 million of additional revenue for the three months ended September 30, 2017. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements, and cost reimbursements and research milestones for performance of research and development services under the respective agreements. The increase in revenue for the period is attributable to €0.5 million of amortization of upfront license payments and milestone payments and €0.3 million of collaboration income for expense reimbursements.

Research and development costs for the three months ended September 30, 2018 were €11.9 million compared to €8.0 million for the same period in 2017. The increase in research and development costs reflects the increase in manufacturing costs as well as additional spending in support of the Company's clinical and preclinical development programs.

Management and administration costs for the three months ended September 30, 2018 were €2.7 million compared to €3.6 million for the same period in 2017. The decrease relates primarily to lower share-based compensation expenses.

Other expenses for the three months ended September 30, 2018 were €3.9 million compared to €2.2 million for the same period in 2017. 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, 2018, Merus reported a net loss of €10.7 million, or €0.47 net loss per share (basic and diluted), compared to a net loss of €13.4 million, or €0.69 net loss per share (basic and diluted), for the same period in 2017. Net loss for the three months ended September 30, 2017 has been restated for the adoption of IFRS 15 which resulted in a reduction of net loss of €2.3 million or €0.12 per share (basic and diluted). The net loss for the three months ended September 30, 2018 includes approximately €0.9 million of unrealized foreign currency gains as compared to €5.5 million of unrealized foreign currency losses in the same period 2017.

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. The extended cash runway is primarily due to proceeds received from the $15 million investment by Regeneron Pharmaceuticals as part of a litigation settlement, the re-prioritization of MCLA-128 spending and expected efficiencies in CMC related expenses.

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 ability to produce differentiated, best-in-class bispecific antibody programs, the importance of 2019 for our company, including potential milestones and unveiling details about our pipeline, MCLA-128 warranting further evaluation in rational therapeutic combinations in the GC/GEJ patient population, the timing of updates, guidance, information and data readouts for our product candidates, the design and treatment potential of our bispecific antibody candidates, clinical study design, and the potential contributions of MCLA-117's full length IgG format with a silenced constant region to safety and predictability . 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 Incytemay 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 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.

Unaudited Condensed Consolidated Statement of Financial Position

	September 30, 2018	December 31, 2017 Restated*
	(euros in thousands)	
Non-current assets		
Property, plant and equipment	1,960	1,168
Intangible assets, net	2,390	312
Non-current investments	16,764	7,060
Other assets	955	129
	22,069	8,669
Current assets		
Trade and other receivables	9,505	4,413
Current investments	50,233	34,043
Cash and cash equivalents	142,867	149,678
	202,605	188,134
Total assets	224,674	196,803
Shareholders’ equity		
Issued and paid-in capital	2,046	1,749
Share premium account	258,757	213,618
Accumulated loss	(175,877)	(158,775)
Total shareholders’ equity	84,926	56,592
Non-current liabilities		
Deferred revenue, net of current portion	101,501	112,551
Current liabilities		
Trade payables	7,188	2,855
Taxes and social security liabilities	194	243
Deferred revenue	17,362	15,935
Other liabilities and accruals	13,503	8,627
	38,247	27,660
Total liabilities	139,748	140,211
Total shareholders’ equity and liabilities	224,674	196,803

* Accumulated loss and deferred revenue (current and non-current) have been restated for the impact of the adoption of IFRS 15, an accounting standard related to revenue recognition, by decreasing accumulated loss and net deferred revenue by a total of €8.7 million at December 31, 2017.

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three-months ended September 30,		Nine-months ended September 30,	
	2018	2017 Restated**	2018	2017 Restated**

	(euros in thousands, except per share data)			
Revenue	6,514	5,724	22,978	15,845
Research and development costs	(11,896)	(8,040)	(34,717)	(23,075)
Management and administration costs	(2,658)	(3,634)	(8,149)	(11,432)
Other expenses	(3,949)	(2,180)	(9,932)	(6,588)
Total operating expenses	(18,503)	(13,854)	(52,798)	(41,095)
Operating result	(11,989)	(8,130)	(29,820)	(25,250)
Finance income	1,369	254	6,314	864
Finance cost	(3)	(5,519)	(4)	(28,215)
Net finance income (expense)	1,366	(5,265)	6,310	(27,351)
Result before taxation	(10,623)	(13,395)	(23,510)	(52,601)
Income tax expense	(67)	(64)	(206)	(181)
Result after taxation	(10,690)	(13,459)	(23,716)	(52,782)
Other comprehensive income				
Exchange differences from the translation of foreign operations	5	33	26	51
Total other comprehensive income for the period	5	33	26	51
Total comprehensive loss for the period	(10,685)	(13,426	(23,690)	(52,731)
Loss per share - basic and diluted*	(0.47)	(0.69	(1.07)	(2.76)
Weighted average shares outstanding - basic and diluted*	22,687,034	19,402,667	22,105,524	19,120,081

* 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.

** Revenue for the three and nine months ended September 30, 2017 has been restated to reflect additional revenue of €2.3 million, or €0.12 per share, and €6.1 million, or €0.32 per share, respectively, related to the amortization of the up-front license payment received from Incyte due to the impact of the adoption of IFRS 15, an accounting standard related to revenue recognition.

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