Merus Announces Third Quarter 2017 Financial Results and Clinical Highlights

November 30, 2017

UTRECHT, The Netherlands, Nov. 30, 2017 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced financial results for the third quarter ended September 30, 2017 and provided a clinical update.

“Merus continues to make meaningful advances with both our proprietary pipeline, led by MCLA-128, and our various collaboration programs,” said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. “We look forward to several milestones over the balance of the year, including our plan to initiate a Phase 2 clinical trial of MCLA-128 in combination with other therapies in HER2 positive and ER+/HER2 low metastatic breast cancer and plan to file a Clinical Trial Application (“CTA”) for a first-in-human clinical trial of MCLA-158 in patients with colorectal cancer. Our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric, ovarian, endometrial and non-small cell lung (NSCL) cancers is ongoing and we anticipate defining the clinical plan for MCLA-128 for additional solid tumors in early 2018. Also in 2018, we intend to continue to advance MCLA-117 in the clinic for acute myeloid leukemia (AML) and progress MCLA-145, being developed in collaboration with Incyte.”

“We are committed to unlocking the full potential of our Biclonics ®-based bispecific antibody platform, and we anticipate 2018 will be an important year for advancing multiple programs in the clinic,” added Dr. Logtenberg.

Upcoming Milestones

MCLA-128, an enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) Biclonics® that binds to HER2 and HER3-expressing solid tumor cells

Merus intends to initiate a Phase 2 clinical trial of MCLA-128 in combination with other therapies in HER2 positive and ER+/HER2 low metastatic breast cancer by the end of 2017. In early 2018, Merus expects to formulate its clinical development plans in gastric, ovarian, endometrial and NSCL cancers based on a data readout from its ongoing Phase 1/2 clinical trial.

MCLA-117, a Biclonics® that binds to CD3 and CLEC12A

Merus is continuing its dose escalation of the Phase 1 clinical trial for MCLA-117 in Europe, and expects to submit an Investigational New Drug application to the U.S. Food and Drug Administration in the first half of 2018.

MCLA-158, an ADCC-enhanced Biclonics® designed to bind to cancer stem cells expressing Lgr5 and EGFR

Merus expects to file a CTA for a first-in-human clinical trial of MCLA-158 in patients with colorectal cancer by the end of 2017.

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

Merus and Incyte are conducting an IND-enabling study for MCLA-145, the first drug candidate co-developed under their global research collaboration. Merus has full rights to develop and commercialize MCLA-145 in the United States and Incyte is responsible for its development and commercialization outside the United States.

Third Quarter 2017 Financial Results

Merus ended the third quarter of 2017 with cash and cash equivalents of €202.4 million compared to €56.9 million at December 31, 2016.

Total revenue for the three months ended September 30, 2017 was €3.5 million compared to €1.2 million for the same period in 2016. Revenue is comprised primarily of cost reimbursements, amortization of the Incyte upfront license payment, research funding and income from grants on research projects.

Research and development costs for the three months ended September 30, 2017 were €8.0 million compared to €4.1 million for the same period in 2016. The increase in research and development costs reflects higher enrollment in our clinical trials and expansion of research efforts to support our internal programs and collaboration with Incyte.

For the three months ended September 30, 2017, Merus reported a net loss of €15.7 million, or a loss of €0.81 per basic and diluted share, compared to a net loss of €4.9 million, or a loss of €0.31 per basic and diluted share, for the same period in 2016. The net loss for the three months ended September 30, 2017 includes approximately €5.5 million of foreign currency losses and approximately €2.7 million of non-cash, share option expenses.

Financial Outlook

Based on current operating plans, Merus expects that its current cash and cash equivalents balance will be sufficient to fund its research and development programs and operations well into 2019.

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 studies to have similar

features as conventional 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 Europe in gastric, ovarian, endometrial and non-small cell lung cancers. Merus' second most advanced bispecific antibody candidate, MCLA-117, is being developed in a Phase 1 clinical trial in patients with acute myeloid leukemia. The Company also has a pipeline of proprietary bispecific antibody candidates in preclinical development, including MCLA-158, which is designed to bind to cancer stem cells and is being developed as a potential treatment for colorectal cancer and other solid tumors, as well as MCLA-145, which is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target and is being developed in collaboration with Incyte Corporation. 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 statements regarding the timing of initiating the Phase 2 combination clinical trial of MCLA-128 and defining the clinical development plan for MCLA-128 in additional solid tumors, clinical development plans for MCLA-117, the timing of filing a Clinical Trial Application for MCLA-158 for a clinical trial in patients with colorectal cancer, the progress of developing MCLA-145 with Incyte, 2018 being an important period for advancing multiple clinical programs, each statement under "Upcoming Milestones," and the sufficiency of our cash and cash equivalents.

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 28, 2017, 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.

Merus N.V.
Unaudited Condensed Consolidated Statement of Financial Position
(after appropriation of result for the period)

	September 30, 2017	December 31, 2016
	(euros in thousands)	
Non-current assets		
Property, plant and equipment	1,008	648
Intangible assets	328	374
Restricted cash	—	167
Other assets	123	109
	1,459	1,298
Current assets		
Financial asset	—	11,847
Trade receivables and other current assets	4,062	2,248
Cash and cash equivalents	202,424	56,917
	206,486	71,012
Total assets	207,945	72,310
Shareholders' equity		
Issued and paid-in capital	1,747	1,448
Share premium account	213,551	139,878
Accumulated loss	(155,553)	(107,295)
Total equity	59,745	34,031
Non-current liabilities		
Borrowings	—	319
Deferred revenue, net of current portion	131,903	30,206
Current liabilities		
Borrowings	—	167
Trade payables	2,837	2,298
Taxes and social security liabilities	242	29
Deferred revenue	7,052	1,610
Other liabilities and accruals	6,166	3,650

	16,297	7,754
Total liabilities	148,200	38,279
Total equity and liabilities	207,945	72,310

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended September 30,		**Nine months ended September 30,**	
	(euros in thousands, except per share data)			
	2017	**2016**	**2017**	**2016**
Revenue	3,471	1,182	9,784	3,127
Research and development costs	(8,040)	(4,074)	(23,075)	(11,924)
Management and administration costs	(3,634)	(546)	(11,432)	(1,560)
Other expenses	(2,180)	(1,522)	(6,588)	(4,977)
Total operating expenses	(13,854)	(6,142)	(41,095)	(18,461)
Operating result	(10,383)	(4,960)	(31,311)	(15,334)
Finance income	254	25	864	74
Finance costs	(5,519)	(10)	(28,215)	(21)
Total finance (expense) / income	(5,265)	15	(27,351)	53
Result before taxation	(15,648)	(4,945)	(58,662)	(15,281)
Income tax expense	(64)	—	(181)	—
Result after taxation	(15,712)	(4,945)	(58,843)	(15,281)
Other comprehensive income				
Exchange differences on the translation of foreign operations	33	3	51	3
Total other comprehensive income for the period	33	3	51	3
Total comprehensive loss for the period	(15,679)	(4,942)	(58,792)	(15,278)
Basic (and diluted) loss per share	(0.81)	(0.31)	(3.08)	(1.24)
Weighted average shares outstanding				
Basic (and diluted)	19,402,667	16,085,851	19,120,081	12,293,405

Contacts:

Media:

Eliza Schleifstein
+1 973 361 1546
eliza@argotpartners.com

Investors:

Kimberly Minarovich
+1 646 368 8014
kimberly@argotpartners.com

Source: Merus N.V.