Merus Announces Second Quarter 2017 Financial Results and Highlights Recent Progress

September 19, 2017

UTRECHT, The Netherlands, Sept. 19, 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 second quarter ended June 30, 2017 and provided a corporate and clinical update.

“Merus has had a productive year to date, marked by progress in our work with Incyte and our other collaborators, the presentation at ASCO of positive Phase 1/2 data for our lead candidate MCLA-128 in the first of several indications, and progress among a stable of very exciting Biclonics®-based bispecific antibody therapy candidates toward and through the clinic,” said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. “We believe that the potential of Merus’ Biclonics® platform, which holds a number of key advantages over other bispecific antibody approaches, has only just begun to reveal itself.”

“The balance of the year holds a number of key anticipated milestones, including initiating a Phase 2 trial of MCLA-128-based combinations in two metastatic breast cancer (MBC) populations, a decision on development of MCLA-128 in gastric, ovarian and endometrial cancers based on an expected data readout, progression of dose escalation in the Phase 1 trial evaluating MCLA-117 in acute myeloid leukemia (AML) under a Clinical Trial Authorization (CTA), filing of an Investigational New Drug (IND) submission for MCLA-117, and filing of a CTA for a first-in-human clinical trial of MCLA-158 in patients with colorectal cancer. We also look forward to initiating an IND-enabling study for MCLA-145, a bispecific antibody designed to bind to PD-L1 and to another undisclosed immunomodulatory target, a program that is part of our collaboration with Incyte,” added Dr. Logtenberg.

Recent Clinical & Corporate Developments

- In Part 2 of the Phase 1/2 MCLA-128 study in solid tumors, treatment was completed for a cohort of heavily pre-treated HER2+ MBC patients (n=11) using MCLA-128 as a single agent which resulted in an overall clinical benefit rate (defined as complete response plus partial response plus stable disease lasting at least 12 weeks) of 64%. With single agent activity established in MBC, the initiation of a Phase 2 clinical trial is anticipated in the fourth quarter of 2017 described further below under “Anticipated 2017 Milestones”.

- Merus and Incyte Corporation (NASDAQ:INCY) have advanced the first candidate from their global strategic research collaboration into an IND-enabling study. MCLA-145 is designed to bind to PD-L1 and to a second undisclosed immunomodulatory target to treat various solid tumors. 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.

- Merus received a favorable ruling from the U.S. Court of Appeals for the Federal Circuit which affirmed that Regeneron Pharmaceuticals engaged in inequitable conduct during the patent prosecution of U.S. Patent No. 8,502,018, resulting in the patent’s unenforceability.

Anticipated 2017 Milestones

- During the fourth quarter, Merus expects to initiate a Phase 2, open label, multi-center international clinical trial to evaluate MCLA-128-based combinations in two MBC populations: (1) confirmed HER2-positive MBC patients (progressing on 2 to 4 anti-HER2 therapies, including TDM-1) who will receive MCLA-128 in combination with trastuzumab with and without chemotherapy, and (2) confirmed ER+/HER2-low MBC patients progressing on one or more prior endocrine therapies and CDK4/6 inhibitors who will receive MCLA-128 in combination with endocrine therapy. The trial is expected to enroll approximately 120 patients in total with approximately 60 patients targeted in each cohort.

- Merus is continuing its dose escalation of the Phase I clinical trial for MCLA-117 in Europe and expects to submit an IND application to the U.S. Food and Drug Administration in the fourth quarter of 2017.

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

Second Quarter 2017 Financial Results

Merus ended the second quarter of 2017 with cash and cash equivalents of €215.8 million compared to €56.9 million at December 31, 2016.

Total revenue for the three months ended June 30, 2017 was €4.0 million compared to €1.1 million for the same period in 2016. Revenue is comprised primarily of 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 June 30, 2017 were €8.4 million compared to €3.8 million for the same period in 2016. The increase in research and development costs quarter over quarter, reflects higher enrollment in our clinical trials and expansion of pre-clinical research efforts to support our

collaboration with Incyte.

For the three months ended June 30, 2017, Merus reported a net loss of €21.8 million, or a loss of €1.12 per basic and diluted share, compared to a net loss of €4.9 million, or a loss of €0.40 per basic and diluted share, for the same period in 2016. The net loss for the three months ended June 30, 2017 includes approximately €12.0 million of unrealized foreign currency losses and approximately €3.3 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' lead bispecific antibody candidate, MCLA-128, is expected to begin a Phase 2 combination trial in the second half of 2017 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 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 designed to bind to PD-L1 and a non-disclosed second immunomodulatory target, which 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 potential of our Biclonics® platform, the timing of initiating the Phase 2 combination trial of MCLA-128 in MBC patients, the treatment potential of our Biclonics® candidates, and key anticipated milestones, including each statement under "Anticipated 2017 Milestones."

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)

	June 30, 2017	December 31, 2016
	(euros in thousands)	
Non-current assets		
Property, plant and equipment	**1,057**	648
Intangible assets	**343**	374
Restricted cash	**—**	167
Other assets	**109**	109
	1,509	1,298
Current assets		
Financial asset	**—**	11,847
Taxes and social security receivables	**2,024**	—
Trade receivables and other current assets	**4,308**	2,248
Cash and cash equivalents	**215,788**	56,917
	221,120	71,012

Total assets	**223,629**	72,310
Shareholders' equity		
Issued and paid-in capital	**1,746**	1,448
Share premium account	**213,541**	139,878
Accumulated loss	**(142,529)**	(107,295)
Total equity	**72,758**	34,031
Non-current liabilities		
Borrowings	**—**	319
Deferred revenue, net of current portion	**133,666**	30,206
Current liabilities		
Borrowings	**—**	167
Trade payables	**3,971**	2,298
Taxes and social security liabilities	**748**	29
Deferred revenue	**7,052**	1,610
Other liabilities and accruals	**5,434**	3,650
	17,205	7,754
Total liabilities	**150,871**	38,279
Total equity and liabilities	**223,629**	72,310

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended June 30,		**Six months ended June 30,**	
	(euros in thousands, except per share data)			
	2017	**2016**	**2017**	**2016**
Revenue	4,027	1,098	6,313	1,945
Research and development costs	(8,420)	(3,822)	(15,427)	(8,028)
Management and administration costs	(3,492)	(496)	(7,694)	(1,014)
Other expenses	(2,277)	(1,664)	(4,120)	(3,277)
Total operating expenses	(14,189)	(5,982)	(27,241)	(12,319)
Operating result	(10,162)	(4,884)	(20,928)	(10,374)
Finance income	420	23	610	56
Finance costs	(11,962)	(13)	(22,696)	(18)
Total finance (expense) / income	(11,542)	10	(22,086)	38
Result before taxation	(21,704)	(4,874)	(43,014)	(10,336)
Income tax expense	(107)	-	(118)	-
Result after taxation	(21,811)	(4,874)	(43,132)	(10,336)
Other comprehensive income				
Exchange differences on the translation of foreign operations	13	-	18	3
Total other comprehensive income for the period	13	-	18	3
Total comprehensive loss for the period	(21,798)	(4,874)	(43,114)	(10,333)
Basic (and diluted) loss per share	(1.12)	(0.40)	(2.27)	(1.00)
Weighted average shares outstanding				
Basic (and diluted)	19,392,495	12,133,195	18,976,446	10,365,753

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.