Merus Announces Second Quarter 2016 Financial Results and Reviews Recent Clinical Progress and Corporate Developments

August 8, 2016

UTRECHT, The Netherlands, Aug. 08, 2016 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, today announced financial results for the second quarter ended June 30, 2016 and provided a review of recent accomplishments and clinical development plans.

“We ended the second quarter with €71.1 million of cash and cash equivalents, which provides us with the funding to achieve several development milestones,” said Ton Logtenberg, PhD, Chief Executive Officer of Merus. “We look forward to reporting on the progress of our lead HER2 x HER3 bispecific candidate, MCLA-128, our CLEC12A x CD3 bispecific candidate, MCLA-117, as well as our earlier stage pipeline.”

Recent Clinical Developments

- Announced that the first patient has been dosed in a Phase 1/2 clinical trial evaluating Merus’ second Biclonics® therapeutic candidate, MCLA-117, in patients with acute myeloid leukemia (AML).
- Presented interim Phase 1/2 clinical data in a poster presentation at the American Association for Cancer Research (AACR) 2016 Annual Meeting demonstrating a favorable safety profile and early signs of anti-tumor activity of MCLA-128 in patients with advanced solid tumors.

Upcoming Milestones

- By the end of 2016, Merus expects to report interim results from Part 2 of a Phase 1/2 clinical trial of MCLA-128 in breast cancer.
- Also by the end of 2016, Merus expects to file an Investigational New Drug application with the U.S. Food and Drug Administration for a Phase 1/2 trial of MCLA-128.
- During the second half of 2017, Merus expects to report topline data from its Phase 1/2 monotherapy trial of MCLA-128 in patients with solid tumors in multiple indications.
- By the end of 2017, Merus expects to report interim results from Part 1 of its Phase 1/2 clinical trial evaluating MCLA-117 in patients with AML.

Corporate Highlights

- Closed a successful initial public offering in May which raised net proceeds to Merus, after deducting underwriting discounts and commissions and offering expenses, of $53.3 million.
- Issued three patents related to the generation of bispecific antibodies and high-throughput functional screening methods of large collections of bispecific antibodies.
- Formed a strategic collaboration with Institut Gustave Roussy, a leading Comprehensive Cancer Centre in Europe, to jointly develop bispecific antibodies for therapeutic immuno-oncology applications.
- Announced the closing of a commercial multi-product license for Probiogen’s Glymaxx © ADCC Enhancement technology.
- Appointed Mr. Gregory Perry to the Supervisory Board as well as Chair of the Audit Committee.
- Incorporated Merus US, Inc and opened a new office in Cambridge, Massachusetts, USA.

Second Quarter 2016 Financial Results
(Euros in millions)

Total revenue for the three months ended June 30, 2016 was €1.1 million compared to €1.2 million for the same period in 2015. Revenue is comprised primarily of research funding and income from grants on research projects.

Research and development expenses for the three months ended June 30, 2016 were €3.9 million compared to €3.8 million for the same period in 2015. Research and development costs are comprised primarily of R&D headcount and other costs related to the development of Merus' two lead bispecific antibody candidates, MCLA-128 and MCLA-117, as well as manufacturing costs related to MCLA-158.

For the three months ended June 30, 2016, Merus reported a net loss of €(4.9) million, or €(0.40) per basic and diluted share, compared to a net loss of €(5.6) million, or €(1.25) per basic and diluted share, for the same period in 2015.

Merus ended the quarter with cash and cash equivalents of €71.1 million.

About MCLA-128
MCLA-128 is an ADCC-enhanced Biclonics® that binds to HER2- and HER3- expressing solid tumor cells. MCLA-128 is designed to overcome the inherent and acquired resistance of tumor cells to HER2-targeted therapies using two mechanisms: 1) blocking growth and survival pathways to stop tumor expansion while preventing tumor cells escaping through activation of the HER3/heregulin pathway and 2) recruitment and enhancement of immune effector cells to directly kill the tumor.

About MCLA-117
MCLA-117 is a Biclonics® that is designed to bind to CD3 expressed by T-cells and CLEC12A expressed by acute myeloid leukemia (AML) tumor cells and stem cells. In preclinical studies, MCLA-117 has been shown to recruit and activate the immune system's own T-cells to kill AML tumor cells and stem cells.

About MCLA-158
MCLA-158 is an ADCC-enhanced Biclonics® being developed for the treatment of colorectal cancer and other solid tumors. MCLA-158 is designed to bind to Lgr5 and EGFR expressing cancer stem cells, block growth and survival pathways and enhance the recruitment of immune effector cells to directly kill cancer stem cells that persist in solid tumors causing relapse and metastasis.

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 based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical studies to have several of the same features of conventional monoclonal antibodies, such as long half-life and low immunogenicity. Merus' lead bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 1/2 clinical trial in Europe as a potential treatment for HER2-expressing solid tumors. Merus' second bispecific antibody candidate, MCLA-117, is being developed as a potential treatment for 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, and Biclonics® designed to bind to various combinations of immunomodulatory molecules, including PD-1 and PD-L1.

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 sufficiency of our cash and cash equivalents for advancing our therapeutic candidates, the timing of results from our clinical trials and of regulatory filings, each statement under "Upcoming Milestones," and the treatment potential for bispecific antibody candidates.

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: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding, which may not be available and which may require us to restrict out operations or require us to relinquish rights to our technologies or bispecific antibody candidates; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; the unproven approach to therapeutic intervention of our Biclonics® technology; potential difficulties in validating and developing companion diagnostics, which could harm our development strategy; our limited operating history; economic, political, regulatory and other risks involved with international operations; exchange rate fluctuations or abandonment of the euro currency; 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 adverse public reaction to the use of cancer immunotherapies; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; our potential exposure to costly and damaging liability claims; post-marketing restrictions or withdrawal from the market; failure to obtain marketing approval internationally; compliance with environmental, health, and safety laws and regulations; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; failure to compete successfully against other drug companies; potential competition from other drug companies if we fail to obtain orphan drug designation or maintain orphan drug exclusivity for our products; the possibility that governmental authorities and health insurers may not establish adequate reimbursement levels and pricing policies to support our products; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; potential competition from biosimilars; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; 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 being found invalid or unenforceable; potential lawsuits for infringement of third-party intellectual property; adequate protection of our trademarks; our potential failure to obtain extensions of the terms of patents covering our products; potential difficulties protecting our intellectual property rights in certain jurisdictions; changes in United States patent law; protection of the confidentiality of our trade secrets; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; compliance with patent regulations; potential system failures; our ability to attract and retain key personnel; managing our growth could result in difficulties; the price of our common stock may fluctuate substantially; certain of our shareholders and members of our management board own a majority of our outstanding shares and exercise significant control over us; a significant portion of our total outstanding shares are eligible to be sold into the market; provisions of our Articles of Association or Dutch corporate law might deter favorable acquisition bids for us or prevent a beneficial change of control; we may lose our foreign private issuer status and incur significant expenses as a result; and unfavorable or lacking analyst research or reports might cause the price of our common shares to decline.

These and other important factors discussed under the caption "Risk Factors" in our final prospectus filed with the Securities and Exchange Commission, or SEC, on May 20, 2016 relating to our Registration Statement on Form F-1, 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. 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.

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Unaudited Condensed Consolidated Statement of Financial Position

(after appropriation of result for the period)

	June 30, 2016	December 31, 2015
	(euros in thousands)	
Non-current assets		
Property, plant and equipment	428	325
Intangible assets	404	435
Restricted cash	195	218
Total non-current assets	1,027	978
Current assets		
Trade and other receivables	1,440	1,665
Cash and cash equivalents	71,149	32,851
Total current assets	72,589	34,516
Total assets	73,616	35,494
Shareholders' equity		
Issued and paid-in capital	1,448	775
Share premium account	139,981	90,909
Accumulated loss	(73,067)	(63,382)
Total equity	68,362	28,302
Non-current liabilities		
Borrowings	417	486
Deferred revenue	279	390
Current liabilities		
Borrowings	167	167
Trade payables	1,711	2,419
Taxes and social security liabilities	65	142
Deferred revenue	223	223
Other liabilities and accruals	2,392	3,365
Total current liabilities	4,558	6,316
Total liabilities	5,254	7,192
Total equity and liabilities	73,616	35,494

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Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three month period ended June 30,	
	2016	**2015**
	(euros in thousands, except per share data)	
Revenue	1,098	1,157
Research and development costs	(3,945)	(3,786)
Management and administration costs	(373)	(149)
Other expenses	(1,664)	(2,775)
Total operating expenses	(5,982)	(6,710)
Operating result	(4,884)	(5,553)
Finance income	23	1
Finance costs	(13)	(11)
Total finance income / (expenses)	10	(10)
Result before tax	(4,874)	(5,563)
Income tax expense	-	-
Result after taxation	(4,874)	(5,563)
Other comprehensive income		

Exchange differences on the translation of foreign operations	-		-	
Total other comprehensive loss for the period	(4,874	)	(5,563	)
Total comprehensive loss for the period	(4,874	)	(5,563	)
Basic (and diluted) loss per share	(0.40	)	(1.25	)

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