

Merus

Merus Announces Recent Corporate Developments and Financial Results for the First Quarter 2018

July 26, 2018

- *Initiation of Phase 1, first-in-human clinical trial of MCLA-158 in patients with solid tumors* -
- *MCLA-128's unique mechanism of action published in the scientific journal *Cancer Cell** -

UTRECHT, The Netherlands, July 26, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS) ("Merus", "we", "our" or the "Company"), a clinical-stage immunology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced financial results for the first quarter ended March 31, 2018 and provided a corporate and clinical update.

"In May, we advanced MCLA-158, a Biclonics® designed to bind to cancer-initiating cells expressing Lgr5 and EGFR, into the clinic with the commencement of patient dosing in a Phase 1, first-in-human clinical trial in patients with solid tumors," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "Clinical trials for MCLA-128 and MCLA-117 are ongoing. Potential early activity data for MCLA-117 is expected in 2018, and we anticipate reporting data for MCLA-128 later this year."

Dr. Logtenberg continued, "Notably, the unique mechanism of action of MCLA-128 was recently published in the scientific journal *Cancer Cell* and highlighted the screening of a panel of more than 500 bispecific antibodies binding to the HER2/HER3 target pair in relevant functional assays. This unbiased functional screening led to the identification of development candidate MCLA-128, a bispecific antibody that employs a unique mechanism, DOCK & BLOCK®, for the selective and potent inhibition of the heregulin/HER3 tumor-signaling pathway. These results reinforce the potential of our functional screening process that allows for the discovery of unique biology driven by the bispecific antibody format."

Recent Clinical & Corporate Developments

- **Patient Dosing Commenced in a Phase 1 Clinical Trial of MCLA-158 in Patients with Solid Tumors** - Merus announced in May 2018 that the first patient was dosed in a Phase 1, first-in-human clinical trial of MCLA-158 in patients with solid tumors with an initial focus on metastatic colorectal cancer. The trial consists of two parts, a dose escalation and a dose expansion. The dose escalation part is intended to determine the appropriate dose of MCLA-158. The dose escalation and expansion parts of the trial will also examine the preliminary antitumor activity of single-agent MCLA-158.
- **DOCK & BLOCK® Mechanism of Action (MOA) of MCLA-128 Published in *Cancer Cell*** –The MOA of MCLA-128, the Company's most-advanced Biclonics® candidate that binds to HER2 and HER3-expressing solid tumor cells and potently blocks the heregulin/HER3 tumor-signaling pathway, was published in the May 2018 edition of *Cancer Cell* titled, "Unbiased Combinatorial Screening Identifies a Bispecific IgG1 that Potently Inhibits HER3 Signaling via HER2-Guided Ligand Blockade." Using a structure function approach, Merus demonstrated that PB4188, the research candidate described in the paper, employs a unique mechanism to inhibit the growth of tumors by docking to HER2 and blocking ligand interaction with HER3, thereby preventing stabilization of the HER2:HER3 heterodimer and sustained signaling. MCLA-128, the development candidate of PB4188, is currently being studied in a Phase 2 combination trial in two metastatic breast cancer populations and a Phase 1/2 study evaluating single-agent activity for MCLA-128 in gastric, ovarian, endometrial and non-small cell lung cancer (NSCLC).
- **Awarded Fees and Costs in Regeneron Patent Litigation** - On June 25, 2018, in a decision which published on July 10, 2018, the United States District Court for the Southern District of New York granted Merus' motion for approximately \$10.5 million of attorneys' fees, expert fees and costs, plus pre- and post-judgment interest, incurred by Merus in its defense of Regeneron Pharmaceutical Inc.'s suit initiated in March 2014. The District Court's decision recounts Regeneron's inequitable conduct before the United States Patent and Trademark Office while prosecuting the U.S. Patent No. 8,502,018 (the '018 patent), entitled "Methods of Modifying Eukaryotic Cells."

Anticipated 2018 Milestones

MCLA-128, an antibody-dependent cell-mediated cytotoxicity (ADCC) enhanced Biclonics® that binds to HER2 and HER3-expressing solid tumor cells
The Phase 1/2 study evaluating single-agent activity for MCLA-128 in various solid tumor indications is ongoing and Merus expects to provide an update on the gastric cohort in the fourth quarter of 2018.

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

Merus is continuing dose escalation in the Phase 1 clinical trial of MCLA-117 in Europe and the U.S. Safety and potential early activity data is expected in the second half of 2018.

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

Recruitment for the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is ongoing. The trial is being conducted in Europe and the U.S.

MCLA-145, a Biclomics® designed to bind to PD-L1 and a second undisclosed immunomodulatory target

MCLA-145, the first drug candidate co-developed under the Merus and Incyte global research collaboration, continues to progress in IND-enabling studies. Merus has full rights to develop and commercialize MCLA-145 in the U.S. and Incyte is responsible for its development and commercialization outside the U.S.

First Quarter 2018 Financial Results

Merus ended the first quarter of 2018 with cash, cash equivalents and investments of €220.1 million compared to €190.8 million at December 31, 2017, the increase primarily being the result of the closing of a \$55.8 million (€44.8 million) private placement of 3.1 million common shares completed in February 2018.

Total revenue for the three months ended March 31, 2018 was €9.9 million compared to €3.9 million for the same period in 2017. Revenue for the three months ended March 31, 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 €1.6 million of additional revenue for the three months ended March 31, 2017. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements and collaboration income related to 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 €1.9 million of amortization of upfront license payments, €1.6 million of collaboration income for expense reimbursements and €2.5 million for research milestones earned under Merus' agreement with Ono Pharmaceuticals.

Research and development costs for the three months ended March 31, 2018 were €10.3 million compared to €7.0 million for the same period in 2017. The increase in research and development costs reflects higher enrollment in Merus' clinical trials, expansion of research efforts to support its internal programs and collaborations and additional manufacturing expenses.

Management and administration costs for the three months ended March 31, 2018 were €2.9 million compared to €4.2 million for the same period in 2017. The decrease relates primarily to lower share-based compensation expenses.

Other expenses for the three months ended March 31, 2018 were €2.7 million compared to €1.8 million for the same period in 2017. The increase in other expenses was the result of higher consulting, accounting and professional fees.

For the three months ended March 31, 2018, Merus recorded a net loss of €8.4 million, or €(0.40) per share (basic and diluted), compared to a net loss of €19.7 million, or €(1.06) per share (basic and diluted), for the same period in 2017. The net loss for the three months ended March 31, 2017 included a non-cash charge of €10.7 million for the accounting impact of a financial derivative related to the obligation to deliver shares to Incyte in 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 through the end of 2020.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclomics®. Biclomics®, 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, ovarian, endometrial 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, a Biclomics® 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 a preclinical bispecific antibody 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 formulation of clinical development plans and clinical development of our bispecific antibody candidates, anticipated clinical data points for 2018, the timing of expected patient recruitment and dosing, presentations, clinical data announcements, and the advancement of the Phase 2 combination trial for MCLA-128, the potential of our functional screening process, each statement under "Anticipated Milestones," the sufficiency of our cash, cash equivalents and investments, and the design and treatment potential of our bispecific antibody candidates including MCLA-128, MCLA-117, MCLA-158 and MCLA-145.

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 Biclomics® 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 Biclomics® 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 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.

March 31, December 31,
2018 2017 Restated*

(euros in thousands)

Non-current assets

Property, plant and equipment	1,139	1,168
Intangible assets	297	312
Non-current investments	15,758	7,060
Other assets	137	129
	17,331	8,669

Current assets

Taxes and social security assets	924	-
Trade and other receivables	11,473	4,413
Current investments	39,869	34,043
Cash and cash equivalents	164,492	149,678
	216,758	188,134

Total assets 234,089 196,803

Shareholders' equity

Issued and paid-in capital	2,036	1,749
Share premium account	258,109	213,618
Accumulated loss	(164,778)	(158,775)
Total equity	95,367	56,592

Non-current liabilities

Deferred revenue	109,736	112,551
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Current liabilities

Trade payables	5,221	2,855
Taxes and social security liabilities	240	243
Deferred revenue	17,286	15,935
Other liabilities and accruals	6,239	8,627
	28,986	27,660

Total liabilities 138,722 140,211

Total equity and liabilities 234,089 196,803

*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 Consolidated Statement of Profit or Loss and Comprehensive Loss

Three months ended March 31,
2018 2017 Restated**

(euros in thousands, except per
share data)

Revenue	9,921	3,884
Research and development costs	(10,298)	(7,007)
Management and administration costs	(2,852)	(4,202)
Other expenses	(2,686)	(1,843)
Total operating expenses	(15,836)	(13,052)
Operating result	(5,915)	(9,168)
Finance income	340	190
Finance costs	(2,806)	(10,734)
Net finance expense	(2,466)	(10,544)
Result before tax	(8,381)	(19,712)
Income tax expense	(52)	(11)

Result after taxation	(8,433)	(19,723)
Exchange differences from translation of foreign operations	(15)	5
Other comprehensive (loss) / income for the period	(15)	5
Total comprehensive loss for the period	(8,448)	(19,718)
Basic (and diluted) loss per share	(0.40)	(1.06)
Basic (and diluted)	20,984,663	18,555,775

** Revenue for the three months ended March 31, 2017 has been restated to reflect additional revenue of €1.6 million, or €0.09 per share, 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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