

Merus Announces Financial Results for the Full Year 2018 and Provides Business Update
Multiple Updates from Biclomics® Clinical Trials Expected in 2019

UTRECHT, The Netherlands, April 3, 2019 (GLOBE NEWSWIRE) — Merus N.V. (Nasdaq: MRUS) (“Merus”, “we”, “our” or the “Company”), a clinical-stage immuno-oncology company developing Biclomics®, innovative full-length human bispecific antibody therapeutics, today announced financial results for the full year ended December 31, 2018 and provided a business update.

“2018 was an exciting year for Merus with several developments that have helped to advance our leadership position in bispecific antibodies,” said Ton Logtenberg, Ph.D., President, Chief Executive Officer and Principal Financial Officer of Merus. “We have continued to make significant progress in our clinical programs and further advances in our R&D platform. Looking ahead, 2019 will be an important year as we anticipate reaching several clinical milestones in our programs, including a trial initiation in MCLA-145, first clinical data for MCLA-117 and MCLA-158, and Phase 2 data for MCLA-128. ”

Clinical Programs and Business Update:

MCLA-128: Phase 2 metastatic breast cancer cohort update planned for 2H 2019

The Phase 2 clinical trial evaluating MCLA-128 in combination treatments in two metastatic breast cancer (“MBC”) populations continues to enroll patients in the U.S. and Europe. The Phase 2 study was initiated following data from a Phase 1/2 study in patients with MBC, where MCLA-128 was observed to be well tolerated and evidence of single-agent, antitumor activity in heavily pretreated patients was seen. Merus plans to provide an update on the Phase 2 MBC trial in the second half of 2019.

The single agent Phase 1/2 trial in solid tumors is ongoing in the non-small-cell lung cancer and gastric cancer (“GC”) cohorts, with the GC cohort enrollment now complete. In October 2018, Merus presented a poster at the European Society for Medical Oncology (ESMO) Congress outlining overall safety data as well as preliminary activity data in the GC patient cohort of the Phase 2 portion of the 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 observed to be well tolerated. In gastric patients, single-agent, antitumor activity was observed 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, Merus is evaluating options and timing for potential combination trials in rational therapeutic combinations in the GC/GEJ cancer patient population.

MCLA-128 is an antibody-dependent cell-mediated cytotoxicity (“ADCC”) -enhanced Biclomics® that inhibits the heregulin/HER3 tumor-signaling pathway in solid tumors. MCLA-128 is believed to work with HER2-targeted therapies and to overcome the resistance of tumor cells 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: Initial data from Phase 1 trial expected 2H 2019

The Phase 1 clinical trial for MCLA-117 is progressing and preliminary anti-tumor activity has been observed. Dose escalation continues steadily and carefully in order to establish the optimal therapeutic window. Merus anticipates initial data for the Phase 1 trial in the second half of 2019 and plans to provide further guidance on the program upon announcement of the maximum tolerated dose.

MCLA-117 is a Biclomics® that binds with relative low affinity to CD3, a component of the T cell receptor present on all T cells, and relative high affinity to CLEC12A, a cell surface molecule present on acute myeloid leukemia (“AML”) tumor cells and AML stem cells. MCLA-117 has been shown in preclinical studies to recruit and activate T-cells to kill CLEC12A-expressing malignant cells which may prevent recurrence of the tumor, while sparing hematopoietic stem cells. MCLA-117 has a full-length IgG format with a silenced constant region, which Merus believes may contribute to safety and attractive dosing schedules for patients.

MCLA-158: Emerging data from Phase 1 trial expected at end of 2019

The dose escalation of the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is ongoing. Emerging data for the Phase 1 trial is expected at the end of 2019.

On March 12, 2019, Merus presented preclinical data on MCLA-158 at the 26th International Molecular Med Tri-Con Conference, showing arrested tumor organoid growth ex vivo, and inhibition of primary tumor formation and metastasis in vivo.

Importantly, preclinical data showed MCLA-158 activity in >60% of patient tumor organoids (15/24) regardless of RAS mutational status, which indicates that MCLA-158 has the potential to be the first targeted colorectal cancer (“CRC”) treatment to block growth of tumors with RAS mutations (present in ~50% of all CRC patients).

MCLA-158 is an ADCC-enhanced Biclomics® that binds to cancer initiating cells expressing Lgr5 and EGFR. MCLA-158 has 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 can cause relapse and metastasis.

MCLA-145: Expected to enter clinical trials 2Q 2019 in collaboration with Incyte

On January 7, 2019, the United States (U.S.) Food and Drug Administration (FDA) accepted the Investigational New Drug (IND) application for MCLA-145. MCLA-145 is a potential first-in-class PD-L1 x CD137 Biclomics® being developed in collaboration with Incyte Corporation (“Incyte”) (Nasdaq: INCY), for the treatment of solid tumors. The Phase I clinical trial for MCLA-145 is expected to initiate in the second quarter of 2019.

On March 31, 2019, Merus and Incyte presented two posters at the American Association for Cancer Research (AACR) Annual Meeting outlining preclinical data on MCLA-145. Data presented showed a potent triple action, designed to recruit and activate T cells through CD137 and prevent their exhaustion through inhibition of the PD-1 checkpoint pathway for patients with solid tumors. Because the T cell activation was shown to be context-dependent, requiring PD-L1 expression in the tumor microenvironment, MCLA-145 has the potential to overcome known side effects of CD137 agonists currently in development.

Merus is developing MCLA-145 as part of a collaboration entered into with Incyte in December 2016 to potentially develop and commercialize up to 11 bispecific and monospecific antibodies from the Merus Biclomics® platform. Under the terms of the collaboration, Merus retains all rights to develop and commercialize MCLA-145, if approved, in the United States, while Incyte has rights to develop and commercialize MCLA-145, if approved, outside the United States.

MCLA-145 is a Biclomics® T-cell agonist that has been observed to bind to human PD-L1 and CD137 in preclinical models. Discovered through an unbiased functional screening of multiple immunomodulatory target combinations, the differentiated profile of MCLA-145 derives from its potential to attract T cells into solid tumors, potently activate immune effector cells in the context of the tumor microenvironment and simultaneously block inhibitory signals in the same immune cell population.

Collaborations in China provide capital efficient approach to expand Merus clinical pipeline

Following the collaboration with Simcere Pharmaceutical Group, on January 2, 2019 Merus announced a strategic collaboration with Betta Pharmaceuticals Co. Ltd. (“Betta”) to develop and commercialize MCLA-129 in China. Under the terms of the agreement, Betta is responsible for clinical development and commercialization of MCLA-129 in China. Merus retains all rights outside of China. As a key strategic component of the collaboration, Betta has agreed to retain a contract manufacturing organization with experience in filing global IND applications within the U.S. and Europe in order to produce MCLA-129 clinical trial materials for China and rest of world. Betta has agreed to facilitate regulatory filings and early stage clinical trial materials supply for potential use by Merus for development of MCLA-129 outside of China.

In preclinical studies, MCLA-129 showed a significant reduction in tumor volume for EGFR inhibitor resistant lung cancer models lacking immune cells. Additionally, in cell lines that co-express both EGFR and c-MET, MCLA-129 effectively induced tumor cell lysis at low antibody concentrations. Because its Dock & Block® and ADCC mechanism of action is based on the co-expression of EGFR and c-MET, it is expected to have less toxicity compared to agents targeting EGFR alone.

This latest deal is representative of the strategic collaborations Merus plans to continue to seek in order to leverage collaborators’ investment, particularly in Chemistry, Manufacturing and Controls (CMC) and IND-enabling studies, to advance more programs from Merus’ rich preclinical pipeline into the clinic.

MCLA-129 is a Biclomics® binding to EGFR and c-MET for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers. The upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. MCLA-129 has two distinct mechanisms of action. First, Merus' Dock & Block® mechanism of action blocks the signaling of EGFR as well as c-MET, with the potential to inhibit tumor growth and survival. Second, MCLA-129 utilizes GlymaxX® ADCC-enhancement technology designed for greater cell-killing potential.

2018 court rulings and global litigation settlement

In December 2018, Merus reached a global settlement of all outstanding litigation and adversarial proceedings with Regeneron Pharmaceuticals Inc. ("Regeneron") that began in 2014 on patents related to each other's respective platform technology.

In July 2018, the U.S. trial court awarded Merus approximately \$10.5 million in litigation expenses and costs that Merus incurred in its defense of a claim of alleged patent infringement by Regeneron. On December 20, 2018, all pending litigation and adversarial proceedings were settled between Merus and Regeneron, culminating in a cross-license and the purchase by Regeneron of 600,000 Merus common shares at \$25 per share, a 118% premium from the closing share price on December 20, 2018. The cross-license and stock purchase were made in conjunction with Regeneron's agreement to withdraw its appeal of the fee award, and Merus' agreement to dismiss all claims to the trial court awarded fees.

New U.S. headquarters planned for Q2 2019 opening

In March 2019, Merus US, Inc. executed a lease for its new U.S. headquarters, located at 139 Main Street Cambridge, MA in Kendall Square. This second location for the subsidiary of the Dutch company is a strategic decision to further enhance its global leadership in bispecific antibodies and a commitment to attracting and retaining top talent in biotech worldwide. The office is scheduled to open in the second quarter of 2019, and will help to secure a permanent footprint in the United States.

Fourth Quarter 2018 Financial Results

Total revenue for the three months ended December 31, 2018 was €8.5 million compared to €6.1 million for the same period in 2017. Revenue for the three months ended December 31, 2017 has been restated for the retrospective effects of 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 under its collaboration and license agreement with Incyte from 21 years to 9 years, which resulted in €2.3 million of additional revenue for the three months ended December 31, 2017. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements, and R&D cost reimbursements and milestones for performance of research and development or manufacturing services under the respective agreements. The increase in revenue for the three months ended December 31, 2018 was primarily attributable to a €1.5 million milestone recognized under a collaboration and license agreement with ONO Pharmaceutical Co., Ltd. ("ONO") and a €1.0 million increase in R&D cost reimbursements.

Research and development costs for the three months ended December 31, 2018 were €12.0 million compared to €11.1 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 December 31, 2018 were €2.2 million compared to €2.3 million for the same period in 2017.

Other expenses for the three months ended December 31, 2018 were €3.2 million compared to €2.8 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 December 31, 2018, Merus reported a net loss of €0.5 million, or €0.02 net loss per share (basic and diluted), compared to a net loss of €12.0 million, or €0.62 net loss per share (basic and diluted), for the same period in 2017. Net loss for the three months ended December 31, 2017 has been restated for the adoption of IFRS 15, which resulted in a reduction of net loss of €2.3 million or €0.11 per share (basic and diluted). The net loss for the three months ended December 31, 2018 includes a gain of approximately €7.1 million related to the settlement of certain litigation with Regeneron and €1.0 million of foreign currency gains as compared to €1.9 million of foreign currency losses in the same period in 2017.

Full Year 2018 Financial Results

Merus ended 2018 with cash, cash equivalents and investments of €205.5 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 and proceeds received from the \$15.0 million investment by Regeneron as part of a litigation settlement.

Total revenue for the year ended December 31, 2018 was €31.4 million compared to €21.9 million for the same period in 2017. Revenue for the year ended December 31, 2017 has been restated for the retrospective effects of the adoption of IFRS 15 resulting in €8.3 million of additional revenue for the year ended December 31, 2017. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements, and R&D cost reimbursements and milestones for performance of research and development or manufacturing services under the respective agreements. The increase in revenue for the period is primarily attributable to €4.0 million in research milestones earned under agreements with ONO, a €3.4 million increase in R&D cost reimbursements and a €2.8 million increase in amortization of upfront license payments, partially offset by a €1.0 million decrease in grant income.

Research and development costs for the year ended December 31, 2018 were €46.7 million compared to €34.1 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 year ended December 31, 2018 were €10.4 million compared to €13.7 million for the same period in 2017. The decrease relates primarily to lower share-based compensation expenses.

Other expenses for the year ended December 31, 2018 were €13.2 million compared to €9.4 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 year ended December 31, 2018, Merus reported a net loss of €24.2 million, or €1.09 net loss per share (basic and diluted), compared to a net loss of €64.7 million, or €3.37 net loss per share (basic and diluted), for the same period in 2017. Net loss for the year ended December 31, 2017 has been restated for the retrospective effects of the adoption of IFRS 15, which resulted in a reduction of net loss of €8.3 million or €0.43 per share (basic and diluted). The net loss for the year ended December 31, 2018 includes a gain of approximately €7.1 million related to the settlement of certain litigation with Regeneron and €6.0 million of foreign currency gains as compared to €19.4 million of foreign currency losses in the same period 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 into the second quarter of 2021.

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. For additional information on the company and programs, 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 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 the content and timing of potential milestones described in this press release, the timing of updates, guidance, information, clinical trials and data readouts for our product candidates, the design and treatment potential of our bispecific antibody candidates, clinical

study designs, our options and timing for potential combination trials for MCLA-128 in rational therapeutic combinations in the GC/GEJ cancer patient population, the potential contributions of MCLA-117's full length IgG format with a silenced constant region to safety and predictability, preclinical data for MCLA-158, which indicates its potential to be the first targeted CRC treatment to block growth of tumors with RAS mutations, the characteristics and immunostimulatory profile of MCLA-145, and this profile having a potential of MCLA-145 to overcome known side effects of CD137 agonists, the potential for MCLA-145 to be first-in-class, our ability to use Betta's regulatory filings and early stage clinical trial materials for potential ex-China development of MCLA-129, MCLA-129 toxicity compared to agents targeting EGFR alone, the potential of our current collaborations and our ability to engage in any future strategic collaborations to leverage collaborators' investment, particularly in CMC and IND-enabling studies, to advance more programs from our rich preclinical pipeline into the clinic, and the opening of our U.S. headquarters and its value to our business and ability to secure a permanent footprint in the United States.

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 collaborations or our collaborators may fail to perform adequately under our collaborations; 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 Consolidated Statement of Financial Position

	December 31, 2018	December 31, 2017 Restated*
(euros in thousands)		
Non-current assets		
Property, plant and equipment, net	2,420	1,168
Intangible assets, net	2,445	312
Non-current investments	16,945	7,060
Other assets	1,075	129
	22,885	8,669
 Current assets		
Trade and other receivables	7,032	4,413
Current investments	44,855	34,043
Cash and cash equivalents	143,747	149,678
	195,634	188,134
 Total assets	 218,519	 196,803
 Shareholders' equity		
Issued and paid-in capital	2,102	1,749
Share premium account	264,854	213,618
Accumulated loss	(175,085)	(158,775)
Total shareholders' equity	91,871	56,592
 Non-current liabilities		
Deferred revenue, net of current portion	97,675	112,551
Current liabilities		
Trade payables	3,819	2,855
Taxes and social security liabilities	256	243
Deferred revenue	16,934	15,935
Other liabilities and accruals	7,964	8,627
	28,973	27,660
 Total liabilities	 126,648	 140,211
 Total shareholders' equity and liabilities	 218,519	 196,803

* Accumulated loss and deferred revenue (current and non-current) have been restated for the impact of the retrospective effects 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		Year ended	
	December 31,		December 31,	
	2018	2017 Restated**	2018	2017 Restated**
(euros in thousands, except per share data)				
Revenue	8.470	6.070	31.448	21.915
Research and development costs	(12.023)	(11.050)	(46.740)	(34.125)
Management and administration costs	(2.246)	(2.265)	(10.395)	(13.697)
Other expenses	(3.228)	(2.807)	(13.160)	(9.395)
Total operating expenses	<u>(17.497)</u>	<u>(16.122)</u>	<u>(70.295)</u>	<u>(57.217)</u>
Operating result	(9.027)	(10.052)	(38.847)	(35.302)
Finance income	1.529	248	7.843	1.112
Finance cost	-	(2.120)	(4)	(30.335)
Other income	7.095	-	7.095	-
Other income (expense)	<u>8.624</u>	<u>(1.872)</u>	<u>14.934</u>	<u>(29.223)</u>
Result before taxation	(403)	(11.924)	(23.913)	(64.525)
Income tax expense	(150)	(68)	(356)	(249)
Result after taxation	<u>(553)</u>	<u>(11.992)</u>	<u>(24.269)</u>	<u>(64.774)</u>
Other comprehensive income				
Exchange differences from the translation of foreign operations	8	38	34	89
Total other comprehensive income for the period	<u>8</u>	<u>38</u>	<u>34</u>	<u>89</u>
Total comprehensive loss for the period	<u>(545)</u>	<u>(11.954)</u>	<u>(24.235)</u>	<u>(64.685)</u>
Loss per share - basic and diluted*	(0,02)	(0,62)	(1,09)	(3,37)
Weighted average shares outstanding - basic and diluted*	22.824.397	19.423.027	22.286.720	19.196.440

* 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 twelve months ended December 31, 2017 has been restated to reflect additional revenue of €2.3 million, or €0.11 per share, and €8.3 million, or €0.43 per share, respectively, related to the amortization of the upfront license payment received from Incyte due to the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition.

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