

# Merus

## Merus Announces First Quarter 2017 Financial Results and Mid-Year Operating Results

July 11, 2017

*Balance sheet strengthened with \$120 million upfront payment and an \$80 million share purchase from Incyte Corporation for global strategic research collaboration to discover and develop bispecific antibodies*

*Based on single agent activity in the MCLA-128 Phase 1/2 clinical trial, Phase 2 combination clinical trials planned to initiate in second half of 2017 for MCLA-128 in two metastatic breast cancer populations: HER2-positive patients and hormone receptor-positive/HER2-low patients*

*Conference call and webcast to be held today at 4:30 pm ET*

UTRECHT, The Netherlands, July 11, 2017 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics<sup>®</sup>), today announced financial results for the first quarter ended March 31, 2017 and provided a corporate and clinical update.

"The first quarter and recent period were marked most notably by the announcement of Phase 1/2 clinical trial data for our lead product candidate MCLA-128, an ADCC-enhanced Biclonics<sup>®</sup> designed to bind to and block growth factor receptors HER2 and HER3, which demonstrated single-agent anti-tumor activity in a heavily pre-treated cohort of metastatic breast cancer (MBC) patients," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "Given these encouraging results, we plan to initiate a Phase 2 open-label, multicenter clinical trial of MCLA-128 in HER2-positive MBC patients and in hormone receptor-positive/HER2-low MBC patients in the fourth quarter of 2017."

Dr. Logtenberg continued, "Also in the second half of this year, we expect to reach important clinical and regulatory milestones for two other Biclonics<sup>®</sup> therapeutic candidates, MCLA-117 and MCLA-158. Biclonics<sup>®</sup> are designed to have functionalities that compare favorably against other forms of immunotherapeutics, such as conventional mAbs as well as their combinations, and have the potential to be a more effective treatment for cancer patients. With the Biclonics<sup>®</sup> therapeutic candidates arising from this platform now emerging in the clinic, we look forward to providing additional updates across our pipeline in the coming quarters."

### Recent Developments

- At the 2017 American Society of Clinical Oncology (ASCO) in May 2017, Merus presented a poster entitled, "*First in human phase 1/2 study of MCLA-128, a full length IgG1 bispecific antibody targeting HER2 and HER3; final phase 1 data and preliminary activity in HER2+ metastatic breast cancer (MBC)*," which detailed clinical results from a Phase 1/2 clinical trial of MCLA-128 in solid tumors, including final Phase 1 data in patients with HER2+ MBC. Part 1 of the Phase 1/2 clinical trial showed that MCLA-128 was safe and well-tolerated and established the Phase 2 recommended dose of MCLA-128 in a cohort of 28 advanced solid tumor patients.

In the ongoing Part 2 of the study, treatment was completed for a cohort of heavily pre-treated HER2+ MBC patients (n=11) using MCLA-128 as a single agent. Overall, the clinical benefit rate (defined as complete response plus partial response plus stable disease lasting at least 12 weeks) among a total of 11 MBC patients was 64%. Evaluation of MCLA-128 in other indications, including endometrial, ovarian, and gastric cancers and NSCLC is ongoing.

- Shelley Margetson, Chief Operating Officer, will leave the Company effective August 1, 2017. Ms. Margetson has served in her current role since November 2016. She also served as Executive Vice President and Chief Financial Officer of Merus from 2010 until 2016.

### Anticipated 2017 Milestones

- With single agent activity established in MBC, the initiation of a Phase 2, open label, multi-center international clinical trial is anticipated in the fourth quarter of 2017 to evaluate MCLA-128-based combinations in two MBC populations: (1) confirmed HER2-positive MBC patients (progressing on 2-4 anti-HER2 therapies, including TDM-1) who will receive MCLA-128 in combination plus 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 a total of 120 patients with 60 patients targeted in each cohort.
- Decision to support further development path on MCLA-128 in gastric cancer expected in the fourth quarter of 2017.
- During the second half of 2017, Merus expects to complete the dose escalation phase of its Phase 1 clinical trial evaluating MCLA-117 in patients with AML. The study is being conducted in Europe under a Clinical Trial Application (CTA). An Investigational New Drug application to the U.S. Food and Drug Administration of MCLA-117 for the ongoing Phase 1 trial is planned during the second half 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.

#### **First Quarter 2017 Financial Results**

Merus ended the first quarter of 2017 with cash and cash equivalents of €236.5 million. The increase in the Company's cash position from €56.9 million at December 31, 2016 was the result of a \$120 million upfront payment and an \$80 million share purchase by Incyte Corporation (NASDAQ:INCY) (Incyte) under the terms of a global, strategic research collaboration for the development of bispecific antibodies utilizing Merus' Biclomics<sup>®</sup> technology platform. In connection with the collaboration, Incyte purchased 3.2 million common shares of Merus at \$25 per share, for a total equity investment of \$80 million. The collaboration was announced in December 2016 and became effective in January 2017 upon the closing of the share purchase by Incyte.

Total revenue for the three months ended March 31, 2017 was €2.3 million compared to €0.8 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 expenses for the three months ended March 31, 2017 were €7.0 million compared to €4.2 million for the same period in 2016.

For the three months ended March 31, 2017, Merus reported a net loss of €21.3 million, or €(1.15) per share (basic and diluted), compared to a net loss of €5.5 million, or €(0.63) per share (basic and diluted), for the same period in 2016. The net loss for the three months ended March 31, 2017 includes 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.

#### **Conference Call Details**

Merus will hold a conference call to provide a mid-year update and discuss its financial results today, July 11, 2017 at 4:30 p.m. ET. To listen to the conference call, dial (646) 722-4972 (domestic); international callers dial (866) 978-9968 (international) and provide the passcode 98331903. In addition, the presentation will be webcast live, and may be accessed for up to 90 days following the call, by visiting the "Investors" section of the Company's website, [www.merus.nl](http://www.merus.nl). An accompanying slide presentation also can be accessed via the "Investors" section of the website.

#### **About MCLA-128**

MCLA-128 is an ADCC-enhanced Biclomics<sup>®</sup> designed to block HER3/herregulin-dependent tumor growth and survival as well as effectively recruit immune cells to attack tumor cells. MCLA-128 employs a 'dock and block' mechanism in which the HER2 receptor binding orientates the HER3 binding arm to effectively block oncogenic signaling through the HER2:HER3 heterodimer even under high heregulin concentrations.

#### **About MCLA-117**

MCLA-117 is an Fc-silenced Biclomics<sup>®</sup> 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. Through Fc-silencing, MCLA-117 avoids binding to Fc receptors present on macrophages and other blood cells that could result in toxicity.

#### **About MCLA-158**

MCLA-158 is an ADCC-enhanced Biclomics<sup>®</sup> 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 Biclomics<sup>®</sup>. Biclomics<sup>®</sup> 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 expected to begin a Phase 2 clinical 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.

#### **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 clinical trial of MCLA-128 in MBC patients, the timing for meeting clinical and regulatory milestones for MCLA-117 and MCLA-158, the treatment potential of our Biclomics<sup>®</sup> candidates, including their ability to treat cancer, the effectiveness of Ms. Margetson's departure from Merus, and 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 Biclomics<sup>®</sup> and 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 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<sup>®</sup> 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; our ability to protect 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; 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)

	March 31, 2017	December 31, 2016
	(euros in thousands)	
<b>Non-current assets</b>		
Property, plant and equipment	758	648
Intangible assets	358	374
Restricted cash	—	167
	<b>1,116</b>	1,189
<b>Current assets</b>		
Financial asset	—	11,847
Taxes and social security assets	1,082	—
Trade and other receivables	2,190	2,357
Cash and cash equivalents	236,512	56,917
	<b>239,784</b>	71,120
<b>Total assets</b>	<b>240,900</b>	72,310
<b>Shareholders' equity</b>		
Issued and paid-in capital	1,745	1,448
Share premium account	213,523	139,878
Accumulated loss	(123,985 )	(107,295 )
Total equity	<b>91,283</b>	34,031
<b>Non-current liabilities</b>		
Borrowings	—	319
Deferred revenue	135,529	30,206
<b>Current liabilities</b>		
Borrowings	—	167
Trade payables	4,275	2,298
Taxes and social security liabilities	203	29
Deferred revenue	6,943	1,610
Other liabilities and accruals	2,667	3,650
	<b>14,088</b>	7,754
<b>Total liabilities</b>	<b>149,617</b>	38,280
<b>Total equity and liabilities</b>	<b>240,900</b>	72,310

### Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three month period ended	
	March 31,	
	2017	2016
	(euros in thousands, except per share data)	
<b>Revenue</b>	<b>2,286</b>	847
Research and development costs	(7,007 )	(4,206 )
Management and administration costs	(4,202 )	(518 )
Other expenses	(1,843 )	(1,613 )
<b>Total operating expenses</b>	<b>(13,052 )</b>	(6,337 )
<b>Operating result</b>	<b>(10,766 )</b>	(5,490 )
Finance income	190	33
Finance costs	(10,734 )	(5 )
<b>Total finance income / (expenses)</b>	<b>(10,544 )</b>	28
<b>Result before tax</b>	<b>(21,310 )</b>	(5,462 )
Income tax expense	(11 )	—

<b>Result after taxation</b>	<b>(21,321</b>	<b>)</b>	<b>(5,462</b>	<b>)</b>
<b>Other comprehensive income</b>				
Exchange differences on the translation of foreign operations	5		3	
<b>Total other comprehensive loss for the period</b>	<b>5</b>		<b>3</b>	
<b>Total comprehensive loss for the period</b>	<b>(21,316</b>	<b>)</b>	<b>(5,459</b>	<b>)</b>
<b>Basic (and diluted) loss per share*</b>	<b>(1.15</b>	<b>)</b>	<b>(0.63</b>	<b>)</b>

\* For the periods included in these financial statements, the share options are not included in the diluted loss per share calculation as the Company was loss-making in all these periods. Due to the anti-dilutive nature of the outstanding options, basic and diluted loss per share is equal. Basic and diluted loss per share as of March 31, 2016 was adjusted to conform to the current period presentation.

Contacts:

Media:

Eliza Schleifstein  
+1 973 361 1546  
[eliza@argotpartners.com](mailto:eliza@argotpartners.com)

Investors:

Kimberly Minarovich  
+1 646 368 8014  
[kimberly@argotpartners.com](mailto:kimberly@argotpartners.com)

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