

Merus

Merus Announces Financial Results for the First Quarter and Provides Business Update

May 6, 2021

*Clinical data update on zenocutuzumab selected for oral presentation at ASCO
MCLA-145 clinical update planned for 2H21
MCLA-129 first patient dosed in phase 1/2 trial
Cecile Geuijen, Ph.D., promoted to Chief Scientific Officer*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 06, 2021 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", the "Company," "we", or "our"), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclomics[®] and Triclomics[®]), today announced financial results for the first quarter that ended March 31, 2021, and provided a business update.

"We have made significant progress on our clinical programs this quarter and we are excited to provide a clinical data update on Zeno in an oral presentation at ASCO in June, and on MCLA-145 later this year," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "In addition we continue to validate our multispecific platforms with our recent value-generating deal with Loxo Oncology at Lilly, progress with our Incyte collaboration and further development of our own pipeline, including the start of clinical development for MCLA-129."

Clinical Programs

Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclomics[®])

Oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

Title: Efficacy and safety of zenocutuzumab in advanced pancreas cancer and other solid tumors harboring NRG1 fusions

Abstract #: 3003

Session Title: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

Session Date and Time: June 4, 2021, 11:00 AM-2:00 PM EDT

We plan to present interim efficacy and safety data from the eNRGy trial and Early Access Program (EAP) of Zeno in patients with NRG1 fusion positive (NRG1+) pancreatic, non-small cell lung and other cancers.

Zeno is currently in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. We continue to be encouraged by the ongoing trial, observed clinical activity and safety profile and look forward to sharing an interim clinical data update at ASCO on June 4.

In the first quarter of 2021, we opened additional clinical trial sites, which are now at more than 35 locations, and we entered into more agreements and collaborations with companies and medical organizations with the goals of raising awareness of the eNRGy trial and providing access to molecular screening opportunities for eligible patients with cancers that may have NRG1 fusions. Merus is now working with more than ten different industry and academic collaborations across Asia, North America and Europe aimed to enhance testing for NRG1 fusions and to raise awareness of the eNRGy trial.

Details of the eNRGy trial can be found at www.ClinicalTrials.gov and Merus' trial website at www.nrg1.com, or by calling 1-833-NRG-1234.

At the American Association for Cancer Research 2021 Annual Meeting we presented two posters on the mechanism of action of Zeno. Both posters present preclinical data demonstrating that the Dock & Block[®] activity of Zeno can potently inhibit NRG1 (and NRG1 fusion) signaling through HER3:HER2 and tumorigenesis. In addition, a dose dependent inhibition of tumor growth was observed in NRG1 fusion lung and ovarian cancers in a mouse model.

Both posters can be found on our [website](#).

MCLA-158 (Lgr5 x EGFR Biclomics[®]): Solid Tumors

Phase 1 trial continues with dose expansion cohorts

Phase 1 clinical trial of MCLA-158 is ongoing in the dose expansion phase of the open-label, multicenter trial. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues and preliminary evidence of antitumor activity has been observed.

MCLA-145 (CD137 x PD-L1 Biclomics[®]): Solid Tumors

Phase 1 trial clinical data will be presented 2H21

The phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing and consists of dose escalation followed by dose expansion. MCLA-145 is the first drug candidate co-developed under Merus' global collaboration and license agreement with Incyte Corporation, which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the Biclomics[®] platform. Merus has full rights to develop and commercialize MCLA-145 if approved in the United States and Incyte is responsible for its development and commercialization outside the United States.

MCLA-129 (EGFR x c-MET Biclomics[®]): Solid Tumors

First patient dosed in the phase 1/2 trial

Enrollment is on-going in the phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. MCLA-129 is a Biclomics[®], which binds to EGFR and c-MET and is being investigated for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers, and upregulation of c-MET signaling has been associated with resistance to EGFR inhibition.

At the American Association for Cancer Research 2021 Annual Meeting, we presented data that demonstrate in preclinical models MCLA-129 blocks EGF and HGF binding to their respective receptors EGFR and c-MET and MCLA-129's enhanced Fc is capable of potent promotion of antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis. The data also show MCLA-129 potentially inhibits NSCLC tumor growth as monotherapy and in combination with an EGFR TKI and overcomes HGF-mediated EGFR-TKI resistance in preclinical models.

The poster can be found on our [website](#).

Corporate Activities

In May, Merus promoted Cecile Geuijen, Ph.D, to Chief Scientific Officer. Cecile joined Merus twelve years ago as Senior Scientist. Dr. Geuijen has over two decades of experience in discovering and developing antibodies as medicines for clinical evaluation. "We are delighted to have Cecile join our Management Team as CSO," said Bill Lundberg, M.D. CEO of Merus. "She is an outstanding scientist and leader, having a pivotal role in the discovery, design and development of each of Merus' current clinical-stage assets and many of our preclinical programs." Before joining Merus, Cecile worked on the identification of new therapeutic targets in oncology at Crucell and evaluated new therapeutic targets in oncology at Genmab. She holds a Ph.D. in Biology from the University of Utrecht, was a Marie Curie Fellow at the Duve Institute in Brussels and completed Post-Doctoral studies in cancer biology at the Dutch NKI.

Expanding Collaborations

In January 2021 Merus and Loxo Oncology at Lilly, a research and development group of Eli Lilly and Company (Lilly) announced a research collaboration and exclusive license agreement that will leverage Merus' proprietary Biclomics[®] platform along with the scientific and rational drug design expertise of Loxo Oncology at Lilly to research and develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies. Merus received an upfront cash payment of \$40 million, as well as an equity investment by Lilly of \$20 million in Merus common shares. Merus is also eligible to receive up to \$540 million in potential development and commercialization milestones per product, for a total of up to approximately \$1.6 billion for three products, as well as tiered royalties ranging from the mid-single to low-double digits on product sales should Lilly successfully commercialize a therapy from the collaboration. Under the terms of the agreement, Merus will lead the discovery and early-stage research and Loxo Oncology at Lilly will be responsible for subsequent research, development and commercialization activities.

Cash Runway extended, Merus expects to be funded to at least 2H 2024 through its second follow-on offering and Lilly upfront cash payment and equity investment

On January 21, 2021, Merus successfully priced its second follow-on offering since its 2016 IPO, raising a total of approximately \$129.4 million in net proceeds. Based on the Company's current operating plan, we expect our existing cash, cash equivalents and marketable securities inclusive of the proceeds of \$60.0 million from the collaboration with and equity investment by Lilly in January 2021 and aggregate net proceeds from the January follow-on offering will fund Merus' operations at least into the second half of 2024.

Annual General Meeting and Board of Directors

The Company's annual general meeting of shareholders (AGM) is planned to be held on May 28, 2021.

First Quarter 2021 Financial Results

We ended the first quarter with cash, cash equivalents and marketable securities of \$374.4 million compared to \$207.8 million at December 31, 2020. The increase was primarily the result of net proceeds from our follow-on offering and proceeds from the collaboration with and equity investment by Lilly, net of cash used in operations and other items.

Collaboration revenue for the three months ended March 31, 2021 increased by \$2 million as compared to the three months ended March 31, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of \$1.4 million that commenced in the first quarter, and \$0.8 million increases related to Incyte reflecting activities in the period for MCLA-145. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended March 31, 2021 increased by \$3.8 million as compared to the three months ended March 31, 2020, primarily as a result of an increase in external and manufacturing costs related to our programs and stock-based compensation.

General and administrative expense for the three months ended March 31, 2021 increased by \$0.4 million as compared to the three months ended March 31, 2020, which is not a significant change and no significant offsetting items in the period.

Other income, net for the three months ended March 31, 2021 was \$11.7 million as compared to \$3.2 million for the three months ended March 31, 2020. Other income, net consists of interest earned on the Company's cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains on the Company's foreign denominated cash, cash equivalents and marketable securities.

MERUS N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(Amounts in thousands, except per share data)

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 327,137	\$ 163,082
Marketable securities	47,248	44,673
Accounts receivable	294	46
Accounts receivable (related party)	1,631	1,623
Prepaid expenses and other current assets	9,814	8,569
Total current assets	<u>386,124</u>	<u>217,993</u>
Property and equipment, net	3,766	4,115
Operating lease right-of-use assets	3,501	3,907
Intangible assets, net	2,645	2,843

Deferred tax assets		41	410
Other assets		1,872	1,949
Total assets		<u>\$ 397,949</u>	<u>\$ 231,217</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	3,715	\$ 3,126
Accrued expenses and other liabilities		22,356	21,803
Income taxes payable		—	206
Current portion of lease obligation		1,130	1,432
Current portion of deferred revenue		7,070	625
Current portion of deferred revenue (related party)		18,684	19,554
Total current liabilities		<u>52,955</u>	<u>46,746</u>
Lease obligation		2,397	2,521
Deferred revenue, net of current portion		34,752	237
Deferred revenue, net of current portion (related party)		71,308	79,450
Total liabilities		<u>161,412</u>	<u>128,954</u>
Stockholders' equity:			
Common shares, €0.09 par value; 45,000,000 shares authorized; 38,271,641 and 31,602,953 shares issued and outstanding as at March 31, 2021 and December 31, 2020, respectively	\$	3,940	\$ 3,211
Additional paid-in capital		643,183	490,093
Accumulated other comprehensive income		(320)	9,071
Accumulated deficit		(410,266)	(400,112)
Total stockholders' equity		<u>236,537</u>	<u>102,263</u>
Total liabilities and stockholders' equity	\$	<u>397,949</u>	<u>\$ 231,217</u>

MERUS N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(Amounts in thousands, except per share data)

	Three Months Ended	
	March 31,	
	2021	2020
Collaboration revenue	\$ 1,599	\$ 328
Collaboration revenue (related party)	6,751	5,973
Total revenue	<u>8,350</u>	<u>6,301</u>
Operating expenses:		
Research and development	20,806	16,987
General and administrative	9,333	8,882
Total operating expenses	<u>30,139</u>	<u>25,869</u>
Operating loss	(21,789)	(19,568)
Other income, net:		
Interest (expense) income, net	(82)	280
Foreign exchange gains	12,203	2,885
Other losses	(437)	—
Total other income, net	<u>11,684</u>	<u>3,165</u>
Net loss before income taxes	(10,105)	(16,403)
Income tax expense	49	97
Net loss	<u>\$ (10,154)</u>	<u>\$ (16,500)</u>
Other comprehensive loss:		
Currency translation adjustment	(9,391)	(3,107)
Comprehensive loss	<u>\$ (19,545)</u>	<u>\$ (19,607)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.28)	\$ (0.68)
Weighted-average common shares outstanding:		
Basic and diluted	36,210	28,946

About Merus N.V.

Merus is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as Multiclonics®. Multiclonics® 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, please visit Merus' website, www.merus.nl and <https://twitter.com/MerusNV>.

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 marketable securities; the content and timing of potential milestones, updates, guidance, information, clinical trials and

data readouts for our product candidates, including with respect to the phase 1/2 eNRGy trial, EAP and planned presentation at ASCO in June 2021, the advancement of the Phase 1 trial of MCLA-145, and plan to present a clinical update at a major medical conference in 2H 2021, the advancement of the phase 1 trial for MCLA-158, and the advancement of the phase 1/2 trial for MCLA-129; the design and treatment potential of our bispecific antibody candidates, clinical study designs, the preclinical data and further advancement of our internal pipeline; our belief of the promise of and potential benefit of our clinical assets; the impact and benefit, if any, from increased clinical trial site opening, and agreements and collaborations with companies and medical organizations in North America, Europe and Asia with the goal of raising awareness of the eNRGy trial and providing molecular screening opportunities for eligible patients with cancers that may have NRG1 fusions; the continued enrollment of patients with gastro-esophageal and head-and-neck cancer in the MCLA-158 trial in the dose expansion phase, and preliminary evidence of antitumor activity observed; the benefits of a collaboration between Loxo Oncology at Lilly and Merus, its potential for future value generation, including whether and when Merus will receive any future payment under the collaboration, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; Merus' and Lilly's activities under the agreement; and our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclomics® platform. 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 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; impacts of the COVID-19 pandemic; 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 10-K for the period ended December 31, 2020 filed with the Securities and Exchange Commission, or SEC, on March 16 2021, 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.

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The Merus logo consists of the word "Merus" in a bold, blue, sans-serif font. The letter "M" is significantly larger than the other letters, and the "e" and "s" are also larger than the "r" and "u".