Merus Announces Financial Results for the Fourth Quarter and Full Year 2020 and Provides Business Update

March 16, 2021

Clinical data and program update planned for lead program zenocutuzumab (“Zeno”) in 2Q 2021

Clinical update planned for MCLA-145 in 2H 2021

MCLA-129 expected to enter clinic in the United States in 2021

UTRECHT, The Netherlands and CAMBRIDGE, Mass., March 16, 2021 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (“Merus”, “we”, or “our”), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®), today announced financial results for the fourth quarter and full year ended December 31, 2020 and provided a business update.

“We have made significant progress in 2020, advancing our clinical programs, further developing our discovery and research pipeline and strengthening our financial position,” said Bill Lundberg, M.D., Chief Executive Officer of Merus. “Our most advanced program zenocutuzumab remains on track for a clinical update on more than 30 patients with NRG1 fusion cancers in 2Q21, and we plan to bring our next program, MCLA-129, into the clinic in the US this year. In addition, our best-in-class Biclonics®, bispecific antibody technology platform has been further validated by the significant collaboration with Loxo Oncology at Lilly, as we announced earlier this year. We look forward to a productive year across our entire portfolio of innovative cancer therapeutic candidates.”

Clinical Programs and Business Update

Zenocutuzumab, or “Zeno” (MCLA-128: HER3 x HER2 Biclonics ®)
NRG1 gene fusion (NRG1+) Cancers: Phase 1/2 eNRGy trial clinical data and program update planned for Q2 2021

We plan to present efficacy and safety data from the eNRGy trial and Early Access Program (EAP) at the 2021 American Society of Clinical Oncology Annual Meeting with results on more than 30 patients with NRG1+ pancreatic, non-small cell lung and other cancers across the eNRGy trial and EAP with the opportunity for four or more months of follow up. At that time, we plan to also discuss details of the program and overall strategy.

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 believe that Zeno continues to demonstrate encouraging single agent activity in NRG1+ cancers and has been observed to be well tolerated, consistent with previously reported safety data in the overall patient population treated with Zeno monotherapy.

In August 2020, Zeno was granted Orphan Drug Designation by the U.S. Food and Drug Administration for pancreatic cancer and in January 2021, Fast Track Designation for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy.

Over the course of 2020 we have engaged in a series of agreements and collaborations with companies and medical organizations worldwide with the goals of raising awareness of the eNRGy trial and providing molecular screening opportunities for eligible patients with cancers that may have NRG1 fusions.

Details of the eNRGy trial, including current trial sites, can be found at clinicaltrials.gov and Merus’ trial website at www.nrg1.com, or by calling 1-833-NRG-1234.

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors
Phase 1 trial continues: dose expansion in patients with gastro-esophageal and head-and-neck cancers

We are developing MCLA-158 for the potential treatment of solid tumors. Our phase 1 clinical trial of MCLA-158 is ongoing in the dose expansion phase.

On January 15, 2021, we presented in a poster session interim clinical data from the phase 1 dose escalation study of MCLA-158 at the American Society of Clinical Oncology 2021 Gastrointestinal Cancers Symposium. As of a data cut-off of September 2020, MCLA-158 was administered to 33 patients over 11 dose levels (5-1500 mg, flat dose), a heavily pretreated population having received a median of four lines of prior therapy. As of the cut-off date, MCLA-158 was observed to be well tolerated, and no dose limiting toxicities occurred. The recommended phase 2 dose was established at 1500 mg administered intravenously once every two weeks. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues at this dose in the expansion phase of the open-label, multicenter trial, and preliminary evidence of antitumor activity has been observed.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial advancing with clinical update planned for 2H 2021

MCLA-145 is currently being evaluated in a phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, in patients with solid tumors. MCLA-145 is the first drug candidate co-developed under our global collaboration and license agreement with Incyte Corporation (Incyte), which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. Merus retains 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. We plan to present a clinical update at a major medical conference in the second half of 2021.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
First patient planned to be dosed in 2021

We plan to evaluate MCLA-129 in a phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, for the treatment of various solid tumors, with a plan to dose a first patient in the United States in 2021. MCLA-129 is subject to collaboration and license agreement, which permits Betta Pharmaceuticals Co. Ltd. (Betta) to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights.

In January 2021, Betta announced that the Chinese National Medical Products Administration had accepted its Investigational New Drug application of MCLA-129 injection.

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 Biclonics® 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 additional research, development and commercialization activities.

Runway extended to at least 2H 2024

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 a follow-on offering of $129.7 million in January 2021, will fund Merus' operations at least into the second half of 2024.

Full Year 2020 Financial Results

Collaboration revenue for the year ended December 31, 2020 decreased $1.4 million as compared to the year ended December 31, 2019, primarily as a result of a decrease of $4.1 million in Ono Pharmaceutical milestone revenue due to the achievement of milestones in 2019 that did not recur in 2020, partially offset by an increase in Betta milestone revenue due to a $2.0 million earned in the fourth quarter. The change in exchange rates did not materially impact collaboration revenue.

Research and development expense for the year ended December 31, 2020 increased $14.4 million as compared to the year ended December 31, 2019, primarily as a result of an increase in manufacturing related costs, and higher research and development-related costs related to our programs, particularly increases in costs for zenocutuzumab, and a $2.0 million milestone earned by Betta incurred in the fourth quarter, offset by decreases in costs for MCLA-145.

General and administrative expense for the year ended December 31, 2020 increased $1.7 million as compared to the year ended December 31, 2019, primarily as a result increases in stock-based compensation, insurance, facilities, intellectual property related costs and other items, partially offset by a decrease in consulting and personnel costs.

Other income, net consists of interest earned on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains or losses on our foreign denominated cash, cash equivalents and marketable securities.

Merus ended 2020 with cash, cash equivalents and marketable securities of $207.8 million as compared to $241.8 million at December 31, 2019. The decrease was primarily the result of cash used in operations and the effect of exchange rate changes, offset by the net proceeds received from the issuance of common shares through at the market offerings under an August 2020 Open Market Sale Agreement, between us and Jefferies LLC ("Jefferies"), under which Jefferies acted as sales agent.

Financial Outlook

Based on Merus' current operating plan, Merus expects that its existing cash, cash equivalents and marketable securities of $207.8 million as of December 31, 2020, combined with the aggregate immediate proceeds from the closing of the collaboration license agreement and a share purchase agreement with Lilly in January 2021 of $60.0 million and the aggregate net proceeds from a January 2021 follow-on offering of $129.7 million in January 2021, will fund Merus' operations at least into the second half of 2024.

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

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 163,082	$ 197,612
Marketable securities	44,673	42,153
Accounts receivable	46	941
Accounts receivable (related party)	1,623	1,711
Prepaid expenses and other current assets	8,569	4,951
Total current assets	217,993	247,368
Marketable securities	—	2,009
Property and equipment, net	4,115	3,715
Operating lease right-of-use assets	3,907	5,215
Intangible assets, net	2,843	2,876
Deferred tax assets	410	288
Other assets	1,949	1,905
Total assets	$ 231,217	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,126	$ 3,029
Accrued expenses	21,803	13,536
Taxes payable	206	—

Current portion of lease obligation	1,432	1,380
Current portion of deferred revenue	625	941
Current portion of deferred revenue (related party)	19,554	17,901
Total current liabilities	46,746	36,787
Lease obligation	2,521	3,872
Deferred revenue, net of current portion	237	780
Deferred revenue, net of current portion (related party)	79,450	90,637
Total liabilities	128,954	132,076
Commitments and contingencies		
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 31,602,953 and 28,882,217 shares issued and outstanding as at December 31, 2020 and 2019, respectively	$ 3,211	$ 2,918
Additional paid-in capital	490,093	441,395
Accumulated other comprehensive income	9,071	1,586
Accumulated deficit	(400,112)	(314,599)
Total stockholders' equity	102,263	131,300
Total liabilities and stockholders' equity	$ 231,217	$ 263,376

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

	Year Ended December 31,	
	2020	**2019**
Collaboration revenue	$ 3,363	$ 5,517
Collaboration revenue (related party)	26,580	25,831
Grant revenue	—	(215)
Total revenue	29,943	31,133
Operating expenses:		
Research and development	70,040	55,680
General and administrative	35,781	34,110
Total operating expenses	105,821	89,790
Operating loss	(75,878)	(58,657)
Other income, net:		
Interest income, net	300	1,889
Foreign exchange (losses) gains	(9,432)	1,615
Miscellaneous income and gains	—	196
Other income, net	(9,132)	3,700
Loss before income taxes	(85,010)	(54,957)
Tax expense	503	194
Net loss	$ (85,513)	$ (55,151)
Other comprehensive loss:		
Currency translation adjustment	7,485	(1,308)
Comprehensive loss	$ (78,028)	$ (56,459)
Loss per share allocable to common stockholders:		
Basic and diluted	$ (2.92)	$ (2.28)
Weighted average shares outstanding:		
Basic and diluted	29,256,203	24,218,083

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 Statements

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, phase 1 trial for MCLA-145, MCLA-158, and expected phase 1 trial for MCLA-129; the design and treatment potential of our bispecific antibody candidates, clinical study designs, the preclinical data; our belief of the promise of and potential benefit of our clinical assets, guidance that zenocutuzumab remains on track for a clinical update on more than 30 patients with NRG1 fusion cancers in 2Q21 and plan to discuss details of the program and overall strategy; the plan to for MCLA-129 to dose a first patient in the United States in 2021; the impact and benefit, if any, from agreements and collaborations with companies and medical organizations in 2020 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 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 benefits of a collaboration between Loxo Oncology at Lilly and Merus; 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; our clinical trials; our belief in our multispecific technology platforms being best in class and validated by the collaboration with Loxo Oncology at Lilly; productivity for the remainder of 2021 across our entire portfolio; our collaborations with Betta; and our global collaboration and license agreement with Incyte, potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® 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 Biclonics® 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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