Merus Announces Financial Results for the Fourth Quarter and Full Year 2021 and Provides Business Update

February 28, 2022

As of February 2022, more than 100 patients with NRG1 gene fusion positive ("NRG1+") cancer have been treated with zenocutuzumab ("Zeno") monotherapy

Clinical data updates planned for lead program Zeno in 1H22 and for petosemtamab ("MCLA-158") and MCLA-129 in 2H22

Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations beyond 2024

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Feb. 28, 2022 (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, 2021 and provided a business update.

"We made significant progress in 2021, advancing our clinical programs, further developing our discovery and research pipeline and strengthening our balance sheet," said Bill Lundberg, M.D., President and Chief Executive Officer of Merus. "Our most advanced product candidate, zenocutuzumab remains on track for a clinical update on the eNRGy trial in the first half of 2022, and, if the rate of enrollment and efficacy remain consistent, we believe a sufficient number of patients will be enrolled in the eNRGy trial and Early Access Program, with sufficient follow up, by mid-2022, that could form the basis of a potential registrational data set. We also plan to provide clinical updates on our second most-advanced candidate, petosemtamab, and on MCLA-129 in the second half of this year."

Clinical Programs and Business Update

Zenocutuzumab, or "Zeno" (MCLA-128: HER3 x HER2 Biclonics ®)
NRG1+ Cancer: Phase 1/2 eNRGy trial clinical data and program update planned for first half of 2022

Zeno is currently being investigated in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer.

As of February 2022, more than 100 patients with NRG1+ cancer have been treated with Zeno monotherapy in our phase 1/2 eNRGy trial and Early Access Program ("EAP"). Merus plans to provide a clinical program update in the first half of 2022. In June 2021, Merus shared interim clinical data from an April 2021 data cutoff, demonstrating encouraging early clinical activity, with confirmed partial response rates observed to be 42% in NRG1+ pancreatic cancer (5 of 12), and 29% across all NRG1+ tumor types treated (13 of 45).

In November 2021, Merus reported that it met with the U.S. Food and Drug Administration (FDA) in an end-of-phase Type B meeting to discuss interim results from the ongoing phase 1/2 eNRGy trial and EAP in NRG1+ cancer, and to discuss the development plan for Zeno. Based on feedback received from the FDA, Merus believes that the trial design and planned enrollment will be appropriate to potentially support a Biologics License Application ("BLA") submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancer.

In January 2021, the FDA granted Fast Track Designation to Zeno for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions (NRG1+ cancers) that have progressed on standard of care therapy.

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.

Petosemtamab, or "Peto" (MCLA-158: Lgr5 x EGFR Biclonics®): Solid Tumors
Dose expansion continues in the phase 1 trial: update planned for second half of 2022

Peto is currently enrolling in a phase 1 open-label, multicenter study, and is in the expansion phase, in patients with solid tumors.

In October 2021, Merus reported early interim clinical data of our Peto program in patients with advanced head and neck squamous cell carcinoma (HNSCC) at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. Among 10 patients with previously treated advanced HNSCC, as of the August 9, 2021 safety and efficacy data cutoff, the median age was 65 and the median number of prior lines of therapy was two. Seven patients were evaluable for an interim efficacy analysis by investigator assessment (three patients were enrolled <8 weeks before the data cutoff date). Three of seven patients achieved a partial response, with one of these three achieving complete response after the data cutoff date. Tumor reduction was observed in the target lesions of all seven patients. The safety results presented for Peto were based on 29 patients with advanced solid tumors who were treated at the recommended phase 2 dose across the phase 1 trial, and, as of the data cutoff, the most frequent adverse events (AEs) were infusion related reactions with 72% any grade and 7% grade 3 or greater. Mild to moderate skin toxicity (3% grade ≥3) was also observed.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial continues

MCLA-145 is currently enrolling a global, phase 1, open-label, single-agent clinical trial evaluating MCLA-145 in patients with solid tumors. In December 2021, Merus reported interim clinical data on MCLA-145 from the phase 1 trial in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021. As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors with median age of 60.5 years had been treated at 8 dose levels ranging from 0.4-75mg Q2W. The median (range) duration of treatment was approximately 6 (1-74) weeks. AEs observed were consistent with the mechanism of action of MCLA-145 and were generally managed with drug interruption and/or steroids in some patients. Preliminary evidence of antitumor activity was observed at doses ≥ 25 mg. Robust

T-cell activation was observed across the 10 to 75 mg biweekly dosing range, including activation of cytotoxic CD8+ cells and elevation of cytokines.

Following Incyte's (Nasdaq: INCY) election to opt-out of its ex-U.S. development of MCLA-145, announced earlier this year, Merus holds global rights to this program. Further clinical evaluation of MCLA-145 is planned, both as monotherapy and in combination with a PD-1 blocking antibody.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Dose escalation continues in the phase 1 trial: update planned for the second half of 2022

MCLA-129 is currently enrolling in a phase 1/2, open-label clinical trial consisting of dose escalation followed by a planned dose expansion. Primary objectives of phase 1 are to determine the maximum tolerated dose and/or the recommended phase 2 dose, and the objectives of phase 2 are to evaluate safety, tolerability and potential clinical activity of the recommended phase 2 dose in patients with advanced solid tumors. MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to exclusively develop MCLA-129 in China, while Merus retains global rights outside of China. In October 2021, Betta announced that the first patient was dosed in a phase 1/2 trial in China sponsored by Betta, of MCLA-129 in patients with advanced solid tumors.

Collaborations Update

Incyte

In the third quarter of 2021 Merus received a milestone payment for achieving pre-clinical candidate nomination of a novel bispecific antibody (target pair program) under the global collaboration and license agreement with Incyte. Candidate nomination has triggered this program's next phase of IND-enabling studies by Incyte.

Merus receives reimbursement for research activities related to the collaboration and is eligible to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved.

Loxo Oncology at Lilly

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 to develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies. The collaboration is progressing well with active research programs underway.

Corporate Activities

Completed two Public Offerings in 2021

In January and November 2021, Merus closed two public offerings, with the cumulative gross proceeds from the offerings of approximately $250 million, inclusive of underwriters' 30-day option to purchase additional common shares at the public offering price. All of the shares in the offering were sold by Merus. Proceeds from these offerings are planned to be used to continue to fund Merus' product candidates in clinical and preclinical development, as well as for general corporate purposes.

Shannon Campbell Appointed as Chief Commercial Officer

In February 2022, Merus appointed Ms. Campbell as Executive Vice President and Chief Commercial Officer to lead the commercial strategy for the most advanced clinical candidate, Zeno, as well as Merus' robust pipeline of multispecific product candidates in development. Ms. Campbell brings over 25 years of pharmaceutical commercialization experience and joins Merus from Novartis Pharmaceuticals Corporation, where she led Novartis's U.S. Oncology Solid Tumor Franchise and was responsible for a broad portfolio of therapies in oncology and rare diseases. Prior to Novartis, Ms. Campbell was with Bayer HealthCare Pharmaceuticals, where she was instrumental in helping to build, launch and lead Bayer's U.S. Oncology business.

Cash Runway projected to be beyond 2024

Based on the Company's current operating plan, Merus expects our existing cash, cash equivalents and marketable securities will fund Merus' operations beyond 2024.

Full Year 2021 Financial Results

Collaboration revenue for the year ended December 31, 2021 increased $19.2 million as compared to the year ended December 31, 2020, primarily as a result of $17.3 million in Lilly reimbursement revenue that did not occur in 2020, increase of $3.0M in Incyte reimbursement, partially offset by a decrease in other collaboration revenue of $1.2M. The change in exchange rates did not materially impact collaboration revenue.

Research and development expense for the year ended December 31, 2021 increased $28.1 million as compared to the year ended December 31, 2020, 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 for MCLA-129.

General and administrative expense for the year ended December 31, 2021 increased $5.1 million as compared to the year ended December 31, 2020, primarily as a result increases in stock-based compensation, insurance, facilities, and personnel costs, partially offset by a decrease in consulting.

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 2021 with cash, cash equivalents and marketable securities of $430.7 million as compared to $207.8 million at December 31, 2020. The increase was primarily the result of closing of the collaboration and license agreement and a share purchase agreement with Eli Lilly in January 2021 for a total of $60.0 million, the aggregate net proceeds from the January 2021 follow-on offering of $129.4 million and the aggregate net proceeds from the November 2021 follow-on offering of $118.7 million.

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CONSOLIDATED BALANCE SHEETS
(Amounts in thousands except per share data)

	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 241,435	$ 163,082
Marketable securities	168,990	44,673
Accounts receivable	1,697	46

Accounts receivable (related party)	4,609	1,623
Prepaid expenses and other current assets	7,448	8,569
Total current assets	424,179	217,993
Marketable securities	20,297	—
Property and equipment, net	3,549	4,115
Operating lease right-of-use assets	3,733	3,907
Intangible assets, net	2,347	2,843
Deferred tax assets	417	410
Other assets	2,078	1,949
Total assets	$ 456,600	$ 231,217
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,237	$ 3,126
Accrued expenses and other liabilities	22,506	21,803
Income taxes payable	—	206
Current portion of lease obligation	1,494	1,432
Current portion of deferred revenue	16,613	625
Current portion of deferred revenue (related party)	18,048	19,554
Total current liabilities	71,898	46,746
Lease obligation	2,257	2,521
Deferred revenue, net of current portion (related party)	55,282	79,450
Total liabilities	140,399	128,954
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 and 45,000,000 shares authorized as at December 31, 2021 and 2020, respectively; 43,467,052 and 31,602,953 shares issued and outstanding as at December 31, 2021 and 2020, respectively	$ 4,481	$ 3,211
Additional paid-in capital	787,869	490,093
Accumulated deficit	(466,928)	(400,112)
Accumulated other comprehensive (loss) income	(9,221)	9,071
Total stockholders' equity	316,201	102,263
Total liabilities and stockholders' equity	$ 456,600	$ 231,217

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Collaboration revenue	$ 19,503	$ 3,363	$ 5,517
Collaboration revenue (related party)	29,604	26,580	25,831
Grant revenue	—	—	(215)
Total revenue	49,107	29,943	31,133
Operating expenses:			
Research and development	98,187	70,040	55,680
General and administrative	40,896	35,781	34,110
Total operating expenses	139,083	105,821	89,790
Operating loss	(89,976)	(75,878)	(58,657)
Other income (loss), net:			
Interest (expense) income, net	(129)	300	1,889
Foreign exchange (losses) gains, net	24,663	(9,432)	1,615
Other (losses) gains, net	(1,135)	—	196
Total other income (loss), net	23,399	(9,132)	3,700
Loss before income tax expense	(66,577)	(85,010)	(54,957)
Income tax expense	239	503	194
Net loss	$ (66,816)	$ (85,513)	$ (55,151)
Other comprehensive income (loss):			
Currency translation adjustment	(18,292)	7,485	(1,308)
Comprehensive loss	$ (85,108)	$ (78,028)	$ (56,459)
Net loss per share allocable to common stockholders:			
Basic and diluted	$ (1.73)	$ (2.92)	$ (2.28)
Weighted-average common shares outstanding:			
Basic and diluted	38,638,434	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 content and timing of clinical trials, data readouts and clinical updates for our product candidates, including with respect to enrollment and timing of data in our eNRGY trial, the treatment potential of Zeno, the design of the eNRGY clinical trial; our belief that the design and planned enrollment will be appropriate to potentially support a BLA submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers; our belief that, if the rate of enrollment and efficacy remain consistent, we believe a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, that could form the basis of a potential registrational data set, and the impact of regulatory interactions on our development of product candidates; statements regarding the sufficiency of our cash, cash equivalents and marketable securities; the advancement of the phase 1/2 eNRGy trial and planned update by the first half of 2022; the advancement of the Phase 1 trial of MCLA-145, planned, both as monotherapy and in combination with a PD-1 blocking antibody; the advancement of the phase 1 trial for MCLA-158 and the planned update in second half of 2022; the advancement of the phase 1/2 trial for MCLA-129 and the planned update in second half of 2022; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; our global collaboration and license agreement with Incyte, and our eligibility to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved; our collaboration and exclusive license agreement with Lilly and whether any programs under the collaboration will be successful; our collaboration and license agreement with Betta, which permits Betta to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights, and any developments that may arise from these agreements; Merus' appointment of Ms. Campbell as Senior Vice President & Chief Commercial Officer to lead the commercial strategy for the most advanced clinical candidate, Zeno, as well as Merus' robust pipeline of multispecific product candidates in development; and our intended use of proceeds from the two offering from 2021. 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; our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks; and risks related to our ceasing to qualify as an emerging growth company and a smaller reporting company after December 31, 2021.

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, 2021, filed with the Securities and Exchange Commission, or SEC, on February 28, 2022, 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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