Merus Announces Financial Results for the Fourth Quarter and Full Year 2023 and Provides Business Update

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- *Petosemtamab in 1L HNSCC in combination with pembrolizumab initial interim clinical data planned for 2Q24; preparing for a potential phase 3 trial*
- *Petosemtamab in 2L+ HNSCC phase 3 trial planned to initiate mid-2024; interim clinical data planned for 2H24*
- *Petosemtamab in 2L CRC: cohort planned to initiate in 2024*
- *Zeno in NRG1+ cancer: Sufficient clinical data expected in 1H24 to support potential BLA submissions*
- *Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Feb. 28, 2024 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (Merus, the Company, 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 and provided a business update.

"2024 is poised to be a transformational year for Merus. For petosemtamab, we plan to start a phase 3 registration trial in 2L+ HNSCC in mid-2024. In the first-line setting, we plan to provide initial data on the combination with pembrolizumab in the second quarter and are preparing for a potential first-line phase 3 trial. This year, we also plan to evaluate petosemtamab in 2L colorectal cancer," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "Additionally, for Zeno we are preparing our first potential BLA submissions in NRG1+ lung and NRG1+ pancreatic cancer. We are also excited by continued enhancements to our productive Multiclonics® platforms, which serve as our engine to develop innovative antibodies both for our own pipeline and for our collaborators."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
Phase 3 registration trial in 2L+ head & neck squamous cell carcinoma (HNSCC) on track to initiate mid-2024; dose comparison of petosemtamab monotherapy 1100 vs 1500 mg in previously treated (2L+) HNSCC ongoing; evaluation in combination with pembrolizumab as first-line (1L) therapy ongoing; planned initiation of 2L colorectal cancer (CRC) cohort in 2024

Merus plans to initiate a phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in 2L+ HNSCC. In the planned trial, patients will be randomized to petosemtamab monotherapy or investigators' choice of single agent chemotherapy or cetuximab. Merus believes a randomized registration trial in HNSCC with an overall response rate (ORR) endpoint could potentially support accelerated approval and the overall survival (OS) results from the same study could potentially verify its clinical benefit to support regular approval.

Merus continues to evaluate approximately 40 patients treated with petosemtamab monotherapy at either 1100 or 1500 mg dose levels to confirm a suitable dose for future potential phase 3 trials. Merus plans to share clinical data from this cohort in the second half of 2024.

Merus also continues to evaluate patients with untreated advanced PD-L1+ HNSCC treated with petosemtamab 1500 mg in combination with pembrolizumab. Initial safety data from this single arm cohort may support the initiation of a 1L phase 3 trial with this combination. Among the initial patients dosed in the 1L combination cohort, the safety profile has been observed to be generally favorable. Merus plans to report initial interim efficacy and safety data from this cohort in the second quarter of 2024.

At the American Association of Cancer Research (AACR) Annual Meeting 2023, Merus provided interim data on 49 2L+ HNSCC patients that were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous every two weeks. 43 patients were evaluable for efficacy. As of a February 1, 2023 data cutoff date, the ORR was 37.2% by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 per investigator assessment. Petosemtamab continued to demonstrate a manageable safety profile. Merus plans to provide updated efficacy, durability and safety data of this cohort in the second half of 2024.

The U.S. Food & Drug Administration (FDA) has granted Fast Track Designation (FTD) for petosemtamab for the treatment of patients with recurrent or metastatic HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-programmed cell death protein 1 (anti-PD-1) antibody. FTD is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill unmet medical needs.

In 2024, Merus is planning to initiate the evaluation of petosemtamab monotherapy in 2L CRC.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion-positive (NRG1+) lung, pancreatic and other solid tumors
Sufficient clinical data expected in 1H24 to support potential BLA submissions in NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ pancreatic cancer (PDAC)

Zeno is being investigated in the phase 1/2 eNRGy trial and Early Access Program (EAP) which are assessing the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer.

In 2023, Merus met with the FDA and based on these productive and collaborative discussions, the Company believes it will have sufficient clinical data in the first half of 2024 to support potential Biologics License Application (BLA) submissions in NRG1+ NSCLC and NRG1+ PDAC.

Merus believes that obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved.

In 2023, the FDA granted Breakthrough Therapy Designation (BTD) to Zeno for the treatment of patients with advanced unresectable or metastatic NRG1+ pancreatic

cancer following progression with prior systemic therapy or who have no satisfactory alternative treatment options. Additionally, the FDA granted BTD to Zeno for the treatment of patients with advanced unresectable or metastatic NRG1+ NSCLC, following progression with prior systemic therapy.

Merus shared updated interim clinical data on our Zeno program (eNRGy trial and EAP) in patients with NRG1+ NSCLC and NRG1+ PDAC at the European Society for Medical Oncology (ESMO) Congress 2023. In 78 evaluable NRG1+ NSCLC patients, as of a July 31, 2023 data cutoff date, a 37% ORR per RECIST v1.1 by investigator assessment and 14.9 months median duration of response (DOR) was reported. In 33 evaluable NRG1+ PDAC patients, a 42% ORR per RECIST v1.1 by investigator assessment and 9.1 months median DOR was reported. Zeno continued to demonstrate a well-tolerated safety profile.

Merus also evaluated patients with castration resistant prostate cancer (CRPC) treated with Zeno in combination with an androgen deprivation therapy (enzalutamide or abiraterone), irrespective of NRG1+ status. Enrollment is complete and Merus plans to continue monitoring these patients. The Company also continues to monitor and evaluate patients treated with Zeno in combination with afatinib but no further enrollment is planned at this time.

The Company is also conducting ongoing translational work on potential biomarkers outside of NRG1+ cancer which may support development opportunities for Zeno in additional areas of unmet need.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Investigation of MCLA-129 continues in the MET ex14 NSCLC expansion cohort in the phase 1/2 trial; MCLA-129 in combination with chemotherapy in 2L+ EGFR mutant (EGFRm) NSCLC planned to start in 2024

MCLA-129 is in clinical development in a phase 1/2, open-label clinical trial evaluating MCLA-129 monotherapy in patients with MET ex14 NSCLC and Merus plans to start a cohort of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in 2024.

In December at the ESMO Asia Congress 2023 interim data was presented on MCLA-129 from ongoing expansion cohorts in NSCLC and in previously treated HNSCC. Patients with advanced/metastatic EGFRm NSCLC were treated with MCLA-129 combined with osimertinib as first-line therapy or in the 2L+ setting after progression on osimertinib. In the 1L setting, all 16 evaluable patients experienced tumor shrinkage. In the 2L+ setting, 34 patients were evaluable for response with 11 experiencing confirmed PRs and 1 unconfirmed PR by RECIST v1.1. per investigator assessment. We continue to monitor these patients and evaluate potential for biomarkers to maximize efficacy, while proactively addressing safety signals seen to date.

We also remain interested in exploring partnering MCLA-129 with other companies to sufficiently resource the development of MCLA-129 and potential benefit it may have for patients.

MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains global rights outside of China.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Investigation continues of the phase 1 trial of MCLA-145 in combination with pembrolizumab

MCLA-145 is in clinical development in a global, phase 1, open-label, clinical trial evaluating MCLA-145 in patients with solid tumors. The trial is in the dose expansion phase, with the Company monitoring and evaluating patients on treatment with the combination of MCLA-145 with pembrolizumab.

Collaborations

Incyte Corporation
Since 2017, Merus has been working with Incyte Corporation (Incyte) under a global collaboration and license agreement focused on the research, discovery and development of bispecific antibodies utilizing Merus' proprietary Biclonics® technology platform. The agreement grants Incyte certain exclusive rights for up to ten bispecific and monospecific antibody programs. The collaboration is progressing, with multiple programs in various stages of preclinical and clinical development. For each program under the collaboration, Merus receives reimbursement for research activities and is eligible to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved. Further, Incyte announced, in 2023, that INCA33890, a novel TGFBr2xPD-1 bispecific antibody developed through the collaboration is currently being evaluated in clinical trials. Merus achieved a milestone and received a payment of $2.5 million related to the advancement of this program in the third quarter of 2023. Merus also achieved an additional milestone of $1 million for candidate nomination in the fourth quarter of 2023. This is the third program to undergo candidate nomination under the collaboration.

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 utilizing Merus' Biclonics® platform and proprietary CD3 panel along with the scientific and rational drug design expertise of Loxo Oncology at Lilly. The collaboration is progressing with multiple active research programs underway.

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027
As of December 31, 2023, Merus had $411.7 million cash, cash equivalents and marketable securities. Based on the Company's current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into 2027.

Full Year 2024 Financial Results
Collaboration revenue for the year ended December 31, 2023 increased $2.4 million as compared to the year ended December 31, 2022, primarily as a result of increases in Incyte revenue of $2.6 million, and Lilly revenue of $1.0 million, offset by decreases in Other revenue of $1.2 million. The increase in Incyte revenue is primarily the result of increases in milestone revenue of $5.0 million and upfront payment amortization of $0.4 million due to changes in foreign exchange rates, partially offset by decreases in reimbursement revenue of $2.8 million. The increase in Lilly revenue is primarily the result of increases in reimbursement revenue of $0.7 million and upfront payment amortization of $0.3 million.

Research and development expense for the year ended December 31, 2023 decreased $8.8 million as compared to the year ended December 31, 2022, primarily as a result of decreases in external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements related to our programs of $18.8 million and partner expenses of $0.7 million, partially offset by increases to personnel related expenses including share-based compensation of $6.5 million due to an increase in employee headcount, consultancy expenses of $2.9 million, facilities expenses of $1.1 million, consumables expenses of $0.3 million, and travel expenses of $0.3 million.

General and administrative expense for the year ended December 31, 2023 increased $7.6 million as compared to the year ended December 31, 2022, primarily as a result of increases in consultancy expenses of $3.1 million, personnel related expenses including share-base compensation of $2.1 million due to an increase in employee headcount, intellectual property and licenses expenses of $1.0 million, facilities and depreciation expense of $0.9 million, legal expenses of $0.8 million and travel expenses of $0.5 million, partially offset by decreases in finance and human resources expenses of $0.9 million.

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, and payables and receivables.

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

	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 204,246	$ 147,749
Marketable securities	150,130	142,480
Accounts receivable	2,429	4,051
Prepaid expenses and other current assets	12,009	12,163
Total current assets	368,814	306,443
Marketable securities	57,312	36,457
Property and equipment, net	12,135	12,222
Operating lease right-of-use assets	11,362	12,618
Intangible assets, net	1,800	1,950
Deferred tax assets	1,199	2,041
Other assets	2,872	4,811
Total assets	$ 455,494	$ 376,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,602	$ 9,834
Accrued expenses and other liabilities	38,482	35,590
Income taxes payable	1,646	2,400
Current portion of lease obligation	1,674	1,684
Current portion of deferred revenue	22,685	29,418
Total current liabilities	69,089	78,926
Lease obligation	10,488	11,790
Deferred revenue, net of current portion	19,574	38,771
Total liabilities	99,151	129,487
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 and 67,500,000 shares authorized at December 31, 2023 and 2022, respectively; 57,825,879 and 46,310,589 shares issued and outstanding at December 31, 2023 and 2022, respectively	5,883	4,751
Additional paid-in capital	1,126,054	870,874
Accumulated deficit	(753,061)	(598,122)
Accumulated other comprehensive (loss) income	(22,533)	(30,448)
Total stockholders' equity	356,343	247,055
Total liabilities and stockholders' equity	$ 455,494	$ 376,542

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

	Year Ended December 31,		
	2023	2022	2021
Collaboration revenue	$ 43,947	41,586	$ 19,503
Collaboration revenue (related party)	—	—	29,604
Total revenue	43,947	41,586	49,107
Operating expenses:			
Research and development	140,658	149,424	98,187
General and administrative	59,836	52,200	40,896
Total operating expenses	200,494	201,624	139,083
Operating loss	(156,547)	(160,038)	(89,976)
Other income (loss), net:			
Interest (expense) income, net	14,510	2,722	(129)
Foreign exchange (losses) gains, net	(9,710)	26,022	24,663
Other (losses) gains, net	—	1,059	(1,135)
Total other income (loss), net	4,800	29,803	23,399
Loss before income tax expense	(151,747)	(130,235)	(66,577)
Income tax expense	3,192	959	239
Net loss	$ (154,939)	$ (131,194)	$ (66,816)

Other comprehensive income (loss):			
Currency translation adjustment	7,915	(21,227)	(18,292)
Comprehensive loss	$ (147,024)	$ (152,421)	$ (85,108)
Net loss per share allocable to common stockholders:			
Basic and diluted	$ (3.00)	$ (2.92)	$ (1.73)
Weighted-average common shares outstanding:			
Basic and diluted	51,605,444	44,919,084	38,638,434

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, and LinkedIn.

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, regulatory, strategy and development updates for our product candidates; our belief that 2024 is poised to be a transformational year for Merus; our plan to start a phase 3 registration trial in 2L+ HNSCC in mid-2024; our plan to provide initial interim efficacy and safety data on the combination with pembrolizumab in the second quarter of 2024; our preparation for a potential first-line phase 3 trial of petosemtamab in combination with pembrolizumab in untreated advanced PD-L1+ HNSCC; our plan to initiate investigation of petosemtamab in 2L colorectal cancer patients; our preparing for potential BLA submissions for Zeno in the treatment of NRG1+ PDAC and NRG1+ NSCLC; the continued enhancements to our productive Multiclonics® platforms, which serve as our engine to develop innovative antibodies both for our own pipeline and for our collaborators; our belief that we expect to have data in the 1H of 2024 in NRG1+ NSCLC and NRG1+ PDAC for potential BLA submissions; our preparation for a phase 3 study in 2L+ expected to start mid-2024; the potential design and details of our planned phase 3 trial investigating monotherapy petosemtamab in 2L HNSCC; the enrollment of approximately 40 patients in previously treated HNSCC with petosemtamab monotherapy at the 1100 or 1500 mg dose levels to confirm a suitable dose for future randomized trials and plan to share the clinical data form this cohort in the second half of 2024; our plan to provide updated efficacy, durability and safety data in the second half of 2024 of the cohort disclosed at the AACR Annual Meeting 2023; our plan to initiate a cohort investigating petosemtamab in 2L colorectal cancer; the potential benefits of FTD for petosemtamab and BTD designations for Zeno and the ability of Merus to maintain such designations; our belief that obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved; our continued monitoring and evaluation of patients with CRPC receiving Zeno in combination with ADT, and patients with NRG1+ NSCLC receiving Zeno in combination with afatinib; our conduct of ongoing translational work on potential biomarkers outside of NRG1+ tumors, which may support development opportunities for Zeno in additional areas of unmet need; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2027; the ongoing monitoring and evaluation of patients the phase 1 trial of MCLA-145 in combination with pembrolizumab; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in Met ex14 NSCLC; the ongoing monitoring and evaluation of patients receiving MCLA-129 in combination with osimertinib; our plan to initiate a cohort of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in 2024; the benefits of the 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; our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to ten bispecific and monospecific antibodies from our Biclonics® platform, 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; and our collaboration and license agreement with Betta, which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains full ex-China rights, including any future clinical development by Betta of MCLA-129. 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-Q for the period ended September 30, 2023, filed with the Securities and Exchange Commission, or SEC, on November 2, 2023, 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. Multiclonics®, Biclonics® and Triclonics® are registered trademarks of Merus N.V.

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