Merus Announces Financial Results for the Second Quarter 2023 and Provides Business Update

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– Petosemtamab granted Fast Track Designation for the treatment of patients with recurrent or metastatic head & neck squamous cell carcinoma

– Phase 3 trial of petosemtamab monotherapy in previously treated (2L/3L) head and neck squamous cell carcinoma planned to initiate in mid-2024

– Zeno granted two Breakthrough Therapy Designations in NRG1 fusion (NRG1+) non-small cell lung and pancreatic cancer

– Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2026

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Aug. 07, 2023 (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 second quarter and provided a business update.

"Receiving Fast Track Designation is an important milestone for petosemtamab, which we believe further validates its potential to address the unmet need of patients with previously treated recurrent or metastatic head and neck cancer," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "We also believe the robust clinical data observed in previously treated HNSCC support a phase 3 trial of petosemtamab monotherapy in this setting, which could potentially start in mid-2024. Additionally, we are encouraged by our progress to date with the combination of petosemtamab and Keytruda® as potential front-line therapy in advanced HNSCC, and are evaluating a phase 3 trial in this setting as well."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
Granted Fast Track Designation (FTD) for the treatment of patients with recurrent or metastatic head & neck squamous cell carcinoma (HNSCC), enrollment continues in dose expansion in the phase 1/2 trial with petosemtamab monotherapy in previously treated HNSCC, as well as in combination with Keytruda® (pembrolizumab) as front-line therapy.

Petosemtamab is in clinical development in the expansion part of a phase 1/2 open-label, multicenter trial evaluating petosemtamab monotherapy in patients with advanced solid tumors, including previously treated (recurrent or metastatic) HNSCC. Enrollment is also ongoing in a cohort investigating petosemtamab in combination with Keytruda® in patients with untreated HNSCC to evaluate the safety and clinical activity in this population. Merus plans to report initial interim clinical data from this cohort in the first half of 2024.

Initiation of potential registration-enabling trial

Merus is enrolling up to a total of approximately 40 patients in previously treated (2L/3L) HNSCC with petosemtamab monotherapy at the 1100 or 1500 mg dose levels to confirm a suitable dose for future randomized trials. Based on these data and additional information and analyses, Merus anticipates potentially initiating a randomized phase 3 trial of petosemtamab monotherapy, or investigators' choice of single agent chemotherapy or cetuximab in 2L/3L HNSCC. Merus anticipates such a trial could potentially start in mid-2024. 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 is also evaluating a phase 3 trial investigating petosemtamab with Keytruda® as a potential front-line therapy for advanced HNSCC expressing PD-L1 (CPS > 1), pending analysis of additional data on the tolerability and safety of the drug combination.

Fast Track Designation

The U.S. Food & Drug Administration (FDA) has granted 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.

Interim data from AACR

In April, Merus provided an interim clinical update at the American Association for Cancer Research (AACR) Annual Meeting 2023. As of a February 1, 2023 data cutoff date, 49 previously treated HNSCC patients were treated with petosemtamab at the initial recommended phase 2 dose of 1500 mg intravenously every two weeks. The ORR, in 43 evaluable patients, was 37.2% by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. per investigator assessment. Median duration of response was 6.0 months and median progression free survival was 5.3 months. 63% of responders had an ongoing response at the data cutoff date. Median OS was 11.5 months. Petosemtamab continued to demonstrate a manageable safety profile.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion (NRG1+) cancer and other solid tumors
Granted Breakthrough Therapy Designation (BTD) for both NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ pancreatic cancer; enrollment continues in the eNRGy trial of Zeno monotherapy in NRG1+ cancer and a phase 2 trial of Zeno in combination with androgen deprivation therapy (ADT) in castration resistant prostate cancer (CRPC); as well as in combination with afatinib in NRG1+ non-small cell lung cancer (NSCLC)

The FDA has granted 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 has granted BTD to Zeno for the treatment of patients with advanced unresectable or metastatic NRG1+ NSCLC, following progression with prior systemic therapy. 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 (Phase 1/2: NCT02912949, EAP: NCT04100694).

As of June 2023, more than 175 patients with NRG1+ cancer have been treated with Zeno monotherapy. The company continues to work with the FDA and is focused on accumulating data to support a potential Biologics License Application.

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

Merus plans to present a clinical update on Zeno in NRG1+ cancer at the European Society for Medical Oncology (ESMO) 2023 taking place in Madrid, Spain October 20-24, 2023. The presentations will consist of a mini-oral lecture titled: *Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) non-small cell lung cancer (NSCLC)* and a poster presentation titled: *Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) pancreatic ductal adenocarcinoma (PDAC).*

Further, Merus is evaluating Zeno in combination with an ADT (enzalutamide or abiraterone) in men with CRPC, irrespective of NRG1+ status. Merus plans to provide initial clinical data on Zeno in CRPC in the second half of 2023.

Merus is also evaluating Zeno in combination with afatinib in patients with NRG1+ NSCLC.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Enrollment continues in the expansion cohorts in the phase 1/2 trial; clinical update planned for 2H23

MCLA-129 is in clinical development in a phase 1/2, open-label clinical trial evaluating MCLA-129 monotherapy in patients with EGFR ex20 NSCLC, MET ex14 NSCLC, and in HNSCC, as well as MCLA-129 in combination with Tagrisso®, a third generation EGFR TKI, in patients with treatment-naïve EGFR mutant (m) NSCLC and in patients with EGFRm NSCLC that have progressed on Tagrisso®.

In April, Merus provided a pre-clinical presentation of MCLA-129 in comparison with amivantamab at the AACR Annual Meeting 2023. The Company plans to provide an initial clinical data update from the expansion cohorts, and a further clinical development strategy update in the second half of 2023.

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.

In July, the National Medical Products Administration in China approved the investigational new drug application permitting Betta to investigate the combination of MCLA-129 and befotertinib, a third generation EGFR tyrosine kinase inhibitor, in adult patients in China that have locally advanced or metastatic NSCLC, with an EGFR Exon 19 deletion mutation or Exon 21 (L858R) substitution mutation.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Enrollment continues in the phase 1 trial, including in combination with Keytruda® (pembrolizumab), a PD-1 inhibitor

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 evaluating the combination of MCLA-145 with Keytruda®, with enrollment ongoing.

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 TGFBr2xPD1 bispecific antibody developed through the collaboration is currently being evaluated in clinical studies. In July 2023, Merus achieved a milestone and expects a payment of $2.5 million related to the advancement of this program in the third quarter of 2023.

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 2026
As of June 30, 2023, Merus had $311.5 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 2026.

Second Quarter 2023 Financial Results

We ended the second quarter with cash, cash equivalents and marketable securities of $311.5 million compared to $326.7 million at December 31, 2022.

Collaboration revenue for the three months ended June 30, 2023 decreased by $2.2 million as compared to the three months ended June 30, 2022, primarily as a result of decreases in reimbursement revenue of $0.5 million, milestone revenue of $1.0 million and amortization of deferred revenue of $0.7 million.

Research and development expense for the three months ended June 30, 2023 decreased by $2.8 million as compared to the three months ended June 30, 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 $3.8 million and a decrease in facilities costs of $0.5 million, partially offset by an increase in personnel related expenses including stock-based compensation of $1.5 million due to an increase in employee headcount.

General and administrative expense for the three months ended June 30, 2023 increased by $3.4 million as compared to the three months ended June 30, 2022, primarily as a result of increases in facilities costs including depreciation of $1.6 million, consulting costs of $1.2 million, IP and license costs of $0.4 million, and travel expenses of $0.4 million, partially offset by a decrease in finance and human resources costs of $0.2 million.

Collaboration revenue for the six months ended June 30, 2023 decreased by $0.3 million as compared to the six months ended June 30, 2022, primarily as a result of a decrease in reimbursement revenue of $0.9 million, decrease of amortization of deferred revenue of $0.9 million partially offset by an increase in milestone revenue of $1.5 million.

Research and development expense for the six months ended June 30, 2023 increased by $5.1 million as compared to the six months ended June 30, 2022, primarily as a result of increases in personnel related expenses including stock-based compensation of $3.7 million, external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $1.6 million, consulting expenses of $0.6 million, and consumables expenses of $0.3 million and travel costs of $0.2 million, partially offset by decreases in facilities costs of $0.8 million and partner expenses of $0.5 million. General and administrative expense for the six months ended June 30, 2023 increased by $7.0 million as compared to the six months ended June 30, 2022, primarily as a result of increases in consulting costs of $3.6 million, facilities costs including depreciation of $2.8 million, travel costs of $0.6 million, personnel related expenses including stock-based compensation of $0.5 million due to an increase in employee headcount, and IP and license costs of $0.3 million, partially offset by decreases in finance and human resources costs of $0.8 million.

Other income (loss), net consists of interest earned and fees paid on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange (losses) gains on our foreign denominated cash, cash equivalents and marketable securities. Other gains or losses relate to the issuance and settlement of financial instruments.

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 101,096	$ 147,749
Marketable securities	163,950	142,480
Accounts receivable	2,836	4,051
Prepaid expenses and other current assets	15,243	12,163
Total current assets	283,125	306,443
Marketable securities	46,501	36,457
Property and equipment, net	13,049	12,222
Operating lease right-of-use assets	11,946	12,618
Intangible assets, net	1,882	1,950
Deferred tax assets	3,057	2,041
Other assets	4,064	4,811
Total assets	$ 363,624	$ 376,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,596	$ 9,834
Accrued expenses and other liabilities	31,143	35,590
Income taxes payable	1,349	2,400
Current portion of lease obligation	1,610	1,684
Current portion of deferred revenue	24,151	29,418
Total current liabilities	65,849	78,926
Lease obligation	11,168	11,790
Deferred revenue, net of current portion	29,202	38,771
Total liabilities	106,219	129,487
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized at June 30, 2023 and December 31, 2022; 49,853,659 and 46,310,589 shares issued and outstanding as at June 30, 2023 and December 31, 2022, respectively	5,099	4,751
Additional paid-in capital	948,913	870,874
Accumulated other comprehensive income	(26,711)	(30,448)
Accumulated deficit	(669,896)	(598,122)
Total stockholders' equity	257,405	247,055
Total liabilities and stockholders' equity	$ 363,624	$ 376,542

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 10,476	$ 12,684	$ 23,975	$ 24,339
Total revenue	10,476	12,684	23,975	24,339
Operating expenses:				
Research and development	28,298	31,096	63,163	58,071
General and administrative	16,063	12,695	31,449	24,448

Total operating expenses	44,361	43,791	94,612	82,519
Operating loss	(33,885)	(31,107)	(70,637)	(58,180)
Other income, net:				
Interest income, net	2,795	316	4,790	422
Foreign exchange gains (loss)	551	24,607	(4,890)	32,337
Other gains, net	—	601	—	1,059
Total other income (loss), net	3,346	25,524	(100)	33,818
Net loss before income taxes	(30,539)	(5,583)	(70,737)	(24,362)
Income tax expense	1,494	131	1,037	245
Net loss	$ (32,033)	$ (5,714)	$ (71,774)	$ (24,607)
Other comprehensive loss:				
Currency translation adjustment	(505)	(19,921)	3,737	(25,969)
Comprehensive loss	$ (32,538)	$ (25,635)	$ (68,037)	$ (50,576)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.66)	$ (0.13)	$ (1.52)	$ (0.56)
Weighted-average common shares outstanding:				
Basic and diluted	48,321,708	43,636,337	47,328,259	43,781,195

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 , Twitter 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; Merus' belief that receipt of FTD for petosemtamab validates its potential to address the unmet need of patients with previously treated recurrent or metastatic HNSCC; Merus' belief that the robust clinical data observed in previously treated HNSCC support a phase 3 trial of petosemtamab monotherapy in patients with previously treated head and neck cancer, which could potentially start in mid-2024; the progress to date with the combination of petosemtamab and Keytruda® as potential front-line therapy in advanced head and neck cancer; Merus' anticipation of potentially initiating a randomized phase 3 trial of petosemtamab monotherapy, or investigators' choice of single agent chemotherapy or cetuximab in 2L/3L HNSCC; the potential design and details of such a phase 3 trial; 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; Merus' consideration of conducting a phase 3 trial in front-line therapy in advanced head and neck cancer; the planned interim clinical data update in the first half of 2024 concerning the combination of petosemtamab with Keytruda® in front-line HNSCC; the potential benefits of FTD for petosemtamab and BTD designations for Zeno and the ability of Merus to maintain such designations; Merus' belief that a obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved; the planned presentations of Zeno at ESMO 2023; any planned updates on Zeno and NRG1+ cancer, and Zeno in combination with an ADT for the potential treatment of CRPC; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2026; the advancement of the phase 1 trial of MCLA-145, as monotherapy and in combination with Keytruda®; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in Met ex14 NSCLC, EGFR ex20 NSCLC, and in HNSCC, as well as in combination with Tagrisso® in treatment naïve EGFRm NSCLC and in patients with EGFRm NSCLC that have progressed on Tagrisso®; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; 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 and Incyte's clinical study of INCA33890 developed in collaboration with us, 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 alone or in combination with befotertinib, a third generation EGFR tyrosine kinase inhibitor. 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 June 30, 2023, filed with the Securities and Exchange Commission, or SEC, on August 7, 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.

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