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

May 4, 2023

– Petosemtamab clinical update presented at the American Association of Cancer Research (AACR) Annual Meeting 2023
– Petosemtamab end-of-phase meeting with U.S. Food & Drug Administration provides clarity to potential registration path in head and neck squamous cell carcinoma (HNSCC)
– Petosemtamab update planned for Q3 2023 on potential registrational path in HNSCC
– Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into second half 2025

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 04, 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 first quarter and provided a business update.

"We were thrilled to share the robust interim clinical results for petosemtamab, our first in class bispecific antibody targeting EGFR and LGR5 in patients with previously treated head and neck squamous cell carcinoma at AACR," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "We are advancing our petosemtamab program diligently toward a registration-directed study in head and neck cancer. We expect our strong cash position to continue to fund the company meaningfully beyond several near-term clinical milestones and program updates, and into the second half of 2025."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
Enrollment continues in dose expansion in the phase 1/2 trial, including in combination with Keytruda (pembrolizumab)

Petosemtamab is in clinical development in the expansion part of a phase 1/2 open-label, multicenter trial in advanced solid tumors, including previously treated head and neck squamous cell carcinoma (HNSCC). The Company also initiated a cohort investigating petosemtamab in combination with Keytruda in patients with untreated HNSCC, designed to evaluate safety and clinical activity in this population.

In April, Merus provided an interim clinical update at the AACR Annual Meeting 2023. As of the February 1, 2023 data cutoff date, 49 previously treated HNSCC patients (pts) were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous every two weeks. Patients had experienced a median of 2 (range 1-4) prior lines of systemic therapy including PD-(L)1 inhibitor in 96% of pts, chemotherapy in 94% and platinum-based chemotherapy in 92% of pts; 2 pts received prior cetuximab. 43 pts were evaluable for efficacy, receiving ≥2 treatment cycles (≥8 weeks) with ≥1 post-baseline tumor assessment or experiencing early progressive disease. The overall response rate was 37.2% (16/43; 95% CI 23%-53.3%) by RECIST 1.1. per investigator assessment, including 15 confirmed partial responses and 1 confirmed complete response (ongoing after 20 months). Median duration of response was 6.0 months (95% CI 3.7-NC), with 10 of 16 (62.5%) responders ongoing at the time of the data cutoff. Median progression free survival was 5.3 months (95% CI 3.7-6.8); with 29 of 43 pts progressing and 14 of 43 pts censored. Median overall survival was 11.5 months (95% CI 7.2-20.6); with 29 of 49 pts still alive at the data cutoff date. Petosemtamab continued to demonstrate a manageable safety profile.

Merus met with the U.S. Food and Drug Administration (FDA) in an end-of-phase meeting to discuss interim results from the previously treated HNSCC cohort of the petosemtamab phase 1/2 trial. The FDA recognized recurrent or metastatic HNSCC represents an area of unmet medical need, and provided clear recommendations for the path to potential registration.

Based on the strong clinical data and discussions with the FDA, Merus believes a randomized clinical trial in previously treated (2L/3L) or untreated (front-line) HNSCC may support a possible registration. Additionally, Merus believes a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval. The Company plans to continue to acquire data to confirm a suitable dose for future randomized clinical trials. Merus plans to provide an update in Q3 2023 on the potential registrational path for this program.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1+ cancer and other solid tumors
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), and in combination with afatinib in NRG1+ non-small cell lung cancer (NSCLC)

Merus plans to provide an update on the potential registrational path and timeline in NRG1+ cancer in the first half of 2023 and a clinical update on Zeno in NRG1+ cancer at a major medical conference in 2023.

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 (osimertinib), 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.

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 consists of a dose escalation phase, followed by a dose expansion phase. Merus is also evaluating the combination of MCLA-145 with Keytruda, with enrollment ongoing.

Collaborations

Incyte Corporation
Since 2017, Merus has been working together 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 INCA32459, a novel Lag3xPD-1 bispecific antibody developed through the collaboration is currently being evaluated in clinical studies. In January 2023, Merus achieved a milestone payment of $2.5 million related to this program.

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 second half 2025
As of March 31, 2023, Merus had $287.3 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 second half 2025.

Annual General Meeting and Board of Directors
The Company's annual general meeting of shareholders is planned to be held on May 26, 2023.

First Quarter 2023 Financial Results
We ended the first quarter with cash, cash equivalents and marketable securities of $287.3 million compared to $326.7 million at December 31, 2022. The decrease was primarily the result of cash used to fund the operations.
Collaboration revenue for the three months ended March 31, 2023 increased by $1.8 million as compared to the three months ended March 31, 2022, primarily as a result of an increase from an Incyte milestone met of $2.5M partially offset by lower cost reimbursement revenue.

Research and development expense for the three months ended March 31, 2023 increased by $7.9 million as compared to the three months ended March 31, 2022, primarily as a result of an increase in clinical and manufacturing costs related to our programs and stock-based compensation.

General and administrative expense for the three months ended March 31, 2023 increased by $3.6 million as compared to the three months ended March 31, 2022, primarily as a result of increases in consulting costs of $2.3 million, facilities costs of $0.8 million and personnel related expenses including stock-based compensation.

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)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,635	$ 147,749
Marketable securities	138,604	142,480
Accounts receivable	4,769	4,051
Prepaid expenses and other current assets	12,156	12,163
Total current assets	258,164	306,443
Marketable securities	46,103	36,457
Property and equipment, net	13,390	12,222
Operating lease right-of-use assets	12,322	12,618
Intangible assets, net	1,933	1,950
Deferred tax assets	2,369	2,041
Other assets	4,239	4,811
Total assets	$ 338,520	$ 376,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 4,987	$ 9,834
Accrued expenses and other liabilities	39,543	35,590
Income taxes payable	2,271	2,400
Current portion of lease obligation	1,588	1,684
Current portion of deferred revenue	26,698	29,418
Total current liabilities	75,087	78,926
Lease obligation	11,588	11,790
Deferred revenue, net of current portion	34,322	38,771
Total liabilities	120,997	129,487
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized at March 31, 2023 and December 31, 2022; 46,341,181 and 46,310,589 shares issued and outstanding as at March 31, 2023 and December 31, 2022, respectively	4,754	4,751
Additional paid-in capital	876,838	870,874
Accumulated other comprehensive income	(26,206)	(30,448)
Accumulated deficit	(637,863)	(598,122)
Total stockholders' equity	217,523	247,055
Total liabilities and stockholders' equity	$ 338,520	$ 376,542

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

	Three Months Ended March 31,	
	2023	**2022**
Collaboration revenue	$ 13,499	$ 11,655
Total revenue	13,499	11,655
Operating expenses:		
Research and development	34,865	26,975
General and administrative	15,386	11,753
Total operating expenses	50,251	38,728
Operating loss	(36,752)	(27,073)
Other (loss) income, net:		
Interest (expense) income, net	1,995	106
Foreign exchange gains (loss)	(5,441)	7,730
Other (losses) gains, net	—	458
Total other income (loss), net	(3,446)	8,294
Net loss before income taxes	(40,198)	(18,779)
Income tax expense	(457)	114
Net loss	$ (39,741)	$ (18,893)
Other comprehensive loss:		
Currency translation adjustment	4,242	(6,048)
Comprehensive loss	$ (35,499)	$ (24,941)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.86)	$ (0.43)
Weighted-average common shares outstanding:		
Basic and diluted	46,323,772	43,489,870

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, regulatory, strategy and development updates for our product candidates; the continuation of enrollment of patients in the eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers; our clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC; our clinical trial evaluating Zeno in combination with an ADT as a potential treatment for CRPC; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into the second half of 2025 and expectation that our cash position will continue to fund the company meaningfully beyond several near-term clinical milestones and program updates; 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 petosemtamab; statements regarding advancing our petosemtamab program diligently toward a registration-directed study in head and neck cancer; 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 INCA32459 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. 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, 2022, filed with the Securities and Exchange Commission, or SEC, on February 28, 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.

Investor and Media Inquiries:
Sherri Spear
Merus N.V.
VP Investor Relations and Corporate Communications
617-821-3246
s.spear@merus.nl

Kathleen Farren
Merus N.V.
Investor Relations and Corporate Communications
617-230-4165
k.farren@merus.nl

Merus