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

November 2, 2023 at 4:12 PM EDT

– Petosemtamab in combination with Keytruda 1L initial interim clinical data planned for 1H24; 2L+ HNSCC monotherapy clinical update planned 2024

– Zeno interim clinical data continue to show robust efficacy in NRG1+ NSCLC and PDAC: Sufficient clinical data expected in 1H24 to support potential BLA submissions

– Based on the Company's current operating plan and recent oversubscribed public offering raising approximately $172M gross proceeds, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 02, 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 third quarter and provided a business update.

"The next several quarters are key for Merus and we are focused on execution of our clinical programs, particularly Zeno and petosemtamab," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "For Zeno, our most advanced clinical candidate, we are looking forward to potential BLA submissions- our first as a company. For petosemtamab, we are preparing for a phase 3 study in 2L+ expected to start mid-2024. In the front line setting we plan to provide initial data on the combination with Keytruda in the 1H24. We are preparing for a potential front line registration trial, with our decision conditioned on the safety profile being confirmed. We believe petosemtamab has the potential to become a new standard of care for HNSCC."

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 comparison of petosemtamab monotherapy 1100 vs 1500 mg in previously treated HNSCC, as well as in combination with Keytruda® (pembrolizumab) as front-line therapy

Merus plans to initiate a phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in previously treated recurrent or metastatic 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 enroll approximately 40 patients with previously treated HNSCC with petosemtamab monotherapy at the 1100 or 1500 mg dose levels to confirm a suitable dose for future potential randomized trials. Merus plans to share the clinical data from this cohort in 2024.

Merus also continues to enroll patients with previously untreated advanced PD-L1+ HNSCC with petosemtamab 1500 mg in combination with Keytruda®. Initial safety data from this single arm cohort may support the initiation of a first-line registration trial with this combination. Among the initial patients dosed in the front-line combination, the safety profile has been observed to be generally favorable. Merus plans to report initial interim safety and efficacy data from this cohort in the first half of 2024.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion-positive (NRG1+) cancer and other solid tumors
Granted Breakthrough Therapy Designations (BTDs) for both NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ pancreatic cancer (PDAC); 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) continues; as well as in combination with afatinib in NRG1+ NSCLC

We shared updated interim clinical data on our Zeno program (eNRGy trial and Early Access Program (EAP)) in patients with NRG1+ NSCLC and PDAC at the European Society for Medical Oncology (ESMO) Congress 2023.

The reported data are from the phase 1/2 eNRGy trial and EAP which are assessing the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancer.

Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced *NRG1* fusion-positive (NRG1+) non-small cell lung cancer (NSCLC)
Observations in the presentation include:

- As of July 31, 2023 data cutoff date, 105 patients with NRG1+ NSCLC were treated with Zeno. 78 patients with measurable disease were treated by February 13, 2023, allowing for the potential for ≥ 24 weeks follow-up, and who met the criteria for the primary analysis population.
    - 37.2% (29/78; 95% CI: 26.5-48.9) overall response rate (ORR) per RECIST (Response Evaluation Criteria in Solid Tumors) v1.1 by investigator assessment
    - 61.5% (95% CI: 49.8 - 72.3) clinical benefit rate (CBR)
    - 14.9 months (95% CI: 7.4-20.4) median duration of response (DOR) and 20 patients were continuing treatment as of the data

cutoff

Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) pancreatic ductal adenocarcinoma (PDAC)
Observations in the presentation include:

- As of July 31, 2023 data cutoff date, 44 patients with NRG1+ PDAC were treated with Zeno. 33 patients with measurable disease were treated by February 13, 2023, allowing for the potential for ≥ 24 weeks follow-up, and who met the criteria for the primary analysis population.
    - 42.4% (95% CI, 25.5–60.8) ORR per RECIST v1.1 by investigator assessment; 1 (3%) patient achieved a complete response, and 13 (39%) patients achieved a partial response
    - 72.7% (95% CI, 54-87) CBR
    - 82% experienced tumor reduction
    - Of 27 evaluable patients for CA 19-9 values, 21 (78%) showed a ≥ 50% decrease in CA 19-9 values from baseline
    - 9.1 months (95% CI, 5.5–12.0) median DOR; and 6 patients were continuing treatment as of the data cutoff

Safety findings from both presentations: Zeno demonstrated a well tolerated safety profile among the 189 NRG1+ cancer patients who were treated at the cutoff date with 750 mg Q2W monotherapy, with only 6% of patients experiencing related grade 3-4 toxicities.

An encore poster presentation will take place at ESMO Asia Congress 2023 in Singapore December 1-3, 2023.

Presentation Details:
Title: Durable efficacy of zenocutuzumab, a HER2 x HER3 bispecific antibody, in advanced NRG1 fusion-positive (NRG1+) non-small cell lung cancer (NSCLC)
Session Category: Poster session
Date: Saturday, December 2, 2023
Time: 17:50-18:45 p.m. SGT
Presentation #: 595P

Merus recently met with the U.S. Food & Drug Administration (FDA) in the context of our two Break Through Designations and based on these productive and collaborative discussions, we believe we will have sufficient clinical data in 1H24 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.

Zeno in combination with ADT in CRPC
Merus is also evaluating Zeno in combination with an ADT (enzalutamide or abiraterone) in CRPC, irrespective of NRG1+ status. As of a data cutoff date of September 12, 2023, 10 patients have been treated, ranging in age from 55-86 years, with a median of three lines of prior therapy, and a median of 16.4 weeks of Zeno exposure, with three patients remaining on treatment as of the data cutoff date. The combination of Zeno and ADT was generally well tolerated with no treatment related AEs of grade 3 or higher. The range of maximum PSA change from baseline was +300% to -35%. Seven patients discontinued for disease progression. Three patients remained on treatment as of the cutoff date and continue to be followed for efficacy and safety. The best overall response by PCWG3-modified RECIST v1.1 by CT and/or bone scan in 9 evaluable patients at the time of data cutoff is stable disease in 7 patients and progressive disease in 2 patients. One patient was excluded from the efficacy population due to less than two cycles of Zeno treatment.

Merus plans to continue monitoring these patients and evaluating these data to determine potential further exploration of this indication. The company is also conducting ongoing translational work on potential biomarkers outside of NRG1+ tumors, in CRPC and beyond which may support development opportunities for Zeno in additional areas of unmet need.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Enrollment continues in the expansion cohorts in the phase 1/2 trial; clinical update planned at ESMO Asia 2023

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 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®.

Merus has discontinued the NSCLC with EGFR exon20 mutation cohort due to the competition in this niche market.

Abstracts on the bispecific antibody MCLA-129 as first line therapy for, and in previously treated, NSCLC and in previously treated HNSCC, were selected for presentation at the ESMO Asia Congress 2023.

Presentation Details:
Title: Efficacy and safety of MCLA-129, an EGFR x c-MET bispecific antibody, combined with osimertinib, as first-line therapy or after progression on osimertinib in non-small cell lung cancer (NSCLC)
Session Category: Mini-oral session 2
Session: Thoracic Cancer
Date: Sunday, December 3, 2023
Time: 9:40 -9:45 a.m. SGT
Presentation #: 516MO

Title: Efficacy and safety of MCLA-129, an anti-EGFR/c-MET bispecific antibody, in head and neck squamous cell cancer (HNSCC)
Session Category: Poster session
Date: Saturday, December 2, 2023
Time: 17:50-18:45 p.m. SGT
Presentation #: 362P

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
The phase 1 trial continues 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®.

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 quarter. 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.

Corporate Activities
Completed public offering raising $172M gross proceeds
In August 2023, Merus closed a public offering, with gross proceeds from the offering of approximately $172 million, inclusive of underwriters' 30-day option to purchase additional common shares at the public offering price. Net proceeds from the offering are planned to be used to advance the clinical development of our product candidates, for preclinical research and technology development, and for working capital and general corporate purposes.

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027
As of September 30, 2023, Merus had $446 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.

Third Quarter 2023 Financial Results
Collaboration revenue for the three months ended September 30, 2023 increased by $4.4 million as compared to the three months ended September 30, 2022, primarily as a result of earning milestones of $3.5 million from Incyte. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended September 30, 2023 decreased by $5.5 million as compared to the three months ended September 30, 2022, primarily as a result of a decrease in external clinical services and drug manufacturing costs.

General and administrative expense for the three months ended September 30, 2023 was flat as compared to the three months ended September 30, 2022.

Collaboration revenue for the nine months ended September 30, 2023 increased by $4.1 million as compared to the nine months ended September 30, 2022, primarily due to $3.5 million in milestones earned from Incyte.

Research and development expense for the nine months ended September 30, 2023 decreased by $0.4 million as compared to the nine months ended September 30, 2022, primarily as a result of a decrease in external clinical services and drug manufacturing costs.

General and administrative expense for the nine months ended September 30, 2023 increased by $7.1 million as compared to the nine months ended September 30, 2022, primarily as a result of an increase in stock-based compensation expense, personnel related expenses, and consultancy costs.

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 share and per share data)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 241,868	$ 147,749
Marketable securities	146,702	142,480
Accounts receivable	3,434	4,051
Prepaid expenses and other current assets	12,828	12,163
Total current assets	404,832	306,443
Marketable securities	57,259	36,457
Property and equipment, net	12,176	12,222
Operating lease right-of-use assets	11,323	12,618
Intangible assets, net	1,771	1,950
Deferred tax assets	702	2,041
Other assets	4,123	4,811
Total assets	$ 492,186	$ 376,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,843	$ 9,834
Accrued expenses and other liabilities	35,712	35,590
Income taxes payable	137	2,400

Current portion of lease obligation	1,607	1,684
Current portion of deferred revenue	23,019	29,418
Total current liabilities	64,318	78,926
Lease obligation	10,506	11,790
Deferred revenue, net of current portion	23,974	38,771
Total liabilities	98,798	129,487
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized at September 30, 2023 and December 31, 2022; 57,729,180 and 46,310,589 shares issued and outstanding as at September 30, 2023 and December 31, 2022, respectively	5,874	4,751
Additional paid-in capital	1,117,855	870,874
Accumulated other comprehensive income	(37,433)	(30,448)
Accumulated deficit	(692,908)	(598,122)
Total stockholders' equity	393,388	247,055
Total liabilities and stockholders' equity	$ 492,186	$ 376,542

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 11,033	$ 6,581	$ 35,008	$ 30,920
Total revenue	11,033	6,581	35,008	30,920
Operating expenses:				
Research and development	36,810	42,307	99,973	100,378
General and administrative	12,591	12,469	44,040	36,917
Total operating expenses	49,401	54,776	144,013	137,295
Operating loss	(38,368)	(48,195)	(109,005)	(106,375)
Other income, net:				
Interest income, net	4,522	866	9,312	1,288
Foreign exchange gains (loss)	11,952	23,041	7,062	55,378
Other gains, net	—	—	—	1,059
Total other income (loss), net	16,474	23,907	16,374	57,725
Net loss before income taxes	(21,894)	(24,288)	(92,631)	(48,650)
Income tax expense	1,118	327	2,155	572
Net loss	$ (23,012)	$ (24,615)	$ (94,786)	$ (49,222)
Other comprehensive loss:				
Currency translation adjustment	(10,722)	(19,475)	(6,985)	(45,444)
Comprehensive loss	$ (33,734)	$ (44,090)	$ (101,771)	$ (94,666)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.43)	$ (0.53)	$ (1.91)	$ (1.11)
Weighted-average common shares outstanding:				
Basic and diluted	53,869,762	46,056,719	49,532,722	44,451,997

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 the next several quarters are key for the Company, our focus on execution of our clinical programs, particularly Zeno and petosemtamab; our looking forward to potential BLA submissions and 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; our plan to provide initial data on the combination with Keytruda in the 1H24; our preparation for a potential front line registration trial investigating petosemtamab in combination with Keytruda in previously untreated advanced PD-L1+ HNSCC, with our decision conditioned on the safety profile of the combination of Keytruda and petosemtamab; our belief that petosemtamab has the potential to become a new standard of care for HNSCC; the potential design and details of our planned phase 3 trial design, potentially initiating a randomized phase 3 trial of petosemtamab monotherapy, or investigators' choice of single agent chemotherapy or cetuximab in 2L/3L 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; 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 data on patients with CRPC receiving Zeno in combination with ADT, and the impact of such data and our plan to continue monitoring these patients and evaluating these data to determine potential further exploration of this indication; our conduct of ongoing translational work on potential biomarkers outside of NRG1+ tumors, in CRPC and beyond which may support development opportunities for Zeno in additional areas

of unmet need; the planned presentations of Zeno and MCLA-129 at ESMO Asia 2023; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2027; our planned use of proceeds from the follow-on offering that raised gross proceeds of approximately $172 million; the advancement of the phase 1 trial of MCLA-145 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, 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. 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.

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