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

November 3, 2022

– Clinical update of MCLA-129 presented at the 34th EORTC/NCI/AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics
– Zenocutuzumab (Zeno) Regulatory update: FDA recommends additional enrollment in eNRGy trial to support potential BLA filing
– Clinical update of petosemtamab planned for first half of 2023

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 03, 2022 (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 that ended September 30, 2022 and provided a business update.

"We continue to advance numerous programs which now demonstrate important clinical activity across the portfolio," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "For MCLA-129, we have recently shared early efficacy and safety data at the ENA 'triple' meeting and are now enrolling expansion cohorts in lung and other cancers; for Zeno, potentially first and best in class for NRG1 fusion cancer, we are continuing to enroll the eNRGy study consistent with recent feedback from the FDA; and for petosemtamab, we are looking forward to providing a clinical update in the first half of 2023. Later this year, Incyte plans to start a clinical study of INCA32459, a novel LAG3xPD-1 bispecific antibody developed in collaboration with Merus."

Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclonics®): NRG1+ cancer and other solid tumors
Enrollment continues in the eNRGy trial; enrollment in combination study in NRG1+ NSCLC as well as monotherapy in castration resistant prostate cancer (CRPC) planned to begin enrollment in 4Q2022

At the end of October, Merus met with the U.S. Food and Drug Administration (FDA) regarding a potential Biologics License Application (BLA) filing for Zeno in NRG1 fusion (NRG1+) cancer. Based on the FDA feedback, Merus believes that a potential registrational path remains viable in a NRG1+ cancer tumor agnostic indication or separate applications for NRG1+ lung and NRG1+ pancreatic cancer, which could then be followed by a potential tumor agnostic filing. The majority of the eNRGy trial and Early Access Program enrollment to date has been NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ pancreatic cancer. The FDA recommended that Merus enroll additional patients under either approach (tissue agnostic or tumor-type specific), to obtain further supportive data for a potential registrational data set, consistent with the recent FDA draft guidance on Tissue Agnostic Drug Development in Oncology. The amount of data needed for a potential filing under either approach will depend upon the magnitude and durability of responses and the overall risk benefit assessment.

Merus is assessing the impact on the timeline for a potential BLA filing for Zeno in NRG1+ cancer. Enrollment continues in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. Merus believes Zeno has the potential to be a first and best in class and a new standard of care for patients with NRG1+ cancer.

Details of the eNRGy trial can be found at www.ClinicalTrials.gov and Merus' trial website at www.nrg1.com, or by calling 1-833-NRG-1234.

Further, Merus is initiating a clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC, and a clinical trial evaluating Zeno outside of NRG1+ cancer, as a treatment for castration resistant prostate cancer. The Company is also actively exploring the ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers.

Petosemtamab (MCLA-158: Lgr5 x EGFR Biclonics®): Solid Tumors
Dose expansion continues in the phase 1 trial: clinical update planned for 1H2023

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

Merus plans to provide a clinical update for petosemtamab at a medical conference in the first half of 2023. The planned presentation will provide the opportunity to present a robust update across the program, including approximately 40 patients with head and neck squamous cell carcinoma (HNSCC) with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy and planned regulatory interactions.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial continues including in combination with a PD1 inhibitor

MCLA-145 is currently enrolling a global, phase 1, open-label, single-agent clinical trial evaluating MCLA-145 in patients with solid tumors. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. Merus is also evaluating the combination of MCLA-145 with a PD-1 blocking antibody, with first patient dosed and enrollment ongoing.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Phase 1 continues with enrollment in expansion cohorts

MCLA-129 is currently enrolling patients in a phase 1/2, open-label clinical trial evaluating patients with MCLA-129 monotherapy in MetEx14 NSCLC, EGFRex20 NSCLC, and in HNSCC, as well as in combination with a third generation EGFR TKI in treatment naïve EGFR mutant (m) NSCLC and in patients with EGFR m NSCLC that have progressed on Tagrisso (osimertinib).

Merus presented initial clinical data regarding MCLA-129 at the 34th EORTC/NCI/AACR (ENA) Symposium. Twenty patients, (14 patients with EGFR m lung cancer, 2 with c-MET exon 14 skipping m NSCLC, 1 patient with c-MET amplified gastric adenocarcinoma, 1 patient with esophageal squamous cell cancer, 2 patients with HNSCC), were treated with MCLA-129 across dose levels of 100 mg-1500 mg. As of an August 15, 2022 data cutoff date, these initial clinical data in 18 evaluable patients show clinical activity at a variety of dose levels with two confirmed partial responses and four additional patients with >20% tumor shrinkage. MCLA-129 was observed to be well tolerated with no dose limiting toxicities. The most frequent adverse events (AEs) observed were infusion-related reactions (IRR); 90% of patients experienced IRR AEs of any grade, one patient (5%) experienced a grade 3, no grade 4 or 5 AEs were observed. Based on pharmacokinetic and pharmacodynamic data, and the safety profile, an initial recommend phase 2 dose was selected at 1500 mg every two weeks. As of the data cutoff date the median duration of exposure was 12.6 weeks and six of 20 patients remained on treatment.

As October 2022, 33 patients have been enrolled in the dose escalation and dose expansion phases of the trial. The additional 13 patients enrolled did not yet have an opportunity to be evaluated as of the August 15, 2022 data cutoff.

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

Collaborations

Incyte

Since 2017, Merus has been working together with Incyte Corporation under global collaboration and license agreement, which grants Incyte exclusive rights for up to ten bispecific and monospecific antibody programs from Merus' Biclonics ® platform. The collaboration is progressing, with multiple programs in various stages of preclinical development. Further, Incyte announced this quarter that it plans to start a clinical study of INCA32459, a novel Lag3xPD-1 bispecific antibody developed in collaboration with Merus using Merus' Biclonics ® antibody platform. 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.

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, Merus expects to be funded beyond 2024

As of September 30, 2022, Merus had $372.9 million cash and cash equivalents sufficient to fund company operations beyond 2024.

Third Quarter 2022 Financial Results

Collaboration revenue for the three months ended September 30, 2022 decreased by $7.1 million as compared to the three months ended September 30, 2021, primarily as a result of a decrease in Lilly upfront payment amortization and reimbursement revenues and Incyte upfront payment amortization. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended September 30, 2022 increased by $16.3 million as compared to the three months ended September 30, 2021, primarily as a result of an increase in external clinical services and drug manufacturing costs.

General and administrative expense for the three months ended September 30, 2022 increased by $2.3 million as compared to the three months ended September 30, 2021, primarily as a result of an increase in stock-based compensation expense and consulting costs.

Collaboration revenue for the nine months ended September 30, 2022 decreased by $3.5 million as compared to the nine months ended September 30, 2021, primarily in Lilly upfront payment amortization and reimbursement revenues and Incyte upfront payment amortization.

Research and development expense for the nine months ended September 30, 2022 increased by $29.0 million as compared to the nine months ended September 30, 2021, primarily as a result of an increase in external clinical services and drug manufacturing costs.

General and administrative expense for the nine months ended September 30, 2022 increased by $6.8 million as compared to the nine months ended September 30, 2021, 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 per share data)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 190,980	$ 241,435
Marketable securities	160,463	168,990
Accounts receivable	2,628	1,697
Accounts receivable (related party)	—	4,609
Prepaid expenses and other current assets	14,128	7,448
Total current assets	368,199	424,179
Marketable securities	21,476	20,297
Property and equipment, net	7,339	3,549
Operating lease right-of-use assets	12,345	3,733
Intangible assets, net	1,889	2,347

Deferred tax assets	435	417
Other assets	3,307	2,078
Total assets	$ 414,990	$ 456,600
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,117	$ 13,237
Accrued expenses and other liabilities	31,190	22,506
Income taxes payable	—	—
Current portion of lease obligation	1,868	1,494
Current portion of deferred revenue	27,975	16,613
Current portion of deferred revenue (related party)	—	18,048
Total current liabilities	64,150	71,898
Lease obligation	11,273	2,257
Deferred revenue, net of current portion	40,790	10,962
Deferred revenue, net of current portion (related party)	—	55,282
Total liabilities	116,213	140,399
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized as at September 30, 2022 and December 31, 2021; 46,302,877 and 43,467,052 shares issued and outstanding as at September 30, 2022 and December 31, 2021, respectively	4,750	4,481
Additional paid-in capital	864,842	787,869
Accumulated other comprehensive income	(54,665)	(9,221)
Accumulated deficit	(516,150)	(466,928)
Total stockholders' equity	298,777	316,201
Total liabilities and stockholders' equity	$ 414,990	$ 456,600

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 6,581	$ 5,919	$ 30,920	$ 12,636
Collaboration revenue (related party)	—	7,750	—	21,762
Total revenue	6,581	13,669	30,920	34,398
Operating expenses:				
Research and development	42,307	26,018	100,378	71,436
General and administrative	12,469	10,171	36,917	30,073
Total operating expenses	54,776	36,189	137,295	101,509
Operating loss	(48,195)	(22,520)	(106,375)	(67,111)
Other (loss) income, net:				
Interest (expense) income, net	866	(25)	1,288	(158)
Foreign exchange gains (loss)	23,041	7,756	55,378	15,434
Other (losses) gains, net	—	(75)	1,059	(460)
Total other income (loss), net	23,907	7,656	57,725	14,816
Net loss before income taxes	(24,288)	(14,864)	(48,650)	(52,295)
Income tax expense	327	(11)	572	100
Net loss	$ (24,615)	$ (14,853)	$ (49,222)	$ (52,395)
Other comprehensive loss:				
Currency translation adjustment	(19,475)	(5,391)	(45,444)	(11,307)
Comprehensive loss	$ (44,090)	$ (20,244)	$ (94,666)	$ (63,702)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.53)	$ (0.39)	$ (1.11)	$ (1.39)
Weighted-average common shares outstanding:				
Basic and diluted	46,057	38,513	44,452	37,708

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 Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the content and timing of clinical trials, data readouts and clinical updates for our product candidates, including with respect to enrollment and timing of data in our eNRGY trial and Early Access Program, the treatment potential of Zeno and to be potentially first and best in class for NRG1 fusion cancer; our belief in the potential registrational path in NRG1+ cancer tumor agnostic indication or separate applications for NRG1+ lung and NRG1+ pancreatic cancer, which could then be followed by a subsequent potential tumor agnostic filing; the impact of additional enrollment of patients under either approach (tissue agnostic or tumor-type specific), to obtain further supportive data for a potential registrational data set; our understanding of the recent FDA draft guidance on Tissue Agnostic Drug Development in Oncology; our potential filing of a BLA for Zeno in NRG1+ cancer under either a tumor agnostic or tumor specific approach; our assessment of the impact on timeline for a potential BLA filing; the continuation of enrollment of patients in the eNRGY trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers; future use and potential benefit of Zeno in combination with other cancer therapies; our planned clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC and planned evaluation of Zeno for castration resistant prostate cancer; our exploring the ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers; the impact of regulatory interactions on our development of product candidates; statements regarding the sufficiency of our cash, cash equivalents and marketable securities; the advancement of the Phase 1 trial of MCLA-145, as monotherapy and in combination with a PD-1 blocking antibody; the advancement of the phase 1 trial for MCLA-158 and the planned update at a medical conference in the first half of 2023 and opportunity to present a robust update across the program, including approximately 40 patients with HNSCC with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy and planned regulatory interactions; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in MetEx14 NSCLC, EGFRex20 NSCLC, and in HNSCC, as well as in combination with a third generation EGFR TKI in treatment naïve EGFRm NSCLC and in patients with EGFRm NSCLC that have progressed on Tagrisso (osimertinib); the selection of the initial recommended phase 2 dose on the MCLA-129 study; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; the benefits of a collaboration between Loxo Oncology at Lilly and Merus, its potential for future value generation; whether any programs under the collaboration will be successful; Merus' and Lilly's activities under the agreement; and 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 plans to start a clinical study of INCA32459 developed in collaboration with us; our collaboration and license agreement with Betta, which permits Betta to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights, and any developments that may arise from these agreements. 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 Quarterly Report on Form 10-Q for the period ended September 30, 2022, filed with the Securities and Exchange Commission, or SEC, on November 3, 2022, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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