Merus Announces Regulatory Update on Zenocutuzumab, Financial Results for the Third Quarter and Provides Business Update

November 2, 2021

- *Merus participated in a Type B meeting with the FDA regarding its zenocutuzumab development program and obtained alignment with FDA on registration approach for a potential tumor agnostic indication*
- *Merus presented early clinical data on MCLA-158 at the AACR-NCI-EORTC Virtual International Conference reporting interim data for patients with advanced head and neck squamous cell carcinoma (HNSCC)*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 02, 2021 (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 a regulatory update for the zenocutuzumab (Zeno) program in NRG1 positive (NRG1+) solid tumors, financial results for the third quarter that ended September 30, 2021, and provided a business update.

"Our recent regulatory interactions with the FDA demonstrate the maturation of the Zeno program as we continue on the path to potential BLA submission," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "In addition, with MCLA-158, we are also encouraged by the early interim clinical data we recently reported in head and neck cancer, and the continued progress of our other clinical programs. We believe the positive results we are seeing in the clinic further validate the strength of our platform."

Clinical Programs

Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclonics®)

Alignment obtained with the FDA on registration approach for a potential tumor agnostic indication: clinical update planned for 1H22

Merus met with the U.S. Food and Drug Administration (FDA) in an end-of-phase Type B meeting to discuss interim results from the ongoing phase 1/2 eNRGy trial and Early Access Program (EAP) in NRG1+ cancers, and to discuss the development plan for Zeno. Merus and the FDA officials discussed the available Zeno monotherapy data and a potential data package to support a biologics license application (BLA) submission.

Merus designed the phase 1/2 eNRGY trial to support potential registration in either a tumor-specific or a tumor agnostic NRG1+ indication(s). Based on feedback received from the FDA, Merus believes that the trial design and planned enrollment will be appropriate to potentially support a BLA submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers. Merus believes that, if the rate of enrollment and efficacy remains consistent, a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, that could provide a potential registrational data set.

Andrew Joe, M.D., Chief Medical Officer of Merus, stated, "We are very pleased with our recent regulatory interactions including alignment with the FDA on a tumor agnostic approach for NRG1+ cancers, for which Zeno has already received Fast Track designation. Regulatory interactions such as these represent continued progress in Merus' mission to bring our novel multispecific antibody therapy candidates to patients with serious unmet medical need."

As of September 1, 2021 more than 80 patients with NRG1+ cancers have been treated with Zeno monotherapy in our phase 1/2 eNRGy trial and EAP. Merus plans to provide a further clinical program update in the first half of 2022.

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.

In addition, we presented preclinical data on Zeno at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. The bispecific HER2/HER3 antibody Zeno blocked cell growth 100 fold more potently than the bivalent HER3 antibody derived from Zeno, in an NRG1 driven growth assay, and potently blocked NRG1-fusion mediated downstream signaling and growth in *in vitro* and *in vivo* models. Zeno induced both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) mediated killing of cancer cells in a dose-dependent manner.

MCLA-158 (petosemtamab: Lgr5 x EGFR Biclonics®): Solid Tumors

Dose expansion continues in the phase 1 trial: update planned for 2022

We shared early interim clinical data of the MCLA-158 program in patients with advanced HNSCC at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. Among 10 patients with previously treated advanced HNSCC, as of the August 9, 2021 safety and efficacy data cutoff, the median age was 65 and the median number of prior lines of therapy was two. Seven patients were evaluable for an interim efficacy analysis by investigator assessment (three patients were enrolled <8 weeks from the data cutoff date). Three of seven patients achieved a best response of partial response, with one achieving complete response after the data cutoff date. Tumor reduction was observed in the target lesions of all seven patients. The safety results presented for MCLA-158 were based on 29 patients with advanced solid tumors who were treated at 1500 mg every two weeks across the phase 1 trial. The most frequent adverse events (AEs) were infusion related reactions with 72% any grade and 7% grade 3 or greater. Mild to moderate skin toxicity (3% grade ≥3) was also observed.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors

Phase 1 trial continues: update planned for ESMO Immuno-Oncology Congress 2021

The phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing. The trial consists of a dose escalation phase, to be followed by a planned dose expansion phase. MCLA-145 is the first drug candidate co-developed under Merus' global collaboration and license agreement with Incyte Corporation ("Incyte"), which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform. Merus retains full rights to develop and commercialize MCLA-145, if approved, in the United States; and Incyte holds full rights to develop and commercialize MCLA-145 outside the United States. We plan to provide an update at ESMO Immuno-Oncology Congress 2021.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors

The phase 1/2, open-label, single-agent clinical trial of MCLA-129 is ongoing and consists of a dose escalation phase, to be followed by planned expansion cohorts evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. MCLA-129 is a Biclonics®, which binds to EGFR and c-MET and is being investigated for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers, and upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. We plan to provide an update after the recommended phase 2 dose has been reached.

MCLA-129 is 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 full ex-China rights.

In October 2021, Betta announced that the first patient was dosed in Betta's sponsored phase 1/2 trial of MCLA-129 in China in patients with advanced solid tumors.

Collaborations Update

Incyte

In the third quarter Merus received a milestone payment for achieving pre-clinical candidate nomination of a novel bispecific antibody (target pair program) under the global collaboration and license agreement with Incyte. Candidate nomination has triggered this program's next phase of IND-enabling studies by Incyte.

Merus receives reimbursement for research activities related to the collaboration 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 that will leverage Merus' proprietary Biclonics® platform along with the scientific and rational drug design expertise of Loxo Oncology at Lilly to research and develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies. The collaboration is progressing well with active research programs underway.

Third Quarter 2021 Financial Results

We ended the third quarter with cash, cash equivalents and marketable securities of $333.2 million compared to $207.8 million at December 31, 2020. The increase was primarily the result of net proceeds from our follow-on offering and proceeds from the collaboration with and equity investment by Eli Lilly and Company ("Lilly"), net of cash used in operations and other items. Based on the Company's current operating plan, we expect that our existing cash and cash equivalents and marketable securities of $333.2 million as of September 30, 2021, will fund the Company's operations into the second half of 2024.

Collaboration revenue for the three months ended September 30, 2021 increased by $5.1 million as compared to the three months ended September 30, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of $5.0 million that commenced in the first quarter of 2021. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended September 30, 2021 increased by $8.5 million as compared to the three months ended September 30, 2020, 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 September 30, 2021 increased by $1.1 million as compared to the three months ended September 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses, partially offset by decreases in legal and depreciation costs.

Collaboration revenue for the nine months ended September 30, 2021 increased by $13.5 million as compared to the nine months ended September 30, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of $11.0 million that commenced in the first quarter of 2021, and $1.0 million of milestone revenue related to Incyte reflecting activities in the period. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the nine months ended September 30, 2021 increased by $23.2 million as compared to the nine months ended September 30, 2020, 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 nine months ended September 30, 2021 increased by $4.0 million as compared to the nine months ended September 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses partially offset by decreases in legal and IP related costs and travel expenses.

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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 159,121	$ 163,082
Marketable securities	150,617	44,673
Accounts receivable	1,642	46
Accounts receivable (related party)	1,595	1,623

Prepaid expenses and other current assets	6,747	8,569
Total current assets	319,722	217,993
Marketable securities	23,489	—
Property and equipment, net	3,450	4,115
Operating lease right-of-use assets	4,143	3,907
Intangible assets, net	2,471	2,843
Deferred tax assets	219	410
Other assets	2,433	1,949
Total assets	$ 355,927	$ 231,217
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,401	$ 3,126
Accrued expenses and other liabilities	27,526	21,803
Income taxes payable	—	206
Current portion of lease obligation	1,506	1,432
Current portion of deferred revenue	18,649	625
Current portion of deferred revenue (related party)	18,451	19,554
Total current liabilities	71,533	46,746
Lease obligation	2,647	2,521
Deferred revenue, net of current portion	14,810	237
Deferred revenue, net of current portion (related party)	61,168	79,450
Total liabilities	150,158	128,954
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 38,605,096 and 31,602,953 shares issued and outstanding as at September 30, 2021 and December 31, 2020, respectively	$ 3,976	$ 3,211
Additional paid-in capital	656,536	490,093
Accumulated other comprehensive income	(2,236)	9,071
Accumulated deficit	(452,507)	(400,112)
Total stockholders' equity	205,769	102,263
Total liabilities and stockholders' equity	$ 355,927	$ 231,217

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,	
	2021	2020	2021	2020
Collaboration revenue	$ 5,919	$ 695	$ 12,636	$ 1,207
Collaboration revenue (related party)	7,750	7,875	21,762	19,720
Total revenue	13,669	8,570	34,398	20,927
Operating expenses:				
Research and development	26,018	17,538	71,436	48,234
General and administrative	10,171	9,136	30,073	26,061
Total operating expenses	36,189	26,674	101,509	74,295
Operating loss	(22,520)	(18,104)	(67,111)	(53,368)
Other (loss) income, net:				
Interest (expense) income, net	(25)	(12)	(158)	367
Foreign exchange (losses) gains, net	7,756	(4,782)	15,434	(4,243)
Other losses, net	(75)	—	(460)	—
Total other (loss) income, net	7,656	(4,794)	14,816	(3,876)
Net loss before income taxes	(14,864)	(22,898)	(52,295)	(57,244)
Income tax (benefit) expense	(11)	177	100	305
Net loss	$ (14,853)	$ (23,075)	$ (52,395)	$ (57,549)
Other comprehensive income (loss):				
Currency translation adjustment	(5,391)	4,414	(11,307)	3,508
Comprehensive loss	$ (20,244)	$ (18,661)	$ (63,702)	$ (54,041)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.39)	$ (0.64)	$ (1.39)	$ (1.86)
Weighted-average common shares outstanding:				
Basic and diluted	38,513	29,061	37,708	29,014

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, http://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 updates for our product candidates, including with respect to enrollment and timing of data in our eNRGY trial, the treatment potential of Zeno, the design of the eNRGY clinical trial; our belief that the positive results we are seeing in the clinic further validate the strength of our platform; our belief that the design and planned enrollment will be appropriate to potentially support a BLA submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers; our belief that a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, that could provide a potential registrational data set, and 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 1/2 eNRGy trial and planned update by the first half of 2022, the advancement of the Phase 1 trial of MCLA-145, and planned update at ESMO Immuno-Oncology Congress 2021, the advancement of the phase 1 trial for MCLA-158 and the planned update in 2022, and the advancement of the phase 1/2 trial for MCLA-129; the design and treatment potential of our bispecific antibody candidates and the planned update after the recommended phase 2 dose has been reached, clinical study designs, the preclinical data and further advancement of our internal pipeline; our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform; and 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, 2021, and our other reports filed with the Securities and Exchange Commission, 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:
Kathleen Farren
Merus N.V.
Corp Comms and IR
617-230-4165
k.farren@merus.nl

Merus