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

November 5, 2020

–Clinical data and program update planned for lead program Zenocutuzumab ("Zeno") in 2Q 2021 –
– MCLA-129 expected to enter clinic in 2021 –

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Nov. 05, 2020 (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, 2020, and provided a business update.

"Our lead program with Zeno in neuregulin 1 (NRG1) fusion cancers continues to advance steadily, and we look forward to sharing data from the eNRGy clinical trial and the Early Access Program in the second quarter of 2021," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "We continue to add eNRGy clinical trial sites globally and expand our comprehensive screening efforts, focused on pancreatic cancer, to aid in identifying patients who may be eligible for our trial. Our additional clinical pipeline programs are progressing, and our preclinical candidate, MCLA-129 targeting EGFR and c-MET, is expected to enter the clinic in 2021."

Clinical Programs

Zenocutuzumab, or "Zeno" (MCLA-128: HER3 x HER2 Biclonics®)
NRG1 gene fusion (NRG1+) Cancers: Phase 1/2 eNRGy trial clinical data and program update planned for 2Q 2021

Merus continues to enroll patients in the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. Merus believes that Zeno continues to demonstrate encouraging single agent activity in NRG1+ cancers and appears to be well tolerated, consistent with previously reported safety data in the overall patient population treated with Zeno monotherapy. The initial clinical responses reported in late 2019 support the potential for Zeno to be particularly effective in patients with NRG1+ cancers, a patient population with significant unmet need.

Earlier this year, Zeno was granted Orphan Drug Designation by the U.S. FDA for pancreatic cancer. Pancreatic cancer is estimated to occur in approximately 57,000 patients annually in the U.S., according to the National Cancer Institute (NCI) SEER database. Pancreatic ductal adenocarcinoma (PDAC), the most common subtype of pancreatic cancer, is one of the most aggressive solid tumor cancers and the fourth leading cause of cancer-related deaths.

Merus plans to present efficacy data from the eNRGy trial and Early Access Program (EAP) at a major medical conference in the second quarter of 2021 including results from more than 30 patients with NRG1+ pancreatic, non-small cell lung and other cancers with the opportunity for four or more months of follow up. At that time, Merus plans to also discuss details of the program and overall strategy.

Clinical trial site activation, patient identification and enrollment, and clinical operations activities for the eNRGy trial have increased since the second quarter of 2020. The Company has previously noted that enrollment and clinical operations activities in this trial have continued, albeit at a slower pace, throughout the COVID-19 pandemic. Over 30 clinical trial sites are now open globally, with additional sites planned for the coming months. Merus expects patient identification and enrollment to continue to accelerate through the Company's ongoing patient screening and patient identification initiatives, including several programs with clinical support and testing collaborators.

Merus' comprehensive patient recruitment strategy includes agreements with Caris Life Sciences (Caris), Foundation Medicine Inc., and Tempus Labs Inc., to identify NRG1+ patients and determine suitability of enrollment of these patients in the eNRGy trial and EAP. Separately, Merus has a collaboration with Caris, through which Caris has agreed to provide tumor DNA and RNA molecular testing, focused on pancreatic cancer, which occurs in a patient population that may otherwise not undergo molecular diagnostic testing due to the current lack of personalized, molecularly-driven treatment options for this cancer type.

In October 2020, Merus entered into an agreement with myTomorrows, in which it has agreed to raise awareness of NRG1+ molecular screening offered by Merus for eligible patients, focusing on pancreatic cancer, to identify the presence of NRG1+ and to increase awareness of and potential enrollment in Merus' eNRGy clinical trial.

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

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors
Phase 1 trial continues; Update expected by year end

MCLA-158 is currently being evaluated in a Phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase in patients with solid tumors. MCLA-158 has demonstrated a favorable safety profile with no observed dose limiting toxicities to date. Merus plans to provide a clinical update on the Phase 1 trial by year end.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial advancing as planned

MCLA-145 is currently being evaluated in a Phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, in patients with solid tumors. MCLA-145 is the first drug candidate co-developed under Merus' global collaboration and license agreement with Incyte Corporation, which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. Merus retains full rights to develop and

commercialize MCLA-145, if approved, in the United States, and Incyte is responsible for its development and commercialization outside the United States.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
IND-enabling studies ongoing, first patient planned to be dosed in 2021

Merus is currently conducting IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals and the first patient is planned to be dosed in 2021. Merus presented preclinical data in late 2019 demonstrating that MCLA-129 inhibited the growth of tyrosine kinase resistant non-small cell lung cancer (NSCLC) cell lines and NSCLC tumors in xenograft models. Betta holds exclusive rights to develop MCLA-129 in China, while Merus retains full ex-China rights.

Third Quarter 2020 Financial Results

The Company ended the third quarter with cash, cash equivalents and marketable securities of $190.2 million compared to $241.8 million at December 31, 2019. The decrease was primarily the result of cash used in operations, and effects of exchange rate changes.

Comparison of the Three Months Ended September 30, 2020 and 2019

Collaboration revenue for the three months ended September 30, 2020 increased by $0.3 million as compared to the three months ended September 30, 2019, primarily as a result of an increase in Incyte reimbursement revenue of $2.0 million due to increased activities, and $0.5 million in other net increases, including the achievement of a Simcere milestone, partially offset by a decrease of $2.2 million in Ono milestone revenue due to the achievement of milestones in the prior year period that did not recur in the current year period. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended September 30, 2020 increased by $4.0 million as compared to the three months ended September 30, 2019, primarily as a result of an increase in headcount, higher manufacturing related costs, and higher pre-clinical research and development-related costs related to the Company's programs, particularly increases in costs for zenocutuzumab.

General and administrative expense for the three months ended September 30, 2020 increased by $1.1 million as compared to the three months ended September 30, 2019, primarily as a result increases in stock-based compensation, insurance, intellectual property related costs and other items, partially offset by a decrease in consulting costs.

Other loss, net for the three months ended September 30, 2020 was $4.8 million as compared to other income, net of $4.1 million for the three months ended September 30, 2019. Other income (loss), net consists of interest earned on the Company's cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains on the Company's foreign denominated cash, cash equivalents and marketable securities.

Comparison of the Nine Months Ended September 30, 2020 and 2019

Collaboration revenue for the nine months ended September 30, 2020 decreased by $2.7 million as compared to nine months ended September 30, 2019 primarily as a result of an increase in Incyte reimbursement revenue of $0.6 million due to increased activities, a decrease of $3.4 million in Ono milestone revenue due to the achievement of milestones in the prior year which period that did not recur in the current year period, partially offset by an increase in Incyte reimbursement revenue of $0.6 million due to increased activities.

Research and development expense for the nine months ended September 30, 2020 increased by $12.1 million as compared to the nine months ended September 30, 2019, primarily as a result of an increase in manufacturing related costs, and higher pre-clinical research and development-related costs related to the Company's programs, particularly increases in costs for zenocutuzumab, offset by decreases in costs for MCLA-145. On a comparative basis, stock-based compensation included in research and development costs for the nine months ended September 30, 2020 decreased by $0.7 million compared to the nine months ended September 30, 2019, primarily due to the modification and forfeiture of awards held by departing executives.

General and administrative expense for the nine months ended September 30, 2020 increased by $3.1 million as compared to the nine months ended September 30, 2019, primarily as a result increases in stock-based compensation, insurance, facilities, intellectual property related costs and other items, partially offset by a decrease in consulting costs.

Other loss, net for the nine months ended September 30, 2020 was $3.9 million as compared to other income, net of $6.2 million for the nine months ended September 30, 2019. Other income (loss), net consists of interest earned on the Company's cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains on the Company's foreign denominated cash, cash equivalents and marketable securities.

Financial Outlook

Based on the Company's current operating plan, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second half of 2022.

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,179	$ 197,612
Marketable securities	51,021	42,153
Accounts receivable	538	941
Accounts receivable (related party)	1,568	1,711
Prepaid expenses and other current assets	9,010	4,951
Total current assets	201,316	247,368
Marketable securities	—	2,009
Property and equipment, net	3,792	3,715

Operating lease right-of-use assets	4,229	5,215
Intangible assets, net	2,784	2,876
Deferred tax assets	291	288
Other assets	1,081	1,905
Total assets	$ 213,493	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,720	$ 3,029
Accrued expenses	19,819	13,536
Current portion of lease obligation	1,536	1,380
Current portion of deferred revenue	699	941
Current portion of deferred revenue (related party)	18,657	17,901
Total current liabilities	45,431	36,787
Lease obligation	2,736	3,872
Deferred revenue, net of current portion	331	780
Deferred revenue, net of current portion (related party)	80,494	90,637
Total liabilities	128,992	132,076
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 29,074,536 and 28,882,217 shares issued and outstanding as at September 30, 2020 and December 31, 2019, respectively	$ 2,938	$ 2,918
Additional paid-in capital	448,617	441,395
Accumulated other comprehensive income	5,094	1,586
Accumulated deficit	(372,148)	(314,599)
Total stockholders' equity	84,501	131,300
Total liabilities and stockholders' equity	$ 213,493	$ 263,376

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,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 695	$ 2,558	$ 1,207	$ 4,496
Collaboration revenue (related party)	7,875	5,690	19,720	19,061
Grant revenue	—	(93)	—	(216)
Total revenue	8,570	8,155	20,927	23,341
Operating expenses:				
Research and development	17,538	13,511	48,234	36,078
General and administrative	9,136	8,024	26,061	22,979
Total operating expenses	26,674	21,535	74,295	59,057
Operating loss	(18,104)	(13,380)	(53,368)	(35,716)
Other income (loss), net:				
Interest (expense) income, net	(12)	591	367	1,756
Foreign exchange (losses) gains	(4,782)	3,468	(4,243)	4,474
Other income (loss), net	(4,794)	4,059	(3,876)	6,230
Net loss before income taxes	(22,898)	(9,321)	(57,244)	(29,486)
Tax expense (benefit)	177	(54)	305	239
Net loss	$ (23,075)	$ (9,267)	$ (57,549)	$ (29,725)
Other comprehensive income (loss):				
Currency translation adjustment	4,414	(3,561)	3,508	(4,363)
Comprehensive loss	$ (18,661)	$ (12,828)	$ (54,041)	$ (34,088)
Net loss per share attributable to common stockholders: Basic and diluted	$ (0.64)	$ (0.55)	$ (1.86)	$ (1.46)
Weighted-average common shares outstanding: Basic and diluted	29,061	23,403	29,014	23,388

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 sufficiency of our cash, cash equivalents and marketable securities, the promise of and potential benefit of our clinical assets, our lead program Zeno in NRG1 fusion cancers continuing to advance steadily; the continuing addition of eNRGy clinical trial sites globally and expanding our comprehensive screening efforts, focused on pancreatic cancer to aid in identifying patients who may be eligible for our trial; our plans to present efficacy data from the eNRGy trial and EAP at a major medical conference in the second quarter of 2021 including results from more than 30 patients with NRG1+ pancreatic, non-small cell lung and other cancers with the opportunity for four or more months of follow up and plans to also discuss details of the program and overall strategy; the potential for Zeno to be particularly effective in patients with NRG1+ cancers, our expectations surrounding patient enrollment in our clinical trials, including enrolling patients for the Phase 1/2 eNRGy trial; the ability of our agreements with Caris, Foundation Medicine Inc., and Tempus Labs Inc. to identify NRG1+ patients and determine suitability of enrollment of these patients in our eNRGy trial and EAP; the ability of the collaboration with Caris to identify patients with NRG1+ cancer, for potential participation in the eNRGy trial and EAP; Caris' performance of tumor DNA and RNA molecular testing in this patient population having pancreatic cancer; myTomorrows' agreement to raise awareness of molecular screening offered by Merus for eligible patients, focusing on pancreatic cancer, to identify the presence of NRG1 fusions and to increase awareness of and potential enrollment in Merus' eNRGy clinical trial; the content and timing of potential milestones, updates, guidance, information, clinical trials and data readouts for our product candidates, including with respect to the Phase 1/2 eNRGy trial, Phase 1 trial for MCLA-158, and MCLA-129; the design and treatment potential of our bispecific antibody candidates, clinical study designs, the preclinical data for MCLA-129 showing that MCLA-129 inhibited the growth of tyrosine kinase resistant NSCLC cell lines and NSCLC tumors in xenograft models, our conducting IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals, our global collaboration and license agreement with Incyte Corporation, potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform; and the impact of COVID-19. 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; and our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 filed with the Securities and Exchange Commission, or SEC, on November 5, 2020, 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:

Jillian Connell
Merus N.V.
Investor Relations and Corporate Communications
617-955-4716
j.connell@merus.nl

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