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

August 6, 2020

– Lead program Zenocutuzumab remains on track –
– Dr. Andrew Joe appointed Chief Medical Officer –
– Merus extends cash runway into 2H 2022 –

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Aug. 06, 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 second quarter that ended June 30, 2020, and provided a business update.

"We are pleased to report several updates and progress with our business this quarter," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "On the clinical side, Dr. Andrew Joe has been appointed Chief Medical Officer, bringing over 20 years of clinical experience developing cancer therapies, including molecularly-targeted and tumor-agnostic therapies, to the Merus team. On the business side, we have prudently focused our projected spend and anticipate our cash runway will fund our operations into the second half of 2022, putting us in a strong financial position. We look forward to providing a substantive clinical update on zenocutuzumab (Zeno) for neuregulin 1 (NRG1) fusion cancers by year end."

Clinical Programs

Zenocutuzumab (MCLA-128: HER3 x HER2 Biclonics®)
NRG1+ Cancers: Phase 1/2 eNRGy trial on track for year-end clinical update

Merus continues to enroll patients in the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of zenocutuzumab (Zeno) monotherapy in NRG1 gene fusion-positive (NRG1+) solid tumors. 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. Zeno was granted Orphan Drug Designation by the U.S. FDA for pancreatic cancer earlier this year.

Over 25 global clinical trial sites for the eNRGy trial are now open, with additional clinical trial sites being added globally. To date, Merus has observed a moderate to high impact on clinical trial enrollment and operations as a consequence of issues related to the COVID-19 pandemic. 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 Early Access Program (EAP). In July 2020, Merus separately announced a collaboration with Caris to identify patients with NRG1+ cancers for potential participation in the eNRGy trial and EAP. This agreement with Caris focuses on screening for pancreatic cancer. Caris has agreed to provide tumor DNA and RNA molecular testing in this 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.

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-117 (CLEC12A x CD3 Biclonics®): Acute Myeloid Leukemia (AML)
MCLA-117 Phase 1 interim data presented at ASCO Virtual Meeting

MCLA-117 is a first-in-class bispecific (Biclonics®) T-cell engager antibody that is designed to engage CD3 on T-cells and to bind to and kill AML blasts via the CLEC12A antigen. It is being evaluated in a Phase 1 open-label, multicenter dose escalation study in patients with AML.

In May, Merus announced that MCLA-117 demonstrated clinical activity in terms of T-cell activation, mild to moderate cytokine release syndrome and blast count reductions in some patients and at some dose cohorts. However, Merus does not plan to continue enrollment into dose expansion cohorts in the trial. Insights from this trial are being used to inform and maximize development of our CD3 T-cell engager platform, which includes a panel of more than 175 novel and diverse T-cell CD3 fragment antigen-binding (Fab) binders across a wide range of affinities and attributes.

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. The trial is ongoing and 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

Merus is currently conducting IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals (Betta). 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.

Corporate Activities

Dr. Andrew Joe appointed Chief Medical Officer

In July, Merus appointed Dr. Andrew Joe as Chief Medical Officer. Dr. Joe oversees all clinical and regulatory strategy and activities at Merus. He brings over 20 years of experience in clinical drug development and translational research within industry and academic medicine. Dr. Joe most recently led the immuno-oncology program at Sanofi, which included co-development of LIBTAYO® (cemiplimab-rwlc) with Regeneron in skin, lung and other cancers. Previously at Merck Sharp & Dohme Corp., he led the KEYTRUDA® (pembrolizumab) New Indications Development Team in obtaining the first tumor/histology-agnostic drug approval in Microsatellite Instability-High (MSI-H) cancer, and the first immuno-oncology drug approval in a gynecological malignancy (cervical cancer). Dr. Joe also played key roles at Novartis in the global approval of Zykadia® (ceritinib) in ALK-positive lung cancer and at Roche in the global approval of ZELBORAF® (vemurafenib) in BRAF-mutant metastatic melanoma. Dr. Joe is an Assistant Professor of Medicine at Columbia University Irving Medical Center. He received B.S. degrees in chemistry and biology from the Massachusetts Institute of Technology and an M.D. from the Mount Sinai School of Medicine.

Cash Runway Extended Two Quarters into 2H 2022

Based on the Company's current operating plan, Merus expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second half of 2022. This represents an expected extension of the cash runway by approximately two quarters, and is based on the program decisions, including no longer planning to enroll the previously planned dose expansion cohort in the MCLA-117 program, lowering general and administrative costs and travel expenses, in part due to COVID-19, and reducing planned personnel and other spend across programs and functions.

Second Quarter 2020 Financial Results

As a consequence of becoming a U.S. domestic issuer as of January 1, 2020, the Company is required to present its financial information in accordance with U.S. generally accepted accounting practices (GAAP) and expressed in U.S. dollars from that date. The below financial information has been prepared in accordance with U.S. GAAP. The financial information should not be expected to correspond to figures the Company has previously presented under International Financial Reporting Standards (IFRS).

Comparison of the three months ended June 30, 2020 and 2019

Collaboration revenue for the three months ended June 30, 2020 decreased by $0.4 million as compared to the three months ended June 30, 2019, primarily as a result of a decrease in Incyte reimbursement revenue of $0.2 million, and a decrease of $0.2 million in reimbursement revenue under other collaboration arrangements. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended June 30, 2020 increased by $2.9 million as compared to the three months ended June 30, 2019, primarily as a result of an increase in headcount and higher pre-clinical research and development-related costs related to the Company's programs, particularly increases in costs for zenocutuzumab. On a comparative basis, stock-based compensation included in research and development costs for the three months ended June 30, 2020 decreased by $1.0 million compared to the three months ended June 30, 2019, primarily due to the modification and forfeiture of awards held by departing executives.

General and administrative expense for the three months ended June 30, 2020 decreased by $0.2 million as compared to the three months ended June 30, 2019, primarily as a result of lower consulting costs offset by increases in stock-based compensation, intellectual property filing related costs and other items.

Other loss, net for the three months ended June 30, 2020 was $2.2 million as compared to $0.7 million for the three months ended June 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 losses on the Company's foreign denominated cash, cash equivalents and marketable securities.

Comparison of the six months ended June 30, 2020 and 2019

Collaboration revenue for the six months ended June 30, 2020 decreased by $3.0 million as compared to the six months ended June 30, 2019 primarily as a result of a decrease in Incyte reimbursement revenue of $1.3 million and amortization of upfront payments of $0.2 million due to the effects of foreign exchange, a decrease in Ono milestone revenue of $1.1 million in addition to other decreases of $0.3 million.

Research and development expense for the six months ended June 30, 2020 increased by $8.1 million as compared to the six months ended June 30, 2019, primarily as a result of an increase in headcount 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 six months ended June 30, 2020 decreased by $0.8 million compared to the six months ended June 30, 2019, primarily due to the modification and forfeiture of awards held by departing executives.

General and administrative expense for the six months ended June 30, 2020 increased by $1.9 million as compared to the six months ended June 30, 2019, primarily as a result of an increase in headcount, stock-based compensation, facilities and professional fees, offset by decreases in consulting cost.

Other income, net for the six months ended June 30, 2020 was $0.9 million as compared to $2.2 million for the six months ended June 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.

The Company ended the second quarter with cash, cash equivalents and marketable securities of $197.4 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.

Financial Outlook

Based on the Company's current operating plan, the Company expects its existing cash, cash equivalents and investments 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 152,088	$ 197,612
Marketable securities	45,278	42,153
Accounts receivable	142	941
Accounts receivable (related party)	1,809	1,711
Prepaid expenses and other current assets	12,087	4,951
Total current assets	211,404	247,368
Marketable securities	—	2,009
Property and equipment, net	3,617	3,715
Operating lease right-of-use assets	4,531	5,215
Intangible assets, net	2,731	2,876
Deferred tax assets	210	288
Other assets	1,168	1,905
Total assets	$ 223,661	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,362	$ 3,029
Accrued expenses	15,931	13,536
Current portion of lease obligation	1,451	1,380
Current portion of deferred revenue	727	941
Current portion of deferred revenue (related party)	17,844	17,901
Total current liabilities	38,315	36,787
Lease obligation	3,119	3,872
Deferred revenue, net of current portion	457	780
Deferred revenue, net of current portion (related party)	81,474	90,637
Total liabilities	123,365	132,076
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 29,047,344 and 28,882,217 shares issued and outstanding as at June 30, 2020 and December 31, 2019, respectively	$ 2,935	$ 2,918
Additional paid-in capital	445,754	441,395
Accumulated other comprehensive (loss) income	680	1,586
Accumulated deficit	(349,073)	(314,599)
Total stockholders' equity	100,296	131,300
Total liabilities and stockholders' equity	$ 223,661	$ 263,376

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 184	$ 336	$ 512	$ 1,938
Collaboration revenue (related party)	5,872	6,144	11,845	13,371
Grant revenue	—	(123)	—	(123)
Total revenue	6,056	6,357	12,357	15,186
Operating expenses:				
Research and development	13,709	10,768	30,696	22,567
General and administrative	8,043	8,214	16,925	14,955
Total operating expenses	21,752	18,982	47,621	37,522
Operating loss	(15,696)	(12,625)	(35,264)	(22,336)
Other income (loss), net:				
Interest income, net	99	535	379	1,165
Foreign exchange gains (losses)	(2,346)	(1,214)	539	1,006
Other income (loss), net	(2,247)	(679)	918	2,171

Net loss before income taxes	(17,943)	(13,304)	(34,346)	(20,165)
Tax expense	31	71	128	293
Net loss	$ (17,974)	$ (13,375)	$ (34,474)	$ (20,458)
Other comprehensive income (loss):				
Currency translation adjustment	2,201	1,098	(906)	(802)
Comprehensive loss	$ (15,773)	$ (12,277)	$ (35,380)	$ (21,260)
Net loss per share attributable to common stockholders: Basic and diluted	$ (0.54)	$ (0.52)	$ (1.22)	$ (0.91)
Weighted-average common shares outstanding: Basic and diluted	29,034	23,388	28,990	23,380

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, the potential for Zeno to be particularly effective in patients with NRG1+ cancers, our 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 that may otherwise not undergo molecular diagnostic testing due to the current lack of personalized, molecularly-driven treatment options; 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 and Phase 1 trial for MCLA-158; 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 June 30, 2020 filed with the Securities and Exchange Commission, or SEC, on August 6, 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.

LIBTAYO® is a registered trademark of Regeneron Pharmaceuticals, Inc. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp. Zykadia® is a registered trademark of Novartis AG. ZELBORAF® is a registered trademark of Genentech Inc.

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