Merus Announces Financial Results for the Fourth Quarter and Full Year 2019 and Provides Business Update

March 12, 2020

UTRECHT, The Netherlands and CAMBRIDGE, Mass., March 12, 2020 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", "we", or "our"), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics™), today announced financial results for the fourth quarter and full year ended December 31, 2019, and provided a business update.

"Significant advancements made in 2019 have set the stage for an exciting and productive year ahead," said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "Merus was founded on strong, sophisticated science and we have now matured into a promising clinical-stage company with compelling early data in our first and most advanced clinical program, zenocutuzumab, for patients with cancers that harbor NRG1 gene fusions. Along with our additional clinical programs, robust platform technology and strong balance sheet, Merus is well-positioned to achieve meaningful results for cancer patients in need."

Clinical Programs and Business Update

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

NRG1+ Cancers: Encouraging, early clinical activity, Phase 1/2 eNRGy trial enrollment continues

On October 27, 2019, Merus provided an update on the eNRGy trial and reported encouraging early clinical activity in several patients with pancreatic or non-small cell lung cancer harboring NRG1 gene fusions, including tumor shrinkage, symptomatic improvement and durability up to the then most recent assessment.

Merus is currently enrolling patients for the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1 gene fusion-positive (NRG1+) cancers. The eNRGy trial consists of three cohorts: NRG1+ pancreatic cancer, NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ other solid tumors. Details of the eNRGy trial evaluating Zeno in patients with solid tumors that have NRG1 gene fusions, including current trial sites, can be found at www.ClinicalTrials.gov and Merus' trial website at www.nrg1.com.

In the fourth quarter, Merus entered into agreements with Caris Life Sciences, Foundation Medicine Inc. and Tempus Labs Inc. to enhance identification of NRG1+ patients, and in conjunction with their physicians, health care providers and institutions, determine the potential suitability of enrollment of these patients in our eNRGy trial and Early Access Program. This is one pillar of our overall strategy to increase awareness of our trial and identification of patients who have the potential to benefit from Zeno.

Merus expects to present data at a medical conference by the end of 2020.

Metastatic Breast Cancer: Phase 2 interim analysis reported

In the Phase 2 metastatic breast cancer trial, in patients enrolled as of August 31, 2019, Merus conducted an unplanned interim efficacy analysis with a data cut-off of October 23, 2019. Enrollment for this study is now completed. Merus expects to present results, including the primary endpoint of clinical benefit rate at 24 weeks, at a medical conference in 2020. With the completion of this trial, Merus will only advance development in metastatic breast cancer with a collaborator and intends to focus efforts on the eNRGy trial going forward.

MCLA-117 (CLEC12A x CD3 Biclonics®): Acute Myeloid Leukemia (AML) – Initial Phase 1 data expected in 1H20

The Phase 1 trial is a single-arm, open-label, global study to assess the safety, tolerability and anti-tumor activity of MCLA-117 in up to 90 patients with relapsed/refractory AML. In July 2019, Merus amended the MCLA-117 protocol to allow for the exploration of higher dose cohorts. Preliminary anti-tumor activity was reported in December 2018 and dose escalation for the Phase 1 clinical trial for MCLA-117 continues. Merus continues to expect to present interim data at a medical conference in the first half of 2020.

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors – Phase 1 trial progressing at higher dose cohorts

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 Phase 1 protocol was amended to allow for the exploration of higher dose cohorts. Dose escalation is ongoing and as of year-end, MCLA-158 has demonstrated a favorable safety profile with no observed dose limiting toxicities.

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

The Phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing and consists of dose escalation followed by dose expansion. MCLA-145 is the first drug candidate co-developed under our 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 has 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 presented preclinical data on MCLA-129 in October 2019, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing that MCLA-129 inhibited the growth of tyrosine kinase resistant NSCLC cell lines and NSCLC tumors in xenograft models. Merus is currently conducting

IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals (Betta Pharma). Betta Pharma has exclusive rights to develop MCLA-129 in China, while Merus has full ex-China rights.

Bill Lundberg, M.D., Named Chief Executive Officer

On December 31, 2019, Dr. Bill (Sven Ante) Lundberg was elected Executive Director, President, Chief Executive Officer and Principal Financial Officer of Merus, succeeding Ton Logtenberg, Ph.D., who stepped down after 16 years of leadership. Dr. Lundberg joined Merus' Board of Directors as a non-executive director in June 2019 and brings more than 15 years of experience managing and leading biotechnology research and development, along with a background as a medical oncologist. Previously, Dr. Lundberg served as Chief Scientific Officer at CRISPR Therapeutics and as Head of Translational Medicine at Alexion Pharmaceuticals.

Cash Runway Extended, Merus Expects to be Funded into 2022 through First Follow-on Offering

On November 5, 2019, Merus priced its first follow-on offering since its 2016 IPO, raising a total of $79.2 million in gross proceeds.

Full Year 2019 Financial Results

In prior periods, the Company prepared its financial information in accordance with IFRS. As a consequence of becoming a domestic issuer as of January 1, 2020, the Company is required to present its financial information in accordance with U.S. GAAP and expressed in U.S. dollars from that date. As U.S. GAAP will be the basis of preparing and presenting financial information, the below unaudited 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 IFRS.

Collaboration revenue for the year ended December 31, 2019 ($31.3 million) decreased $6.8 million as compared to the year ended December 31, 2018 ($38.1 million), primarily as a result of a decrease in Incyte reimbursement revenue of $3.2 million, $1.0 million upfront payment from Betta recognized in 2018 that is non-recurring in 2019, decrease in Ono reimbursement revenue of $0.9 million and $0.6 million lower Ono milestone revenue. The decrease in exchange rates through 2019 negatively impacted collaboration revenue by $1.3 million.

Research and development expense for the year ended December 31, 2019 ($55.7 million) increased $0.9 million as compared to the year ended December 31, 2018 ($54.8 million), primarily as a result of an increase in headcount and higher preclinical research and development-related costs related to the Company's programs, particularly increases in costs for MCLA-117 offset by decreases in costs for zenocutuzumab and MCLA 145.

General and administrative expense for the year ended December 31, 2019 ($34.1 million) increased $4.7 million as compared to the year ended December 31, 2018 ($29.4 million), primarily as a result of an increase in headcount, consulting, accounting and professional fees as well as higher facilities-related expenses.

Other income, net ($3.7 million) consists of interest earned on the Company's cash, cash equivalents and marketable securities held on account, accretion of investment earnings and net foreign exchange gains on our foreign denominated cash, cash equivalents and marketable securities. For the year ended December 31, 2018, other income ($17.6 million) included a gain recognized upon the settlement of litigation with Regeneron of $8.1 million.

The Company ended 2019 with cash, cash equivalents and marketable securities of $241.8 million compared to $235.4 million at December 31, 2018. The increase was primarily the result of net proceeds received from the issuance of common stock, net of cash used in operations and purchases of property, plant and equipment, 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 2022.

MERUS N.V.
Unaudited Consolidated Balance Sheet
(in U.S. dollar thousands, except share data)

	As at December 31, 2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 197,612	$ 164,590
Marketable securities	42,153	70,761
Accounts receivable	941	369
Accounts receivable (related party)	1,711	2,982
Prepaid expenses and other current assets	4,951	4,733
Total current assets	247,368	243,435
Marketable securities	2,009	—
Property and equipment, net	3,715	2,706
Operating lease right-of-use assets	5,215	2,538
Intangible assets, net	2,876	2,864
Deferred tax assets	288	199
Other assets	1,905	1,231
Total assets	$ 263,376	$ 252,973
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,029	$ 3,239
Accrued expenses	13,536	10,386
Current portion of lease obligation	1,380	840
Current portion of deferred revenue	941	1,248
Current portion of deferred revenue (related party)	17,901	18,246
Total current liabilities	36,787	33,959
Lease obligation	3,872	1,849
Deferred revenue, net of current portion	780	683

Deferred revenue, net of current portion (related party)	90,637	110,625
Total liabilities	132,076	147,116
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 28,882,217 and 23,358,977 shares issued and outstanding as at December 31, 2019 and 2018, respectively	$ 2,918	$ 2,366
Additional paid-in capital	441,395	360,045
Accumulated other comprehensive income	1,586	2,894
Accumulated deficit	(314,599)	(259,448)
Total stockholders' equity	131,300	105,857
Total liabilities and stockholders' equity	$ 263,376	$ 252,973

MERUS N.V.
Unaudited Statements of Operations and Comprehensive Loss
(in U.S. dollar thousands, except share data)

	Year Ended December 31,	
	2019	**2018**
Collaboration revenue	$ 5,517	$ 8,176
Collaboration revenue (related party)	25,831	29,969
Grant revenue	(215)	233
Total revenue	31,133	38,378
Operating expenses:		
Research and development	55,680	54,767
General and administrative	34,110	29,354
Total operating expenses	89,790	84,121
Operating loss	(58,657)	(45,743)
Other income, net:		
Interest income, net	1,889	2,132
Foreign exchange gains	1,615	7,126
Miscellaneous income and gains	196	8,380
Other income, net	3,700	17,638
Loss before income taxes	(54,957)	(28,105)
Tax expense	194	205
Net loss	$ (55,151)	$ (28,310)
Other comprehensive loss:		
Currency translation adjustment	(1,308)	(6,498)
Comprehensive loss	$ (56,459)	$ (34,808)
Loss per share allocable to common stockholders:		
Basic and diluted	$ (2.28)	$ (1.27)
Weighted average shares outstanding:		
Basic and diluted	24,218,083	22,286,720

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclonics®. Biclonics® 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 sufficiency of our cash, cash equivalents and investments, the productivity of the year ahead, the promise of and potential benefit of our clinical assets, compelling data in our first and most advanced clinical program concerning zenocutuzumab, the robustness of our platform technology and strength of our balance sheet, our ability to achieve meaningful results for cancer patients in need, our enrollment in our clinical trials, including enrolling patients for the Phase 1/2 eNRGy trial for three cohorts: NRG1+ pancreatic cancer, NRG1+ non-small cell lung cancer (NSCLC) and NRG1+ other solid tumors, the impact of our agreements with Caris Life Sciences, Foundation Medicine Inc., and Tempus Labs Inc., to enhance identification of patients with NRG1+ cancers, and assist such patients in conjunction with their physicians, health care providers and institutions to determine the potential suitability of enrolling in our eNRGy trial and EAP, the content and timing of potential milestones described in this press release, the timing of updates, guidance, information, clinical trials and data readouts for our product candidates, 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 Pharma, our global collaboration and license agreement with Incyte Corporation, and potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. 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 Biclonics® and bispecific 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; 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 30, 2018, 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.

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