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

May 11, 2020

MCLA-128, zenocutuzumab, Phase 1/2 eNRGy trial remains on track

MCLA-117 program update to be presented at upcoming medical meeting

Anand Mehra, M.D. to succeed Russell Greig, Ph.D. as Chairman and Paolo Pucci Nominated for Appointment to Merus Board of Directors

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 11, 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 first quarter that ended March 31, 2020, and provided a business update.

"We have made progress on our clinical programs despite the effects of the current COVID-19 pandemic, and remain on track to provide a clinical update on zenocutuzumab (Zeno) for NRG1 fusion cancers later this year, said Bill Lundberg, M.D., President, Chief Executive Officer and Principal Financial Officer of Merus. "In the near term, more information on our clinical programs as well as preclinical work on our CD3 T-cell engager platform will be presented at upcoming medical meetings. Overall, 2020 continues to be a productive and important year for Merus as we remain focused on delivering innovative treatments for cancer patients in need."

Clinical Programs

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

NRG1+ Cancers: Phase 1/2 eNRGy trial on track for year-end 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.

The NRG1 fusion is a rare, powerful driver of cancer. To better ascertain its occurrence, Merus engaged an independent organization to undertake a robust epidemiology assessment of the frequency of NRG1+ cancers, which will be reported at the American Society of Clinical Oncology (ASCO) Annual Meeting in late May.

The majority of global clinical trial sites for the eNRGy trial are now open and despite slower enrollment and cessation of new recruiting at several clinical trial sites due to COVID-19, Merus remains on track to present data from the Phase 1/2 eNRGy trial by the end of 2020. Merus has also entered into agreements with Caris Life Sciences, Foundation Medicine Inc. and Tempus Labs Inc., to enhance the ability to identify NRG1+ patients and determine suitability of enrollment of these patients in the eNRGy trial and Early Access Program.

In April 2020, following the previously announced departure of former Chief Medical Officer Leonardes Andres Sirulnik, M.D., Dr. Victor Sandor, who has served on the Merus Board of Directors since June 2019 and is Chairman of Merus' Research & Development Committee, agreed to provide strategic oversight of the eNRGy trial on an interim basis until a new Chief Medical Officer is identified. Dr. Sandor brings considerable early and late-stage clinical development expertise, to the eNRGy trial program. He previously served as Chief Medical Officer at Array BioPharma, which was acquired by Pfizer, where he was instrumental in obtaining the approval of BRAFTOVI® (encorafenib) and MEKTOVI® (binimetinib) for the treatment of BRAFV600E/K mutant melanoma.

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 Interim Phase 1 data expected in 1H20

MCLA-117 is a bispecific antibody (Biclonics®) T-cell engager that is designed to engage CD3 on T-cells and to bind to and kill AML blasts via the CLEC12A antigen. It is currently being evaluated in a 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.

Merus has submitted an abstract on interim data from the Phase 1 trial, as well as an abstract on its extensive novel panel of CD3 T-cell engaging common light chain antibodies, to the European Hematology Association Annual Meeting in June, 2020.

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

Phase 1 trial continues with 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. Dose escalation is ongoing and MCLA-158 has demonstrated a favorable safety profile with no observed dose limiting toxicities to date. Merus plans to provide an update on the Phase 1 trial by year end.

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 Merus' global collaboration and license agreement with Incyte Corporation, which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the 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 is currently conducting IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals. 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

COVID-19 Impact and Mitigation

To date, Merus has observed a moderate impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic, including adjustments to allow remote visits for some patient follow-up, and reduced on-site monitoring by the sponsor or CRO. However, all ongoing clinical trials continue to enroll patients. Drug supply for clinical trials remains secure and patients continue to receive treatment.

For Zeno in particular, Merus reaffirms its guidance to present interim data from the eNRGy trial by year end. Through various measures, including physician outreach and site and patient support, the Company has been working to bring patients into either the eNRGy trial or Expanded Access Program (EAP) and keep them on treatment during the pandemic. In addition, the EAP for Zeno remains open to facilitate treatment for eligible patients who are unable to enroll at a clinical trial site.

On the research side, after having previously closed its research laboratories due to the COVID-19 pandemic, Merus has reopened the Utrecht- based labs in compliance with The Netherlands guidelines and is restarting laboratory research activities.

Annual General Meeting and Board of Directors

The Company's annual general meeting of shareholders (AGM) is planned to be held on June 30, 2020. In addition, on May 11, 2020, Merus announced planned changes to its Board of Directors. Dr. Anand Mehra will succeed Dr. Russell Greig as Chairman of the Board of Directors from the conclusion of the Company's AGM when Dr. Greig will be stepping down from the Board of Directors. Mr. Paolo Pucci has been nominated for appointment to the Company's Board of Directors at the upcoming AGM as Dr. John de Koning plans to step down at that time.

Dr. Mehra has been a member of the Board of Directors since August 2015. He most recently served as General Partner at Sofinnova Investments, Inc., a biotech investment firm, which he joined in 2007. Previously, Dr. Mehra worked in J.P. Morgan's private equity and venture capital group, and was a consultant in McKinsey & Company's pharmaceutical practice. Dr. Mehra currently serves on the boards of directors of several private companies and previously served on the boards of directors of the publicly held pharmaceutical companies Marinus Pharmaceuticals, Inc., Spark Therapeutics, Inc. and Aerie Pharmaceuticals, Inc. Dr. Mehra received a Bachelor of Arts in political philosophy from the University of Virginia and a Doctor of Medicine from Columbia University's College of Physicians and Surgeons.

Mr. Paolo Pucci most recently served as the Chief Executive Officer of ArQule, Inc., a biopharmaceutical oncology and rare diseases company that was acquired by Merck in January 2020. Prior to joining ArQule in 2008, Mr. Pucci worked at Bayer AG, where he served in a number of leadership capacities including President of the Oncology & Global Specialty Medicines Business Units and was a member of the Bayer Pharmaceuticals Global Management Committee. Previously, Mr. Pucci held positions of increasing responsibility with Eli Lilly and Company. Mr. Pucci previously served on the Board of several successful biotech companies including Algeta ASA and Dyax Inc. He currently serves as a board member of West Pharmaceuticals Services, Inc and Replimune Group Inc. Mr. Pucci received an MS in economics and accounting from Università degli Studi di Napoli Federico II and an MBA in marketing and finance from the University of Chicago.

The Company is grateful for the leadership that both Dr. Greig and Dr. de Koning have provided on behalf of the Company, and we thank them for their years of service. We look forward to the valuable guidance of Dr. Mehra and Mr. Pucci in their new roles.

First Quarter 2020 Financial Results

In prior periods, Merus prepared its financial information in accordance with IFRS. As a consequence of becoming a domestic U.S. issuer as of January 1, 2020, the Company is required to present its financial information in accordance with U.S. GAAP and express such financial information in U.S. dollars from that date. The below unaudited financial information has been prepared in accordance with U.S. GAAP. The unaudited financial information should not be expected to correspond to figures previously presented under IFRS.

Collaboration revenue for the three months ended March 31, 2020 ($6.3 million) decreased $2.5 million as compared to the three months ended March 31, 2019 ($8.8 million), primarily as a result of a decrease in Incyte reimbursement revenue of $1.3 million, and a decrease in Ono milestone revenue of $1.1 million. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended March 31, 2020 ($17.0 million) increased $5.2 million as compared to the three months ended March 31, 2019 ($11.8 million), primarily as a result of an increase in headcount and higher pre-clinical research and development-related costs related to our programs, particularly increases in costs for zenocutuzumab offset by decreases in costs for MCLA-145.

General and administrative expense for the three months ended March 31, 2020 ($8.9 million) increased $2.2 million as compared to the three months ended March 31, 2019 ($6.7 million), primarily as a result of an increase in headcount, stock-based compensation, facilities and professional fees, offset by decreases in consulting cost.

Other income for the three months ended March 31, 2020 was $3.2 million as compared to $2.8 million for the three months ended March 31, 2019. Other income 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.

The Company ended the first quarter with cash, cash equivalents and marketable securities of $214.0 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, Merus expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into 2022.

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 165,800	$ 197,612
Marketable securities	48,234	42,153
Accounts receivable	244	941
Accounts receivable (related party)	1,258	1,711
Prepaid expenses and other current assets	9,915	4,951
Total current assets	225,451	247,368
Marketable securities	—	2,009
Property and equipment, net	3,545	3,715
Operating lease right-of-use assets	4,841	5,215
Intangible assets, net	2,739	2,876
Deferred tax assets	111	288
Other assets	1,275	1,905
Total assets	$ 237,962	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,381	$ 3,029
Accrued expenses	12,159	13,536
Current portion of lease obligation	1,393	1,380
Current portion of deferred revenue	1,176	941
Current portion of deferred revenue (related party)	17,458	17,901
Total current liabilities	35,567	36,787
Lease obligation	3,484	3,872
Deferred revenue, net of current portion	270	780
Deferred revenue, net of current portion (related party)	84,055	90,637
Total liabilities	123,376	132,076
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 29,009,422 and 28,882,217 shares issued and outstanding as at March 31, 2020 and December 31, 2019, respectively	$ 2,931	$ 2,918
Additional paid-in capital	444,275	441,395
Accumulated other comprehensive (loss) income	(1,521)	1,586
Accumulated deficit	(331,099)	(314,599)
Total stockholders' equity	114,586	131,300
Total liabilities and stockholders' equity	$ 237,962	$ 263,376

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

	Three Months Ended March 31,	
	2020	2019
Collaboration revenue	$ 328	$ 1,602
Collaboration revenue (related party)	5,973	7,227
Total revenue	6,301	8,829
Operating expenses:		
Research and development	16,987	11,799
General and administrative	8,882	6,741
Total operating expenses	25,869	18,540
Operating loss	(19,568)	(9,711)
Other income, net:		
Interest income, net	280	630
Foreign exchange gains	2,885	2,220
Other income, net	3,165	2,850
Net loss before income taxes	(16,403)	(6,861)
Tax expense	97	222
Net loss	$ (16,500)	$ (7,083)
Other comprehensive loss:		
Currency translation adjustment	(3,107)	(1,900)

Comprehensive loss	$ (19,607)	$ (8,983)
Net loss per share attributable to common stockholders: Basic and diluted	$ (0.68)	$ (0.38)
Weighted-average common shares outstanding: Basic and diluted	28,946	23,373

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 marketable securities, 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 Zeno, the potential for Zeno to be particularly effective in patients with NRG1+ cancers, 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, the ability of our agreements with Caris Life Sciences, Foundation Medicine Inc., and Tempus Labs Inc. to enhance the identification of NRG1+ patients and determine suitability of enrollment of these patients in our eNRGy trial and Early Access Program, the agreement by Dr. Victor Sandor to provide strategic oversight of the eNRGy trial on an interim basis until a new Chief Medical Officer is identified and his contribution to the eNRGy trial organization, the content and timing of potential milestones described in this press release, including the timing of and presentation of data from the Phase 1/2 eNRGy trial, the submission of a presentation of interim data from the Phase 1 trial of MCLA-117, as well as an abstract on our analysis of an extensive panel of CD3 T-cell engaging bispecific antibodies, to the European Hematology Association Annual Meeting in June, 2020, the planned presentation of the frequency of NRG1+ cancers at the ASCO Annual Meeting in May, the AGM and anticipated Board of Directors changes; 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 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, the impact of COVID-19 on patient enrollment, clinical trial site operations, patient visits, medical monitoring and our laboratories in Utrecht, and the contributions and valuable guidance anticipated from Dr. Anand Mehra and Mr. Paolo Pucci. 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; 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 March 31, 2020 filed with the Securities and Exchange Commission, or SEC, on May 11, 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.

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