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

August 8, 2022

- Clinical update of zenocutuzumab (Zeno) presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

- Zeno represents a potential new standard of care for NRG1+ cancer

- Clinical update of MCLA-129 planned for second half of 2022; expansion cohorts including combination with osimertinib planned

- Clinical update of petosemtamab (Peto) planned for first half of 2023

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Aug. 08, 2022 (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, 2022 and provided a business update.

"At the 2022 ASCO Annual Meeting, we provided an update on our lead bispecific antibody, Zeno, which demonstrated strong efficacy across multiple tumor types, clinically meaningful duration of response and a very well tolerated safety profile. We continue to believe Zeno has the potential to be both first in class and best in class for patients with NRG1 fusion cancer," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "Additionally, we continue to make progress with our pipeline and look forward to providing an update on MCLA-129 in the second half of 2022, and Peto in the first half of 2023."

Clinical Programs

Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclonics®): NRG1+ cancer and other solid tumors

We shared updated interim clinical data on our Zeno program (eNRGy trial and Early Access Program) in patients with NRG1 fusion (NRG1+) cancer at the ASCO 2022 Annual Meeting. Highlights from the presentation included:

- As of the April 12, 2022 data cutoff date, 110 patients with NRG1+ cancer were treated with Zeno, efficacy was assessed in 79 patients with measurable disease having the opportunity for 6 months or more follow-up and who met the criteria for the primary analysis population
- Overall Response Rate (ORR) per RECIST criteria as assessed by investigator was 34% (27/79) (95% CI; 24%-46%) across multiple tumor types
    - Pancreatic ductal adenocarcinoma ORR 42% (8/19) (95% CI: 20-67%)
    - Non-small cell lung cancer (NSCLC) ORR 35% (16/46) (95% CI: 21-50%)
- Tumor shrinkage was observed in 70% of patients (55/79)
- Median time to response was 1.8 months, and median duration of exposure was 6.3 months
- Median duration of response was 9.1 months, and 20/83 patients were continuing treatment as of the data cutoff date
- Zeno has demonstrated a consistent and well tolerated safety profile, with few grade 3 or 4 treatment-related adverse events

As announced in 2021, based on feedback received from the U.S. Food and Drug Administration (FDA), Merus believes that the eNRGy trial design and planned enrollment has the potential to support a Biologics License Application submission for Zeno for a tumor agnostic indication for the treatment of patients with NRG1+ cancer. To date, we have enrolled a cohort of patients that we believe may constitute a registrational data set, and continue to enroll patients to gather further safety and efficacy data on Zeno in NRG1+ cancer. We believe Zeno has the potential to be first and best in class and a new standard of care for patients with NRG1+ cancer.

We believe the favorable safety profile of Zeno may also allow for future, potential benefit in combination with other cancer therapies. Accordingly, we are initiating a clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC. In addition, beyond NRG1+ cancer, we are initiating a clinical trial evaluating Zeno as a treatment for castration resistant prostate cancer, and are actively exploring ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers.

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.

Petosemtamab (Peto or MCLA-158: Lgr5 x EGFR Biclonics®): Solid Tumors
Dose expansion continues in the phase 1 trial: clinical update planned for 1H2023

Peto is currently enrolling patients with advanced solid tumors in the expansion phase of a phase 1 open-label, multicenter study.

We plan to provide a clinical update for Peto at a medical conference in the first half of 2023. The planned presentation will provide the opportunity to present a robust update across the program, including approximately 40 patients with head and neck squamous cell carcinoma with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy and planned regulatory interactions.

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

MCLA-145 is currently enrolling a global, phase 1, open-label, single-agent clinical trial evaluating MCLA-145 in patients with solid tumors. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. Merus is also planning to evaluate the combination of MCLA-145 with a PD-1 blocking antibody.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Phase 1 trial continues: clinical update planned for 2H2022

MCLA-129 is currently enrolling patients in a phase 1/2, open-label clinical trial consisting of dose escalation followed by dose expansion. 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 global rights outside of China. A clinical update is planned for the second half of 2022.

In July, Merus entered into a clinical supply agreement with AstraZeneca for Tagrisso (osimertinib), a third-generation EGFR-TKI, for a planned investigation of the combination of Tagrisso and MCLA-129 in patients with NSCLC in the dose expansion phase of the trial. Under the terms of the non-exclusive agreement, AstraZeneca will supply Tagrisso for use by Merus in the combination study.

Corporate Activities

Incyte
In the second quarter of 2022, Merus achieved a milestone payment for a pre-clinical candidate nomination of a novel bispecific antibody (target pair program) under the global collaboration and license agreement (“Agreement”) with Incyte Corporation. This marks the third program to reach candidate nomination under the Agreement. Candidate nomination triggers a program advancing to the next phase of development for IND-enabling studies by Incyte. Incyte also recently announced its plan to initiate a clinical program later this year with INCA32459, a novel LAG3xPD-1 bispecific antibody developed under the collaboration agreement with Merus, that achieved candidate nomination in 2021.

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.

Cash Runway, Merus expects to be funded beyond 2024

As of June 30, 2022, Merus had $396.8 million cash and cash equivalents sufficient to fund company operations beyond 2024.

Second Quarter 2022 Financial Results

We ended the second quarter with cash, cash equivalents and marketable securities of $396.8 million compared to $430.7 million at December 31, 2021.

Collaboration revenue for the three months ended June 30, 2022 increased by $0.3 million as compared to the three months ended June 30, 2021, primarily as a result of an earned milestone in 2022 partially offset by decrease in amortization of upfront payment. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended June 30, 2022 increased by $6.5 million as compared to the three months ended June 30, 2021, primarily as a result of a personnel related expenses including stock-based compensation of $2.9 million due to an increase in employee headcount and an increase in external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $1.4 million.

General and administrative expense for the three months ended June 30, 2022 increased by $2.1 million as compared to the three months ended June 30, 2021, primarily as a result of an increase in stock-based compensation expense of $1.1 million, consulting costs of $0.7 million and personnel related expenses of $0.5 million due to an increase in employee headcount.

Collaboration revenue for the six months ended June 30, 2022 increased by $3.6 million as compared to the six months ended June 30, 2021, primarily as a result of an increase from Lilly upfront payment amortization and reimbursement revenues of $4.2 million partially offset by a decrease of Incyte revenue recognized of $0.2 million and a decrease in other upfront payment amortization and reimbursement revenues of $0.4 million. The Incyte decrease is primarily driven by a decrease in cost reimbursements of $0.9 million and amortization of upfront payments of $0.3 million, offset by the achievement and recognition of a $1.0 million development milestone in June 2022. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the six months ended June 30, 2022 increased by $12.7 million as compared to the six months ended June 30, 2021, primarily as a result of an increase in external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $5.2 million and an increase personnel related expenses including stock-based compensation of $5.0 million due to an increase in employee headcount.

General and administrative expense for the six months ended June 30, 2022 increased by $4.5 million as compared to the six months ended June 30, 2021, primarily as a result of an increase in stock-based compensation expense of $2.2 million, personnel related expenses of $1.1 million due to an increase in employee headcount, and finance and human resources costs of $0.9 million.

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)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 213,930	$ 241,435
Marketable securities	162,177	168,990
Accounts receivable	$ 3,896	1,697

Accounts receivable (related party)	—	4,609
Prepaid expenses and other current assets	18,822	7,448
Total current assets	398,825	424,179
Marketable securities	20,694	20,297
Property and equipment, net	6,179	3,549
Operating lease right-of-use assets	13,589	3,733
Intangible assets, net	2,076	2,347
Deferred tax assets	241	417
Other assets	3,189	2,078
Total assets	$ 444,793	$ 456,600
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,961	$ 13,237
Accrued expenses and other liabilities	21,257	22,506
Income taxes payable	—	—
Current portion of lease obligation	1,331	1,494
Current portion of deferred revenue	30,714	16,613
Current portion of deferred revenue (related party)	—	18,048
Total current liabilities	60,263	71,898
Lease obligation	12,291	2,257
Deferred revenue, net of current portion	45,630	10,962
Deferred revenue, net of current portion (related party)	—	55,282
Total liabilities	118,184	140,399
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized as at June 30, 2022 and December 31, 2021; 45,866,820 and 43,467,052 shares issued and outstanding as at June 30, 2022 and December 31, 2021, respectively	$ 4,711	$ 4,481
Additional paid-in capital	848,623	787,869
Accumulated other comprehensive income	(35,190)	(9,221)
Accumulated deficit	(491,535)	(466,928)
Total stockholders' equity	326,609	316,201
Total liabilities and stockholders' equity	$ 444,793	$ 456,600

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,	
	2022	2021	2022	2021
Collaboration revenue	$ 12,684	$ 5,118	$ 24,339	$ 6,717
Collaboration revenue (related party)	—	7,261	—	14,012
Total revenue	12,684	12,379	24,339	20,729
Operating expenses:				
Research and development	31,096	24,612	58,071	45,418
General and administrative	12,695	10,569	24,448	19,902
Total operating expenses	43,791	35,181	82,519	65,320
Operating loss	(31,107)	(22,802)	(58,180)	(44,591)
Other (loss) income, net:				
Interest (expense) income, net	316	(51)	422	(133)
Foreign exchange gains (loss)	24,607	(4,525)	32,337	7,678
Other (losses) gains , net	601	52	1,059	(385)
Total other income (loss), net	25,524	(4,524)	33,818	7,160
Net loss before income taxes	(5,583)	(27,326)	(24,362)	(37,431)
Income tax expense	131	62	245	111
Net loss	$ (5,714)	$ (27,388)	$ (24,607)	$ (37,542)
Other comprehensive loss:				
Currency translation adjustment	(19,921)	3,475	(25,969)	(5,916)
Comprehensive loss	$ (25,635)	$ (23,913)	$ (50,576)	$ (43,458)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.13)	$ (0.71)	$ (0.56)	$ (1.01)
Weighted-average common shares outstanding:				
Basic and diluted	43,636	38,376	43,781	37,299

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 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 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 and Early Access Program, the treatment potential of Zeno and to be a new standard of care in NRG1+ cancer, the design of the eNRGY clinical trial; our belief that the eNRGy trial design and planned enrollment has the potential to support a Biologics License Application submission for Zeno for a tumor agnostic indication of the treatment for patients with NRG1+ cancer; our belief that to date, we have enrolled a cohort of patients that we believe may constitute a registrational data set, and continue to enroll patients to gather further safety and efficacy data on Zeno in NRG1+ cancer; our belief that Zeno has the potential to be a first and best in class and a new standard of care for patients with NRG1+ cancer; future use and potential benefit of Zeno in combination with other cancer therapies; our planned clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC and as a treatment for castration resistant prostate cancer; our exploring the ways in which targeting both HER2 and HER3 with Zeno has potential for the treatment of other cancers; 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 trial of MCLA-145, planned, both as monotherapy and in combination with a PD-1 blocking antibody; the advancement of the phase 1 trial for MCLA-158 and the planned update at a medical conference in the first half of 2023 and opportunity to present a robust update across the program, including approximately 40 patients with head and neck squamous cell carcinoma with meaningful clinical follow up, and an update on the gastro-esophageal cohort, to inform clinical development strategy and planned regulatory interactions; the advancement of the phase 1/2 trial for MCLA-129 and the planned update in second half of 2022; the non-exclusive clinical supply agreement with AstraZeneca for Tagrisso for a planned investigation of the combination of Tagrisso and MCLA-129 in patients with NSCLC in the dose expansion phase of the trial; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; our global collaboration and license agreement with Incyte, and our eligibility to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved; 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 Annual Report on Form 10-K for the period ended December 31, 2021, filed with the Securities and Exchange Commission, or SEC, on February 28, 2022, 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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