Merus Announces Financial Results for the Second Quarter 2024 and Provides Business Update

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– Petosemtamab in combination with pembrolizumab interim data presented at 2024 ASCO® demonstrated robust 67% response rate among 24 evaluable patients

– First patients dosed in phase 3 trial evaluating petosemtamab monotherapy in 2/3L HNSCC, phase 2 trial evaluating petosemtamab in combination with standard chemotherapy in 2L mCRC, and phase 2 trial evaluating MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC

– Based on the Company's current operating plan, existing cash, cash equivalents, including successful public offering raising $460M gross proceeds, and marketable securities expected to fund Merus' operations into 2028

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Aug. 01, 2024 (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 and provided a business update.

"Petosemtamab has already demonstrated potential for best in class efficacy with a favorable safety profile in both 1L and 2L+ HNSCC, major areas of unmet medical need. I'm also looking forward to evaluating petosemtamab in mCRC, another potential important opportunity," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "With the addition of Dr. Fabian Zohren as CMO and the recent successful equity financing raising $460M gross proceeds, we are well positioned for our ambitious phase 3 trial plans for petosemtamab in HNSCC and beyond."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
LiGeR-HN2 phase 3 trial in 2/3L head and neck squamous cell carcinoma (HNSCC) enrolling and LiGeR-HN1 phase 3 trial in 1L HNSCC planned to initiate by year end 2024; phase 2 trial in 2L metastatic colorectal cancer (mCRC) enrolling; clinical data update on 2L+ HNSCC planned for late fourth quarter of 2024

Merus has confirmed through feedback with the U.S. Food and Drug Administration (FDA) that petosemtamab 1500 mg every two weeks is appropriate for further development in HNSCC as monotherapy, and in combination with pembrolizumab.

Merus provided an interim clinical update on petosemtamab with pembrolizumab in 1L HNSCC at the 2024 American Society of Clinical Oncology® (ASCO®) Annual Meeting, demonstrating a 67% response rate among 24 evaluable patients. The oral presentation was detailed in our press release, Merus' Petosemtamab in Combination with Pembrolizumab Interim Data Demonstrates Robust Response Rate and Favorable Safety Profile in 1L r/m (recurrent/metastatic) HNSCC (May 28, 2024). Merus plans to initiate LiGeR-HN1, a phase 3 trial evaluating petosemtamab in combination with pembrolizumab in 1L HNSCC by year end 2024.

Merus provided an interim clinical update on petosemtamab monotherapy in 2L+ HNSCC at the American Association of Cancer Research® (AACR®) Annual Meeting 2023, demonstrating a 37% response rate among 43 evaluable patients. The oral presentation was detailed in our press release Merus' Petosemtamab Interim Data Demonstrates Clinically Meaningful Activity in Previously Treated Head and Neck Squamous Cell Carcinoma (HNSCC) (April 17, 2023). Merus plans to provide updated efficacy, durability and safety data of this cohort along with clinical data from the dose optimization cohort evaluating petosemtamab monotherapy 1500 or 1100 mg dose levels in 2L+ HNSCC in late fourth quarter of 2024.

Merus announced the first patient was dosed in LiGeR-HN2, a phase 3 trial evaluating the efficacy and safety of petosemtamab in 2/3L HNSCC compared to standard of care. In this trial, patients will be randomized to petosemtamab monotherapy or investigator's choice of single agent chemotherapy or cetuximab. This was detailed in our press release, Merus Announces First Patient Dosed in LiGeR-HN2, a Phase 3 Trial Evaluating Petosemtamab in 2/3L r/m HNSCC - Merus (July 24, 2024).

The FDA has granted Breakthrough Therapy Designation (BTD) for petosemtamab for the treatment of patients with recurrent or metastatic HNSCC whose disease has progressed following treatment with platinum based chemotherapy and an anti-programmed cell death receptor-1 (PD-1) or anti-programmed death ligand 1 (PD-L1) antibody. This designation was detailed in our press release, Petosemtamab granted Breakthrough Therapy Designation by the U.S. FDA (May 13, 2024).

Merus believes a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval.

Merus announced the first patient was dosed in the phase 2 open-label trial evaluating the safety and preliminary antitumor activity of petosemtamab with FOLFIRI in 2L mCRC. Trial design was detailed in our press release Merus Announces First Patient Dosed in Phase 2 Trial of Petosemtamab in 2L CRC (July 8, 2024).

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion-positive (NRG1+) lung, pancreatic and other solid tumors
Zeno BLA for treatment of NRG1+ non-small cell lung cancer (NSCLC) and pancreatic cancer (PDAC) accepted for priority review by the FDA

The FDA has accepted for priority review a Biologics License Application (BLA) for the bispecific antibody zenocutuzumab (Zeno) in patients with NRG1+ NSCLC and PDAC cancer. This acceptance was detailed in our press release Merus Announces U.S. FDA Acceptance and Priority Review of Biologics License Application for Zeno for the Treatment of NRG1+ NSCLC and PDAC (May 6, 2024).

Merus believes that obtaining a commercialization partnership agreement is an important step in bringing Zeno to patients with NRG1+ cancer, if approved.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors

Investigation of MCLA-129 is ongoing in METex14 NSCLC; phase 2 trial in combination with chemotherapy in 2L+ EGFR mutant (EGFRm) NSCLC enrolling

At 2024 ASCO® Merus presented efficacy and safety data of MCLA-129, in NSCLC with c-MET exon 14 skipping mutations (METex14). This poster presentation was detailed in our press release Merus' MCLA-129 Demonstrates Promising Single-Agent Efficiency in METex14 NSCLC in Poster Presentation at the 2024 ASCO ® Annual Meeting (June 3, 2024).

The first patients were dosed in the phase 2 trial evaluating MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC, with a cohort receiving MCLA-129 and paclitaxel and carboplatin, and another cohort receiving MCLA-129 and docetaxel. We also remain interested in partnering MCLA-129 to sufficiently resource the development of MCLA-129 and the potential benefit it may have for patients.

MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains global rights outside of China.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors

Investigation continues of the phase 1 trial of MCLA-145 in combination with pembrolizumab

Interim clinical data on MCLA-145 monotherapy and in combination with pembrolizumab in patients with advanced/metastatic solid tumors were presented at 2024 ASCO®. The oral presentation was detailed in our press release Merus Presents Interim Data on MCLA-145 Monotherapy and in Combination with Pembrolizumab at the 2024 ASCO® Annual Meeting (June 2, 2024).

Company News
Merus announced the appointment of Fabian Zohren M.D., Ph.D. as Chief Medical Officer (CMO). This management addition is detailed in our press release Merus Appoints Fabian Zohren M.D., Ph.D., as Chief Medical Officer (July 1, 2024).

Collaborations

Incyte Corporation
Since 2017, Merus has been working with Incyte Corporation (Incyte) under a global collaboration and license agreement focused on the research, discovery and development of bispecific antibodies utilizing Merus' proprietary Biclonics ® technology platform. For each program under the collaboration, Merus receives reimbursement for research activities and is eligible to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved. During the second quarter of 2024, Merus received the milestone payment of $1 million for the candidate nomination accomplished in first quarter of 2024.

Eli Lilly and Company
In January 2021, Merus and Eli Lilly and Company (Lilly), announced a research collaboration and exclusive license agreement to develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies utilizing Merus' Biclonics ® platform and proprietary CD3 panel along with the scientific and rational drug design expertise of Lilly. The collaboration is progressing well with three programs ongoing at various stages of preclinical development.

Gilead Sciences
In March 2024, Merus and Gilead Sciences announced a collaboration to discover novel antibody based trispecific T-cell engagers using Merus' patented Triclonics ® platform. Under the terms of the agreement, Merus will lead early-stage research activities for two programs, with an option to pursue a third. Gilead will have the right to exclusively license programs developed under the collaboration after the completion of select research activities. If Gilead exercises its option to license any such program from the collaboration, Gilead will be responsible for additional research, development and commercialization activities for such program. Merus received an equity investment by Gilead of $25 million in Merus common shares and an upfront payment of $56 million.

Corporate Activities
Completed public offering raising $460M gross proceeds
This equity raise is detailed in a press release: Merus Announces Pricing of Upsized Public Offering of Common Shares (May 29, 2024).

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2028

As of June 30, 2024, Merus had $846.4 million cash, cash equivalents and marketable securities. Based on the Company's current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into 2028.

Second Quarter 2024 Financial Results
We ended the second quarter with cash, cash equivalents and marketable securities of $846.4 million compared to $411.7 million at December 31, 2023.

Collaboration revenue for the three months ended June 30, 2024 decreased by $3.2 million as compared to the three months ended June 30, 2023, primarily as a result of decreases in reimbursement revenue of $1.5 million and amortization of deferred revenue of $1.7 million.

Research and development expense for the three months ended June 30, 2024 increased by $20.8 million as compared to the three months ended June 30, 2023, primarily as a result of increases in external clinical services and drug manufacturing expenses, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $16.2 million, consulting expenses of $2.2 million, facilities and depreciation expenses of $1.2 million, personnel related expenses including share-based compensation of $1.0 million, consumables expenses of $0.1 million, and travel expenses of $0.1 million.

General and administrative expense for the three months ended June 30, 2024 increased by $6.5 million as compared to the three months ended June 30, 2023, primarily as a result of increases in personnel related expenses including share-based compensation of $3.7 million, consulting expenses of $3.6 million, intellectual property and license expenses of $0.5 million, and legal expenses of $0.4 million, partially offset by decreases in facilities and depreciation expense of $1.2 million, travel expenses of $0.3 million, and finance and human resources expenses of $0.2 million.

Collaboration revenue for the six months ended June 30, 2024 decreased by $8.8 million as compared to the six months ended June 30, 2023, primarily as a result of a decrease in reimbursement revenue of $2.2 million, decrease in milestone revenue of $1.5 million and decrease in amortization of deferred revenue of $5.1 million.

Research and development expense for the six months ended June 30, 2024 increased by $24.5 million as compared to the six months ended June 30, 2023, primarily as a result of increases in external clinical services and drug manufacturing expenses, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $19.4 million, consulting expenses of $3.7 million, facilities and depreciation expenses of $2.3 million, pre-launch inventory of $0.2 million, and travel expenses of $0.2 million, partially offset by decreases in personnel related expenses including share-based compensation of $1.2 million and consumables expenses of $0.1 million

General and administrative expense for the six months ended June 30, 2024 increased by $7.3 million as compared to the six months ended June 30, 2023, primarily as a result of increases in personnel related expenses including share-based compensation of $4.5 million, consulting expenses of $3.2 million, legal expenses of $1.0 million, and intellectual property and license expenses of $0.8 million, partially offset by decreases in facilities and depreciation expense of $1.7 million, travel expenses of $0.3 million, and finance and human resources expenses of $0.2 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 share and per share data)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 629,475	$ 204,246
Marketable securities	157,948	150,130
Accounts receivable	1,842	2,429
Prepaid expenses and other current assets	17,288	12,009
Total current assets	806,553	368,814
Marketable securities	58,961	57,312
Property and equipment, net	12,090	12,135
Operating lease right-of-use assets	10,291	11,362
Intangible assets, net	1,658	1,800
Deferred tax assets	543	1,199
Other assets	2,132	2,872
Total assets	$ 892,228	$ 455,494
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,395	$ 4,602
Accrued expenses and other liabilities	40,826	38,482
Income taxes payable	1,605	1,646
Current portion of lease obligation	1,688	1,674
Current portion of deferred revenue	32,350	22,685
Total current liabilities	80,864	69,089
Lease obligation	9,332	10,488
Deferred revenue, net of current portion	55,260	19,574
Total liabilities	145,456	99,151
Commitments and contingencies - Note 6		
Shareholders' equity:		
Common shares, €0.09 par value; 105,000,000 shares authorized at June 30, 2024 and December 31, 2023; 67,852,920 and 57,825,879 shares issued and outstanding as at June 30, 2024 and December 31, 2023, respectively	6,863	5,883
Additional paid-in capital	1,616,367	1,126,054
Accumulated other comprehensive income	(38,899)	(22,533)
Accumulated deficit	(837,559)	(753,061)
Total shareholders' equity	746,772	356,343
Total liabilities and shareholders' equity	$ 892,228	$ 455,494

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 7,332	$ 10,476	$ 15,221	$ 23,975
Total revenue	7,332	10,476	15,221	23,975
Operating expenses:				
Research and development	49,119	28,298	87,703	63,163
General and administrative	22,587	16,063	38,701	31,449
Total operating expenses	71,706	44,361	126,404	94,612
Operating loss	(64,374)	(33,885)	(111,183)	(70,637)
Other income, net:				
Interest income, net	7,130	2,795	12,047	4,790
Foreign exchange gains (loss)	9,519	551	18,053	(4,890)
Total other income (loss), net	16,649	3,346	30,100	(100)

Net loss before income taxes	(47,725)	(30,539)	(81,083)	(70,737)
Income tax expense	2,317	1,494	3,415	1,037
Net loss	$ (50,042)	$ (32,033)	$ (84,498)	$ (71,774)
Other comprehensive loss:				
Currency translation adjustment	(8,978)	(505)	(16,366)	3,737
Comprehensive loss	$ (59,020)	$ (32,538)	$ (100,864)	$ (68,037)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.81)	$ (0.66)	$ (1.41)	$ (1.52)
Weighted-average common shares outstanding:				
Basic and diluted	61,851,260	48,321,708	59,968,338	47,328,259

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, and LinkedIn.

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 content and timing of clinical trials, data readouts and clinical, regulatory, strategy and development updates for our product candidates; our ability to successfully advance Zeno through the regulatory, BLA review and potential commercialization processes; our planned initiation of LiGeR-HN1 by year-end, our planned update by late 4Q 2024 on the HNSCC 2L+ dose cohort and patients previously reported at AACR2023; the potential of petosetmamab for best in class efficacy with a favorable safety profile in both 1L and 2L+ HNSCC; the potential opportunity of petosemtamab being investigated in 2L mCRC in combination with FOLFIRI; our belief that we are well positioned for our ambitious phase 3 trial plans for petosemtamab in HNSCC and beyond; the potential future benefit if any for the receipt of BTD for petosemtamab for the treatment of patients with recurrent or metastatic HNSCC whose disease has progressed following treatment with platinum based chemotherapy and an anti-programmed cell death receptor-1 (PD-1) or anti-programmed death ligand 1 (PD-L1) antibody; our belief that a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval; our belief that obtaining a commercialization partnership agreement is an important step in bringing Zeno to patients with NRG1+ cancer, if approved; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2028; the continued investigation of MCLA-145 in combination with pembrolizumab; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in Met ex14 NSCLC, and MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC; the benefits of the collaborations between Incyte and Merus, Lilly and Merus, Gilead and Merus, and the potential of those collaboration for future value generation, including whether and when Merus will receive any future payment under the collaborations, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; and our collaboration and license agreement with Betta, which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains full ex-China rights, including any future clinical development by Betta of MCLA-129. 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 volatility in the global economy, including global instability, including the ongoing conflicts in Europe and the Middle East; 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 period ended June 30, 2024, filed with the Securities and Exchange Commission, or SEC, on August 1, 2024, 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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