Press Release

Stockholm, Sweden, February 14, 2024

Mendus AB Year-end Report for 2023

Positive ADVANCE II data at ASH caps strong 2023

The fourth quarter of 2023 closes a crucial year for Mendus and delivered additional milestones to further strengthen the development of our lead product vididencel as a novel maintenance treatment for acute myeloid leukemia (AML).

Mendus is at an exciting point in its journey, supported by continued positive clinical data confirming the potential of vididencel to significantly improve disease-free and overall survival in AML. In addition to the financing round and NorthX manufacturing collaboration reported in Q3, Mendus announced in Q4 a collaboration with the Australasian Leukaemia and Lymphoma Group (ALLG) to significantly expand the clinical evaluation of vididencel in combination with current standard of care. The alliances with NorthX and ALLG allow Mendus to take major steps in the advancement of vididencel's clinical development in AML.

Mendus presented three clinical abstracts at the 65th American Society of Hematology Annual Meeting (ASH 2023) in December, including an oral presentation of the ADVANCE II trial survival data. ADVANCE II is a Phase 2 monotherapy trial focused on AML patients in first complete remission after chemotherapy, but with measurable residual disease (MRD), which is associated with a high probability of disease relapse. The presented data showed 14 of 20 patients to be alive in long-term follow-up, with median relapse-free survival currently at 30.4 months (2.5 years). Immunomonitoring data demonstrate broad activation of the immune system following vididencel treatment, associated with the observed durable clinical remissions. The positive survival data presented at ASH strengthen the case that vididencel represents one of the most promising AML maintenance therapies currently in development.

The positive ADVANCE II trial results encourage us to push forward the clinical development of vididencel in AML. As a first next step to expand clinical testing, we announced during the fourth quarter a collaboration with the ALLG, a world-leading clinical trial research group focused on blood-borne tumors. Mendus and ALLG will study vididencel in combination with oral azacitidine (AZA), currently the only approved AML maintenance treatment, in the randomized multi-center AMLM22 CADENCE trial, an adaptive Phase 2 trial consisting of two stages. In December, Mendus and ALLG had completed the preparation for the start of the CADENCE trial in the ALLG AMLM22 adaptive platform, with the CADENCE protocol submitted to the central ethical committee of participating hospitals. Upon committee approval, the trial will be open for enrolment. The first stage of the study will assess the safety of vididencel in combination with oral AZA in 40 patients randomized to either receive vididencel + AZA or AZA alone. In the second stage, the efficacy of the combination will be assessed in an additional 100 patients.

In November we were pleased to announce the publication of data from the completed Phase 1 trial with vididencel in high-risk MDS and AML patients, in the peer-reviewed medical journal HemaSphere. The publication showed that survival following vididencel treatment was largely determined by low disease burden at the start of treatment, confirming the therapeutic setting of the ADVANCE II Phase 2 trial. There was no correlation with commonly used risk-scoring criteria for AML, indicating that also patients with adverse cytogenetic risk profiles can respond to vididencel therapy. Finally, the Phase 1 trial data support the combination potential of vididencel with AZA, the combination to be studied in the CADENCE trial.

Based on the ADVANCE II data and data from the first stage of the CADENCE trial, Mendus expects to be in a position to engage in a global registration path for vididencel in 2025. Additional trials may also allow Mendus to broaden the positioning of vididencel in AML maintenance and adjacent indications, such as myelodysplastic syndromes (MDS). Mendus has announced in June an alliance with the Sweden-based cell and gene therapy manufacturer NorthX Biologics to set up large-scale manufacturing for registrational studies and future commercial launch of vididencel.

Mendus provided a clinical pipeline update in December, confirming full recruitment of the ALISON Phase 1 trial with vididencel in ovarian cancer and continued commitment to prepare a trial in soft tissue sarcomas with its intratumoral immune primer ilixadencel. A primary read-out of the ALISON trial is expected in the second half of 2024.

The successful read-out of the ADVANCE II trial and the progress realized in 2023 puts Mendus in a strong position to expand the clinical development of vididencel in AML and to prepare for a global registration strategy. Combined with additional clinical pipeline progress and ongoing exciting research programs addressing novel therapeutic concepts, we look forward to an eventful 2024.

Many thanks to our shareholders, partners and other stakeholders for supporting the team at Mendus.

Erik Manting
CEO

SIGNIFICANT EVENTS OF Q4 2023

- Net sales for the period amounted to KSEK – (–).
- Result for the period amounted to KSEK -41,165 (-43,280).
- Earnings and diluted earnings per share totalled SEK -0.05 (-0.22).
- Mendus Phase 1 vididencel clinical trial results in AML and high-risk MDS patients published in peer-reviewed medical journal.
- Mendus presents updated ALISON clinical trial data for vididencel in ovarian cancer at SITC 2023.
- Mendus to Host KOL Event to Review Phase 2 Data with Vididencel in Acute Myeloid Leukemia Presented at ASH 2023 on December 14, 2023.
- Mendus and Australasian Leukaemia & Lymphoma Group to expand clinical testing of vididencel as maintenance treatment for AML.
- Mendus announces positive survival data from Phase 2 ADVANCE II trial evaluating vididencel as maintenance therapy for AML at ASH 2023.
- At the extraordinary general meeting (the "EGM") of Mendus AB on 13 December 2023, the EGM resolved, in accordance with the major shareholders' proposal, on the election of a new board member and the determination of remuneration. The EGM further resolved, in accordance with the board of directors' proposal, on amendment of the articles of association and the resolution on an issue of warrants of series 2023/2027 and to implement a performance-based incentive program 2023/2027
- Mendus reports completion of the long-term follow up of the MERECA trial studying the intratumoral immune primer ilixadencel in metastatic renal cell carcinoma (mRCC). Mendus also confirms that the Phase 1 ALISON trial with its cancer maintenance therapy vididencel in ovarian cancer is now fully recruited.

SIGNIFICANT EVENTS AFTER END OF REPORTING PERIOD

- No significant events after the end of the reporting period.

FINANCIAL SUMMARY

Amount in KSEK	2023 Oct - Dec	2022 Oct - Dec	2023 Jan - Dec	2022 Jan - Dec
Revenue	0	0	0	0
Operating profit/loss	-42 720	-41 557	-100 650	-133 957
Net profit/loss	-41 165	-43 280	-101 619	-138 786
Earnings/loss per share, before and after dilution (SEK)	-0,05	-0,22	-0,22	-0,70
Cash	120 782	41 851	120 782	41 851
Shareholders equity	704 727	514 439	704 727	514 439
Number of employees	27	33	30	31

WEBCAST INVESTOR CALL, FEBRUARY 14, 10:00

The company will hold a conference call and an online presentation on the same day at 10:00 CET. The call will be hosted by CEO Erik Manting. The presentation will be in English and followed by a question-and-answer session.

Listen to the presentation webcast: https://ir.financialhearings.com/mendus-q4-2023

The full report is attached as PDF and is available on the company's website: https://mendus.com/investors/financial-reports/

FOR MORE INFORMATION, PLEASE CONTACT:

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ABOUT MENDUS AB (publ)

Mendus is dedicated to changing the course of cancer treatment by addressing tumor recurrence and improving survival outcomes for cancer patients, while preserving quality of life. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based immunotherapies which combine clinical efficacy with a benign safety profile. Based in Sweden and The Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST. https://www.mendus.com/