Press Release

Stockholm, Sweden, November 9, 2023

Mendus AB Interim Report January – September 2023

So far in 2023, Mendus has realized significant progress in its corporate development, and we aim to end the year strong

The progress made in the previous quarters provided the basis for a financing round which we completed in July, to support the next stage of our corporate development. The directed placement and rights issue totaling SEK 317M supports further read-outs of the ongoing ADVANCE II and ALISON vididencel trials, the start of new clinical trials with vididencel and ilixadencel and progressing our preclinical pipeline. Additionally, Mendus has entered into a manufacturing alliance with NorthX Biologics, to support large-scale manufacturing of its lead product candidate vididencel. The regulatory status of vididencel was strengthened in Q3 by the Fast Track Designation granted by the US FDA.

The main milestone ahead of us in the fourth quarter of 2023 is the next read-out of the patient survival data in the ADVANCE II trial, which studies vididencel as a maintenance therapy for acute myeloid leukemia (AML). The data will be presented as an oral presentation at the 65th American Society of Hematology conference (ASH 2023), the largest and most significant hematology conference in the world, to be held December 9-12 in San Diego. It will be the third time Mendus presents the ADVANCE II trial data as an oral presentation at ASH, which underscores the high interest in vididencel as a potential novel AML maintenance treatment by the medical specialist community.

The ADVANCE II trial is a Phase 2 monotherapy trial addressing AML patients in complete remission, but with measurable residual disease (MRD), which is associated with fast relapse and, as a result, strongly reduced overall survival. The ADVANCE II data presented last year at ASH 2022, revealed that the majority of patients were not only alive at the end of the 70-week study period, but also remained alive and disease-free in long-term follow up ranging from 16 to 47 months. The monotherapy survival data, combined with an excellent safety profile, strongly support the development of vididencel as a novel maintenance treatment in AML. The next data read-out to be presented at ASH 2023 will provide an update on both relapse-free and overall survival.

The ADVANCE II trial is reinforced by immunomonitoring studies, which document the effect of vididencel on the immune system. Immunomonitoring data demonstrating the boosting of broad and robust immune responses were presented at leading scientific conferences, including the International Cancer Immunotherapy Conference (CICON) in September. At ASH 2023, next to the oral presentation of the survival data, we and our scientific partners at different academic hospitals will present two additional abstracts, which describe in detail the immune responses observed in the skin and in the blood following intradermal injection of vididencel, supporting its mode of action.

As a next step in the development of vididencel, Mendus is preparing for a combination trial of vididencel with oral azacitidine (oral AZA), currently the only approved AML maintenance drug). Together with the ADVANCE II monotherapy data, the Phase 2 combination trial with oral AZA will be a step up towards pivotal-stage development of vididencel in the AML maintenance setting. Mendus expects to announce details and start of the trial before year-end 2023.

In Q3, Mendus has taken the first steps in implementing the manufacturing alliance with NorthX Biologics, a leading Nordic contract development and manufacturing organization for cell and gene therapies. Large-scale, commercial-grade manufacturing is an important step for late-stage clinical development of vididencel and NorthX will therefore be a significant partner for Mendus going forward.

In September, the US FDA granted Fast Track Designation for the development of vididencel as an AML maintenance therapy, adding substantial regulatory value to the program in the most important healthcare market worldwide. The development of vididencel towards market registration in AML is also supported by Orphan Drug status in the EU and US and the vididencel manufacturing process and regulatory dossier has been validated by an EMA Advanced Therapy Medicinal Products (ATMP) certificate.

Data from the Phase 1 ALISON trial studying vididencel as a maintenance therapy in ovarian cancer were presented at the American Association for Cancer Research (AACR) conference held in April 2023 and the Society for Immunotherapy of Cancer (SITC) conference early November. The data confirmed the benign safety profile and potential of vididencel to stimulate immune responses against tumor antigens previously shown to be relevant for ovarian cancer. Recruitment of the ALISON trial (n = 17) is nearly complete with 16 patients having entered the trial and is expected to close before year-end 2023. Next read-outs of the ALISON trial are expected in the first half of 2024.

Following a series of manufacturing process improvements, Mendus' second clinical-stage program ilixadencel is ready to be tested in a proof-of- concept trial based on initial positive data observed in gastrointestinal stromal tumors (GIST). There is continued clinical interest in pursuing a trial with ilixadencel in soft-tissue sarcomas, of which GIST is a subtype. The trial is expected to commence before year-end 2023. In Q3, Mendus announced the publication of preclinical data supporting the combination of ilixadencel with 4-1BB checkpoint modulators in a peer-reviewed journal.

In 2023, Mendus has so far realized significant progress in its corporate development, and we aim to end the year strong, based on the next ADVANCE II update at ASH, the start of a vididencel combination trial with oral AZA, the shaping of our alliance with NorthX Biologics and additional clinical milestones. We look forward to keeping our shareholders informed of our progress and thank you for your continued support.

Erik Manting, Ph.D.
Chief Executive Officer

SIGNIFICANT EVENTS IN Q3 2023

- Net sales for the period amounted to KSEK - (-)
- Result for the period amounted to KSEK -26,400 (-38,605)
- Earnings and diluted earnings per share totaled SEK -0,05 (-0,19)
- At an extraordinary general meeting in Mendus AB, on 10 July 2023, the meeting resolved in accordance with the board of directors' proposal to amend the articles of association with respect to the Company's limits for the share capital and the number of shares. Furthermore, the AGM approved the issue of shares and warrants (units) with preferential rights for existing shareholders.
- Mendus publishes prospectus regarding previously announced rights issue and directed issue
- Mendus reports outcome of previously announced rights issue and directed issue
- Mendus publishes preclinical data demonstrating synergies of ilixadencel and 4-1BB-targeting immunotherapies
- Mendus receives U.S. FDA Fast Track Designation for vididencel in Acute Myeloid Leukemia (AML)
- Mendus presents novel data supporting the broad potential of its proprietary cancer vaccine platform at CICON23

SIGNIFICANT EVENTS AFTER END OF REPORTING PERIOD

- Mendus announces multiple abstracts to be presented at ASH 2023 including oral presentation on ADVANCE II survival data
- Mendus Phase 1 vididencel clinical trial results in AML and high-risk MDS patients is published in peer-reviewed medical journal
- Mendus presents updated ALISON clinical trial data for vididencel in ovarian cancer at SITC 2023

FINANCIAL SUMMARY

KSEK unless otherwise stated	2023 Jul - Sep	2022 Jul - Sep	2023 Jan - Sep	2022 Jan - Sep	2022 Full year
Operating profit/loss	-25 855	-37 403	-57 930	-92 356	-133 957
Net profit/loss	-26 400	-38 605	-60 454	-95 505	-138 786
Earnings/loss per share, before and after dilution (SEK)	-0,05	-0,19	-0,18	-0,48	-0,70
Cash	143 350	55 403	143 350	55 403	41 851
Shareholders equity	751 135	561 151	751 135	561 151	514 439
Number of employees	26	31	26	31	31

WEBCAST INVESTOR CALL, NOVEMBER 9, 10:00

The company will hold a conference call and webcast presentation on the same day at 10.00am CET, to provide an update on the latest developments and the outlook for the remainder of the year. The webcast will be webcasted live via the link: https://ir.financialhearings.com/mendus-q3-2023

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. http://www.mendus.com/