Press Release

Stockholm, Sweden, May 12, 2023

Mendus AB (publ) Interim Report January – March 2023

In the first quarter of 2023, Mendus continued on the path set out by the key progress realized at the end of 2022. The Phase 2 monotherapy proof-of-concept data from the ADVANCE II trial presented last December at the American Society for Hematology conference support the continued clinical development of vididencel (DCP-001) in combination with standard of care, for which we are preparing the next steps. In the meantime, we continue with the in-depth analysis of the immunomonitoring data collected as part of the ADVANCE II trial. The data teach us a lot about the way vididencel stimulates the immune system and which immunological parameters are important to improve immune control or even achieve complete elimination of residual disease. The successful initial read-outs on safety and feasibility of the ALISON Phase 1 trial studying vididencel in ovarian cancer allow us to continue the enrollment of patients and provide additional trial updates in the remainder of 2023. Our intratumoral primer ilixadencel will benefit from manufacturing process improvements for which we have laid the foundation in 2022, as a prerequisite for continued clinical development. Finally, we have discovered a method to expand memory NK cells using our DCOne platform, allowing us to enter the exciting field of NK cell-based therapies and providing us with a basis for a potential new pipeline program to be further established in 2023 and beyond.

Acute myeloid leukemia (AML) is an aggressive blood-borne tumor leading to rapid disturbance of the bone marrow and blood count. Even when AML is treated successfully with high-dose chemotherapy and results in complete remission according to clinical parameters, relapse rates are very high due to the presence of residual tumor cells. Therefore, there is a big medical need for maintenance therapies, designed to prevent or delay relapse, particularly for patients with measurable residual disease (MRD). In the registration trial for the current standard of care in AML maintenance, oral azacitidine, the median relapse-free survival in MRD-positive patients following high-dose chemotherapy was 7.1 months versus 2.7 months for placebo[1]. These data underline the continued unmet medical need for AML maintenance treatments resulting in more durable clinical responses. In December 2022, Mendus presented survival data from the ADVANCE II trial at the American Society of Hematology (ASH) conference, studying its lead compound DCP-001 as a monotherapy maintenance treatment in AML patients who had undergone high-dose chemotherapy but were still MRD-positive. The majority of patients (14/20) were still alive at the end of the 70-weeks study period and 12 patients remained disease-free during the long-term follow-up ranging from 16 to 47 months. Immunomonitoring data confirmed that DCP-001 treatment resulted in increased immune responses to tumor antigens, whereby highest average levels were observed in patients having a complete MRD response. The safety profile of DCP-001 continues to be excellent, with product-related side effects limited to injection site reactions. Shortly following the successful read out of the ADVANCE II trial, in January 2023, the progress of DCP-001 was reflected in the selection of the INN name “vididencel” by the World Health Organization’s International Nonproprietary Names Expert Committee and we will increasingly use it in all our materials.

While a next survival update of the ADVANCE II trial is expected in the second half of 2023, Mendus continues with the in-depth analysis of the immunomonitoring samples collected as part of the trial. These data help us to enhance the understanding of the immune system of patients before and after vididencel treatment, further supporting the positioning of vididencel as a novel immunotherapy modality in AML maintenance. The data will be prepared for presentation at medical-scientific conferences, starting with the 2023 Cancer Immunotherapy (CIMT) meeting. As a next step in the development of vididencel, Mendus will prepare for a trial in combination with current standard of care as a step-up to pivotal-stage development, with oral azacitidine as the most logical combination partner. In preclinical studies, vididencel was shown to act synergistically with current and two upcoming small molecule AML drugs azacitidine and venetoclax.

Mendus has selected ovarian cancer to explore vididencel in a solid tumor setting. Ovarian cancer is the deadliest gynaecological cancer due to high recurrence rates after initial treatment, providing for the rationale to explore the safety and feasibility of vididencel as maintenance treatment option in this disease. Most recently, data from the ALISON trial were presented at the American Association for Cancer Research (AACR) conference held in April 2023. The initial data are encouraging, confirming safety and the potential of vididencel to stimulate immune responses against tumor antigens previously shown to be relevant for ovarian cancer. Based on the positive data collected so far, recruitment of the ALISON trial will continue, and additional read-outs are expected in the second half of 2023.

Mendus' second clinical-stage program is the intratumoral immune primer, ilixadencel. Mendus is preparing for a next clinical trial with ilixadencel in gastro-intestinal stromal tumors (GIST) as a prioritized indication, based on signs of clinical efficacy in this indication in earlier clinical trials. There continues to be clinical interest to pursue a trial in GIST and potentially the broader group of soft-tissue sarcomas. In parallel, Mendus has successfully implemented a series of technical and equipment-related optimizations of the ilixadencel manufacturing in order to support future product supply and for the continued clinical development of ilixadencel.

In the preclinical pipeline development, we have leveraged our expertise to design next-generation intratumoral immune primers based on our proprietary DCOne cell line, with data being presented at the 2023 CIMT conference. We have furthermore established the rationale to combine vaccination and intratumoral priming and evaluated the use of our DCOne platform to improve other cell-based immunotherapies. The latter showed that DCOne-derived dendritic cells stimulate so-called memory natural killer (NK) cells. This particular NK cell subtype has demonstrated improved persistence, metabolic fitness and tumor cell killing capacity and is associated with reduced relapse rates in blood-borne tumors. The possibility to expand memory NK cells using the DCOne cells could provide the basis for a novel pipeline program and allow Mendus to enter the exciting new field of NK cell-based therapies. Mendus has earmarked the NK cell program as the main focus of its preclinical research activities in 2023.

In the first quarter of 2023, we have continued on the successful path of 2022, and we look forward to sharing with you the next steps in the development of the Company in 2023 and beyond.

Thank You,

Erik Manting, Ph.D.

Chief Executive Officer

SIGNIFICANT EVENTS IN Q1 2023

- Mendus presented an update on the use of its DCOne platform to source high-quality NK cell therapies at the 8th Annual Innate Killer Summit
- Mendus secured a second shareholder loan from Van Herk Investments and reduced the number of outstanding convertible bonds with Negma Group
- The INN name "vididencel" for DCP-001 was selected by the World Health Organization's International Nonproprietary Names Expert Committee
- Mendus announced the request of a first tranche of convertible loan from Negma Group

SIGNIFICANT EVENTS AFTER END OF REPORTING PERIOD

- Mendus presented updated clinical data from ADVANCE II trial in an oral presentation and a scientific poster on a next-generation immune primer program at the 2023 CIMT Annual Meeting
- Mendus presented positive data from the ALISON trial in ovarian cancer at the AACR Annual Meeting 2023
- Mendus held an investor update call following the Annual Report publication on April 17th
- Mendus redeemed the outstanding convertible bonds from Negma Group

FINANCIAL SUMMARY

KSEK unless otherwise stated	Jan-Mar 2023	Jan-Mar 2022	Full Year 2022
Net sales	-	1,794	1,749
Operating profit/loss	-29,609	-26,820	-133,957
Net profit/loss	-30,169	-27,582	-138,786
Earnings/loss per share, before and after dilution (SEK)	-0.15	-0.14	-0.70
Cash	37,496	122,926	41,850
Shareholders' equity	487,791	629,257	514,439
Number of employees at the end of the period	33	32	31

The Q1 2023 report is available on: https://mendus.com/investors/financial-reports/

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/

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