Press Release

Stockholm, Sweden, December 11, 2023

Mendus announces positive survival data from Phase 2 ADVANCE II trial evaluating vididencel as maintenance therapy for AML at ASH 2023

- *As of November 24, 2023, median relapse-free survival (mRFS) stood at 30.4 months*
- *Median overall survival (mOS) was not reached, with the majority of patients (14/20) still alive*
- *Reduction in measurable residual disease (MRD) and induction of immune responses correlate with RFS and OS benefit, confirming vididencel mechanism of action*
- *Virtual KOL event with principal investigator to discuss new ASH data on Thursday, December 14, 2023, at 9.00 am ET/3.00 pm CET; register HERE*

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, today announced positive updated survival data from the Phase 2 ADVANCE II trial evaluating vididencel (DCP-001) in acute myeloid leukemia (AML) at the American Society of Hematology's 65th Annual Meeting (ASH 2023). The longer-term follow up data showed durable treatment responses with survival benefit exceeding historical results expected from the current standard of care in AML maintenance therapy.

ADVANCE II is a Phase 2 monotherapy trial evaluating vididencel as a maintenance therapy in acute myeloid leukemia (AML) for patients brought into first complete remission (CR1) through chemotherapy, but with measurable residual disease (MRD). Professor Dr. Arjan van de Loosdrecht, Principal Investigator, presented updated median relapse-free survival (RFS) and median overall survival (OS) data during an oral presentation on December 11 at the ASH 2023 meeting held in San Diego, California December 9-12. Additionally, Mendus and academic collaborators presented two posters at the meeting, featuring immunomonitoring data that supports vididencel's mechanism of action as an immunotherapy which stimulates anti-tumor activity and improves immune control over residual cancer cells. ASH abstracts can be viewed here.

"The ADVANCE II trial has provided a wealth of clinical data which are highly encouraging and clearly support the continued development of vididencel in AML," **said Prof Dr. Arjan van de Loosdrecht**. "Next to the positive survival data, the trial provides us with strong data on the ability of vididencel to induce an immune response against residual cancer cells and shows that this correlates with survival. The observed efficacy with monotherapy and excellent safety profile makes that vididencel has the potential to advance the standard of care in AML maintenance therapy."

Phase 2 ADVANCE II trial – updated survival data

The ADVANCE II monotherapy trial (N=20) previously completed a 70-week follow-up period from the start of vididencel treatment and patients are now in long-term follow up. As of November 24, 2023, the median follow-up for the entire study population was 31.6 months (range: 6.6-60 months). Median RFS stood at 30.4 months and median OS was not reached, with 14/20 patients still alive and 11 still in CR1 at the cut-off date. The RFS at 2 years was 56%, and the estimated 2-year and 3-year OS stood at 74.9% and 64.7%, respectively.

The only drug approved for AML maintenance therapy is oral azacitidine, which in MRD positive patients led to a median RFS of 7.1 months versus 2.7 months in the placebo arm and an OS of 14.6 months versus 10.4 months in the placebo arm of the registration trial[1].

[1]Roboz *et al.* (April 2022) Blood; volume 139(4):2145

"Results from ADVANCE II further strengthen the case that vididencel represents one of the most promising AML maintenance therapies currently in development," **said Jeroen Rovers, CMO of Mendus**. "Not only do these survival data exceed the historical survival rates observed with current standard of care maintenance therapy, but we have also amassed a significant body of immunomonitoring data that provides further evidence that vididencel treatment can lead to improved immune responses against residual disease and durable remissions in AML patients."

Immune responses were measured on blood samples before, during and after treatment with vididencel. Seventeen patients (85%) showed at least one vaccine-induced T-cell response (VIR) against tumor-associated antigens present in vididencel. Patients remaining in CR during treatment had a significantly higher number of VIRs then patients who relapsed and a clear correlation is seen between the number of VIRs and survival. Patients with 3 or more VIRs were all still alive (100% OS) at the cut-off date.

Blood samples were additionally analyzed to evaluate changes in immune cells induced by vididencel. Increased frequencies of circulating B-cells and dendritic cells were observed, with the level of dendritic cells at the end of treatment correlating with longer RFS and OS.

In depth analysis of skin biopsies of the area where vididencel was injected showed a strong influx of immune cells, indicative of an immune response being triggered. Close interaction was observed between host T-cells and host dendritic cells in the skin as part of the immune priming process following vididencel administration.

Patients with an MRD response demonstrated better RFS and OS, with all patients with an MRD response still alive.

Combined, the immunomonitoring and MRD data confirm the vididencel mechanism of action as an immunotherapy which improves immunity against residual cancer cells.

The ADVANCE II trial has confirmed the excellent safety profile of vididencel, with drug-related adverse events limited to injection-site reactions and no reported drug-related serious adverse events.

"We are obviously very pleased with this latest update from the ADVANCE II trial presented at ASH," **said Erik Manting, CEO of Mendus**. "We are moving ahead expeditiously to expand the clinical testing of vididencel in AML and to prepare for registrational studies. We will next study the combination with oral azacitidine in a larger trial including a comparator arm in our recently announced collaboration with the Australian Leukaemia and Lymphoma Group (ALLG)."

Virtual KOL event to review Phase 2 updated survival data with vididencel in AML presented at ASH 2023

Date: Thursday, December 14, 2023
Time: 9:00 AM ET/3:00 PM CEST
To register and access the live event: https://lifescievents.com/event/mendus/

The company will host virtual KOL Event featuring Dr Arjan van de Loosdrecht, Professor of Hematology at Amsterdam UMC and Principal Investigator of the ADVANCE II trial, who will discuss the current treatment landscape for patients with AML and the development of vididencel, as a potential AML maintenance therapy. A live question and answer session will follow the formal presentations.

Following the live webcast, a replay will be available under the "Events and Webcasts" section on the Investor page of the Company's website: https://mendus.com/investors/events-presentations/

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/

About vididencel

Vididencel is an off-the-shelf immunotherapy which is being developed as a cancer maintenance treatment, aimed at improving disease-free survival following first-line treatment. Vididencel is currently studied in a Phase 2 monotherapy trial in acute myeloid leukemia (AML) and a Phase 1 safety and feasibility trial in ovarian cancer. Positive results from the ADVANCE II monotherapy Phase 2 trial in AML were presented at the American Society of Hematology (ASH) Annual Meeting in 2023. The analyses demonstrated the potential of vididencel to induce durable relapse-free survival in the majority of patients. Vididencel has received Orphan Drug Designation in Europe and the US and Fast Track Designation in the US for the treatment of AML. Mendus has secured a manufacturing alliance with NorthX Biologics for large-scale production of vididencel.