

Press Release

Stockholm, Sweden, November 3, 2023

Mendus Phase 1 vididencel clinical trial results in AML and high-risk MDS patients published in peer-reviewed medical journal

- *Publication provides additional clinical evidence that vididencel has strong potential as a new maintenance therapy in AML and high-risk MDS patients*
- *Patients with low disease burden have the best chance to respond to vididencel treatment, supporting the maintenance therapy setting currently pursued in the ADVANCE II Phase 2 trial*
- *Patients with adverse cytogenetic risk profile may still respond to vididencel therapy*
- *Results also indicate that vididencel can be safely and effectively combined with azacitidine*

Mendus AB (“Mendus” publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, today announced the publication of additional Phase 1 clinical trial data on its lead development program vididencel in the peer-reviewed medical journal *HemaSphere*. The data supports the potential of vididencel as a novel acute myeloid leukemia (AML) maintenance therapy and provides valuable insights for the current and future clinical trials with vididencel in AML and high-risk MDS.

The publication, titled “*Durable Responses and Survival in High-Risk Myelodysplastic Syndrome and Acute Myeloid Leukemia Patients Receiving the Allogeneic Leukemia-derived Dendritic Cell Vaccine DCP-001*”, and written by researchers from the Amsterdam UMC, Cancer Center Amsterdam and Erasmus University Medical Center, describes the long-term follow up data and additional patient characteristics from the Phase 1 clinical trial evaluating vididencel (DCP-001) in acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS).

“There remains a high medical need for new treatment options in AML and MDS. The Phase 1 study with vididencel demonstrated promising signs of efficacy and a benign safety profile, supporting the continued evaluation of this novel immunotherapy as a maintenance treatment, either as a monotherapy or in combination with other treatments,” said Prof. Dr. Arjan van de Loosdrecht, Professor of Hematology at Amsterdam UMC and Principal Investigator in the trial. “Since the completion of the Phase 1 trial, the knowledge in the medical community with respect to relapse dynamics, MRD and maintenance therapy in general has improved and we hope to see the combined impact of this more profound body of expertise in subsequent studies, including the ongoing ADVANCE II trial.”

“In addition to a positive overall outcome based on safety and feasibility of vididencel in AML and high-risk MDS, the Phase 1 trial data support the positioning of vididencel as a maintenance therapy for patients with low tumor burden, but with a high risk of disease relapse. This is the basis of our ongoing ADVANCE II Phase 2 monotherapy study, which has demonstrated the potential of vididencel to reduce residual disease and prolong disease-free survival in AML patients in complete remission, but with measurable residual disease (MRD). The Phase 1 trial data also indicate that vididencel can be safely and effectively combined with azacitidine,” said Jeroen Rovers, MD, PhD, Chief Medical Officer at Mendus.

In the Phase 1 clinical trial 12 patients were treated with vididencel (product ID: DCP-001), six patients with AML, three patients with AML with prior MDS and three patients with MDS with excess of blasts. Seven out of twelve patients showed a response to treatment; five patients showed progression of disease. The main discriminating variables in favor of response were patients who entered the study either in complete remission or who had stable disease status and a low percentage of blasts in the bone marrow at study entry. Importantly, there was no association found between response and disease risk classification with the majority of responding patients having an adverse cytogenetic risk profile, which is highly encouraging given the difficulty in effecting positive outcomes for these patients with a poor prognosis.

In the seven responders, a median relapse free survival (RFS) of 420 days (\approx 14 months) and a median overall survival (OS) of 1090 days (\approx 36 months) was observed as compared to a median OS of 144 days in the five non-responders. The longest surviving patient experienced an RFS of 1,849 days (\approx 5 years) and OS of 2,160 days (\approx 5.9 years) after treatment with vididencel. In a subset of three patients, who initially responded to vididencel but later relapsed, post-vaccination treatment with azacitidine was evaluated and resulted in one complete remission and two partial responses. The data suggest that azacitidine and vididencel may act synergistically.

The publication is available on the *HemaSphere* website. For a link to the article, please click [here](#).

FOR MORE INFORMATION, PLEASE CONTACT:

Erik Manting, CEO
E-mail: ir@mendus.com

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 IMMUS.T. <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. In December 2022, positive results from the ADVANCE II monotherapy Phase 2 trial in AML were presented at the American Society of Hematology (ASH) Annual Meeting. The analysis 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.