Press Release

Stockholm, Sweden, December 6, 2023

Mendus and Australasian Leukaemia & Lymphoma Group to expand clinical testing of vididencel as maintenance treatment for AML

- *CADENCE Phase 2 trial will evaluate vididencel in combination with oral azacitidine*
- *Randomized controlled trial in 40 patients, with potential to extend up to 140 patients*
- *Collaboration with ALLG to significantly strengthen Mendus clinical trial network*

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, today announced that the company has entered into a collaboration with the Australasian Leukaemia & Lymphoma Group (ALLG) to conduct a Phase 2 clinical trial, ALLG AMLM22 CADENCE, evaluating its lead product candidate vididencel in combination with oral azacitidine (AZA) as a potential novel maintenance treatment in acute myeloid leukemia (AML). Mendus and ALLG expect to obtain all approvals required for the start of the CADENCE trial before the year-end.

"We are grateful to work together with ALLG to set up a randomized clinical trial testing vididencel in combination with current standard of care in AML maintenance," said Jeroen Rovers, MD PhD, Chief Medical Officer of Mendus. "Mendus will benefit from ALLG's vast expertise and extensive clinical trial network, which has played an integral role in the clinical evaluation of several therapies to improve clinical outcomes in AML at large, including oral AZA as the current standard of care in AML maintenance."

"Development of novel, minimally toxic approaches to enhance the efficacy of maintenance therapy has the potential to greatly improve clinical outcomes for a large number of patients with AML " said Professor Dr Andrew Wei, Head of the Acute Myeloid Leukemia program at the Peter MacCallum Cancer Centre and Royal Melbourne Hospital in Melbourne, Australia. "Novel treatments to eliminate measurable residual disease and sustain durable responses by leveraging the immune system is a rational and exciting prospect in AML. Results from the ongoing ADVANCE II study indicate that vididencel is safe, well tolerated and an ideal therapeutic candidate to validate in patients with AML who have achieved first remission."

Mendus and ALLG plan to initiate the ALLG AMLM22 CADENCE trial as an adaptive, randomized, multi-center Phase 2 trial consisting of two stages, which will evaluate vididencel in combination with oral AZA as a maintenance therapy in AML. The first stage of the study will assess the safety of vididencel in combination with 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. Vididencel will be administered as four biweekly intradermal injections, followed by 3 booster injections up to 6 months after start of treatment.

Mendus and ALLG have completed the preparations for the start of the CADENCE trial in the ALLG AMLM22 adaptive platform, with the CADENCE protocol domain submitted to the central ethical committee of participating hospitals. Upon committee approval, the trial will be open for enrolment.

An update of the currently ongoing ADVANCE II monotherapy Phase 2 trial evaluating vididencel as a maintenance treatment for AML patients with measurable residual disease (MRD) will be presented at the American Society of Hematology Conference (ASH 2023).

FOR MORE INFORMATION, PLEASE CONTACT:

Erik Manting
Chief Executive Officer
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 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. 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.

ABOUT AUSTRALASIAN LEUKAEMIA & LYMPHOMA GROUP (ALLG)

The mission of ALLG is to improve the treatment and the lives of patients with leukemia, lymphoma and other hematological malignancies by advancing 'leading edge' clinical trials in Australasia. ALLG has been conducting clinical trials for the treatment and cure of blood cancers since 1973. Today, ALLG's 1,000+ members include a robust network of talented clinicians and researchers.