Press Release

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Mendus announces ethics committee approval for the AMLM22-CADENCE trial with lead product vididencel in AML

Mendus AB ("Mendus" publ; IMMU.ST) announces Human Research Ethics Committee (HREC) approval to initiate the AMLM22-CADENCE trial, which studies Mendus' lead product vididencel as a novel maintenance therapy in acute myeloid leukemia (AML).

Following positive Phase 2 monotherapy data from the ongoing ADVANCE II trial with vididencel in AML patients with measurable residual disease (MRD), Mendus announced a collaboration with the Australasian Leukaemia and Lymphoma Group (ALLG) to expand the clinical development of vididencel in December 2023. Mendus and ALLG will study vididencel as a novel AML maintenance treatment in combination with oral azacitidine (AZA), currently the only approved AML maintenance drug, in a multi-center, randomized controlled Phase 2 trial (AMLM22-CADENCE).

In the AMLM22-CADENCE trial, patients in first complete remission following high-intensity chemotherapy will receive standard treatment with AZA or the combination of AZA + vididencel. Vididencel will be administered as 4 biweekly intradermal injections, followed by 3 booster injections up to 6 months after start of treatment. The first stage of the trial will randomize 40 patients and in the second stage, efficacy of the combination will be assessed in an additional 100 patients. This approach will enable safety evaluations and assessment of the therapy.

By the end of 2023, Mendus and ALLG had completed the preparations for the start of the trial, with the CADENCE protocol domain submitted to the Human Research Ethics Committee (HREC) within the ALLG AMLM22 platform. Today, Mendus and ALLG announce that HREC approval was granted, allowing for clinical site initiation and start of enrolment of the trial in April 2024.

"We are pleased to receive HREC approval and progress the AMLM22-CADENCE study for patients with AML," said Professor Dr Andrew Wei, from the Peter MacCallum Cancer Centre and Royal Melbourne Hospital in Melbourne, Australia. "To leverage the immune system to control residual disease and improve treatment outcomes for AML patients is an exciting prospect. Together with my colleagues in the participating hospitals, and Dr Victoria Ling as co-lead, I am looking forward to exploring this opportunity with vididencel."

Based on positive FDA feedback, safety data from the AMLM22-CADENCE trial can be used for the global registration dossier for vididencel in AML. Mendus is preparing to be ready for a global registration trial with vididencel in AML in the second half of 2025, based on trial protocol development and large-scale GMP manufacturing of vididencel.

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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. https://www.mendus.com/

About ALLG
The Australasian Leukaemia & Lymphoma Group mission is to improve the treatment and the lives of patients with leukaemia, lymphoma and other haematological malignancies by advancing 'leading edge' clinical trials in Australasia. The ALLG is a collaborative of over 1,000 blood cancer health care professionals delivering high quality investigator lead trials.