Press Release

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Updated data from the ADVANCE II Phase 2 trial presented at ASH demonstrate durable survival of AML patients treated with vididencel

- *At median follow-up of 41.8 months, 13 out of 20 acute myeloid leukemia (AML) patients treated with vididencel in the ADVANCE II trial were still alive, with 11 remaining in first complete remission*
- *Based on the extended survival data, median relapse-free and overall survival median has not been reached, while estimated 5-year survival stands at 58%*
- *Immunomonitoring data confirm that vididencel acts as an active immunotherapy in AML*
- *Data presented at ASH support the preparations for pivotal-stage development of vididencel in AML*

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, announces that it has presented positive survival data from the ongoing ADVANCE II Phase 2 trial at the ASH 2024 conference. The data showed that the majority of AML patients treated with vididencel remain alive and disease-free in long-term follow-up, with a median follow-up of 41.8 months.

AML is an aggressive blood-borne tumor which requires immediate chemotherapy to reduce the level of malignant blasts in bone marrow and blood. After chemotherapy, the risk of disease relapse due to residual cancer cells is high and the only potentially curative approach in AML is a hematopoietic stem cell transplant (HSCT, or "bone marrow transplant"). Mendus' lead product vididencel is designed to stimulate active immunity against residual cancer cells. Active immunity, built up by the patient's immune system, is the only long-lasting form of immunity. Mendus is developing vididencel as a maintenance therapy in AML, in order to improve disease-free and overall survival in patients who are in first complete remission following first-line chemotherapy.

"We are encouraged by the updated survival data presented at ASH confirming that the majority of patients treated with vididencel as part of the ADVANCE II trial are alive today at a median follow-up of 41.8 months, with all patients having passed 3-year follow-up and two patients already 5-year follow-up." **said Erik Manting, CEO of Mendus**. "These data mark a significant milestone for Mendus, and support our accelerated preparations for a registration trial, bringing vididencel to the final development stage before it can broadly reach patients in need. In parallel, we will look for opportunities to initiate additional trials, such as the ongoing AMLM22-CADENCE trial evaluating vididencel with oral azacitidine, in collaboration with the Australasian Leukaemia and Lymphoma Group. The preclinical data presented at ASH further support the broader exploration of vididencel as a maintenance therapy in AML and potentially other blood-borne tumors, such as CML."

ADVANCE II data presented at ASH

The ADVANCE II Phase 2 trial is an international multi-center Phase 2 trial evaluating vididencel as maintenance treatment for AML patients in first complete remission (CR1) following chemotherapy. Patients participating in the trial were ineligible for HSCT and had measurable residual disease (MRD), which is associated with increased relapse rates. The ADVANCE II trial has completed the active study phase of 70-week follow-up from the start of vididencel treatment and patients are now in long-term follow up.

The updated ADVANCE II data presented at ASH show that 13 out of 20 patients treated with vididencel were alive and 11 patients were still in CR1 as of the November 4, 2024 cut-off-date, with a median follow-up of 41.8 months. Median relapse-free (RFS) and overall survival (OS) was not reached, as the majority of patients remained alive and disease-free. All patients had passed 3-

year follow-up and 2 patients completed 5-year follow-up. The 1-year survival stood at 88%, 3-year survival at 71% and the estimated 5-year survival was 58%.

The only drug approved for post-chemo AML maintenance therapy is oral azacitidine, which in MRD-positive patients led to a median RFS of 7.1 months and a median OS of 14.6 months in the registration trial[1]. The estimated 3-year OS for the whole treated patient population which included MRD-positive and -negative patients was 37.4% and 5-year OS was 26.5%[2].

([1]Roboz *et al*. (2022) Blood; 139(4):2145, [2]Wei *et al*., (2023) Am J Hematol 98: E84)

Immunomonitoring data from the ADVANCE II trial presented at ASH demonstrated that patients with multiple T cell responses following vididencel treatment (sustained vaccine-induced responses, or sVIR) had a significantly better OS than patients without a sVIR (p=0.036) and a higher number of MRD responses, with 6 out of 9 patients showing MRD clearance or > 10-fold reduction in MRD level. There were also clear differences between patient groups at baseline. Particularly patients with high levels of B cells and low levels of inhibitory T cells showed significantly improved OS (p=0.0109) and the majority of these patients (6 out of 8) demonstrated sVIR following vididencel treatment. The data confirm that vididencel stimulates a broad, active immune response against residual disease, which is associated with improved clinical outcome.

"The data presented at ASH confirm that vididencel acts as an active immunotherapy against residual cancer cells and has the potential to deliver durable clinical responses in AML. Combined with a strong safety profile, we believe this makes vididencel one of the most promising maintenance treatments currently in development in AML." **said Jeroen Rovers, CMO of Mendus**. "Based on the positive ADVANCE II data, we are executing on a clinical trial strategy aimed at market registration of vididencel in AML, while exploring opportunities to broaden the addressable patient population."

Other abstracts presented at ASH

In addition to the ADVANCE II Phase 2 trial data in the post-chemotherapy maintenance setting, Mendus presented two abstracts based on preclinical data exploring the use of vididencel in additional patient populations. AML patients ineligible for high-intensity chemotherapy can be treated today with a combination of azacitidine (AZA) and venetoclax (VEN). *In vitro* data demonstrated that AZA and VEN do not interfere with vididencel's mode of action and that VEN stimulates the processing of vididencel by antigen-presenting cells. *In vivo* data confirmed that vididencel and AZA+VEN act synergistically in a humanized mouse model for AML, supporting the clinical exploration of vididencel in AML patients treated with AZA+VEN. The second preclinical abstract addressed the potential use of vididencel in chronic myeloid leukemia (CML). Data showed that vididencel can stimulate cellular immunity against a CML cell line and investigated the combination potential of vididencel with different tyrosine kinase inhibitor drugs currently used for the treatment of CML. The possibility to improve immunity against residual cancer cells with vididencel addresses the need to improve treatment-free remission rates, allowing CML patients to control their disease without the need for life-long medication.
All data presented at ASH are available on the Mendus corporate website What we do - Mendus

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 long-term survival for cancer patients, while preserving health and quality of life. We leverage our understanding of dendritic cell biology to develop an advanced clinical pipeline of immunotherapies which combine clinical efficacy with a benign safety profile. Based in Sweden and The Netherlands, Mendus is publicly traded on the Nasdaq Stockholm exchange under the ticker IMMU.ST. https://www.mendus.com/