

MENDUS ANNOUNCES PRESENTATION OF UPDATED ADVANCE II DATA AND VITAL-CML PROGRESS

- Updated five-year follow-up data from the ADVANCE II trial and an overview of the VITAL-CML trial were presented by Prof Dr Bjørn Tore Gjertsen (University of Bergen & Haukeland University Hospital, Norway) at the Second Bologna Workshop on Immunotherapy for AML.
- The presentation demonstrated the feasibility and favorable safety profile of vididencel-based immunotherapy in adults with acute and chronic myeloid leukemias.

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced the presentation of updated long-term follow-up data from the ADVANCE II trial in acute myeloid leukemia (AML) and a summary of the VITAL-CML trial in chronic myeloid leukemia (CML) during the international Workshop on Immunotherapy for AML, held September 29-30 in Bologna, Italy.

[Prof Dr Bjørn Tore Gjertsen](#), a principal investigator of the ADVANCE II and VITAL-CML trials, presented "**Dendritic cell immunotherapy in myeloid leukemia**". The presentation summarized clinical and translational data supporting the use of vididencel in both AML and CML, including updated ADVANCE II follow-up data and progress in the ongoing VITAL-CML study.

"The completed ADVANCE II trial has demonstrated the principle of immune-mediated control of residual disease and revealed that vididencel-induced immune responses were associated with durable clinical remissions", commented Prof Dr Gjertsen. "Immunotherapy has strong potential to reduce relapse in myeloid leukemias, combined with a favorable safety profile that preserves health and quality of life. Building on proof-of-concept in AML, we have now expanded the clinical development of vididencel into CML with the aim of enabling more patients to achieve successful treatment-free remissions."

ADVANCE II is a Phase 2a trial (N=20) in AML patients with persistent MRD following conventional intensive chemotherapy induction. The trial has been completed: all patients remaining in long-term follow-up have now reached 5-year survival, and the updated median follow-up is 60 months. Immune-cell clustering in biopsies of the injection site confirmed that vididencel triggers local immune activation, which translates into systemic immune responses associated with durable clinical remissions in the majority of patients. There were no product-related serious adverse events. The main side effects were transient, mild to moderate injection-site reactions, consistent with the mechanism of action.

In preclinical experiments, vididencel stimulated CML-directed immune responses and was compatible with standard-of-care tyrosine kinase inhibitors (TKIs), including the novel class of STAMP (Specifically Targeting the ABL Myristoyl Pocket) inhibitors. In his presentation, Prof Gjertsen summarized the ongoing Phase 1b VITAL-CML trial ([NCT07651878](#)), which is evaluating whether vididencel can deepen molecular responses in patients with a suboptimal response to TKIs. As previously communicated, the initial safety and tolerability stage (N=8) has been successfully completed. 13 of the planned 24 patients are now enrolled. Initial data on early molecular responses are expected in Q4 2026, with topline results expected in mid-2027.

About vididencel

Vididencel is an active immunotherapy designed to improve disease-free and overall survival following first-line treatment, by stimulating immune control of residual disease. In AML patients with measurable residual disease (MRD), durable clinical remissions were associated with vididencel-induced immune responses in the ADVANCE II Phase 2a trial. The product is administered as a single course of intradermal injections and has demonstrated an excellent safety profile in multiple clinical trials, with no product-related serious adverse events reported to date. Vididencel has a strong regulatory dossier including a European Medicines Agency (EMA) Advanced Therapy Medicinal Product (ATMP) Manufacturing Certificate, Orphan Drug Designations (EU + US) and Fast Track Designation (US). The product is derived from a proprietary cell line, using a scalable production process that does not require patient material or genetic engineering and is stored frozen, allowing for centralized manufacturing and on-demand delivery to hospitals. In AML, vididencel is currently being evaluated as a post-remission immunotherapy in combination with oral azacitidine in the randomized AMLM22-CADENCE Phase 2b trial and in patients treated with less-intensive first-line treatment comprising venetoclax and azacitidine in the DIVA Phase 1b trial. In CML, the ongoing VITAL-CML Phase 1b trial focuses on patients with a suboptimal response to the current standard-of-care treatment with tyrosine kinase inhibitors, whereas the planned VITAL-TFR2 Phase 2a trial will evaluate vididencel as an immunotherapy to support treatment-free remission, considered the ultimate goal in the treatment of CML.

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About Mendus AB (publ)

Mendus is a clinical-stage biopharmaceutical company dedicated to transforming immunotherapy for myeloid blood cancers. Based in Sweden and the Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST.
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