

MENDUS REPORTS COMPLETE ENROLLMENT OF THE FIRST STAGE OF THE VITAL-CML TRIAL

- *VITAL-CML is a pivotal trial to confirm the safety and feasibility of vididencel immunotherapy in patients with suboptimal responses to current standard of care with tyrosine kinase inhibitors (TKIs)*
- *Completion of first-stage enrollment supports milestone read-out in H2 2026*

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced successful recruitment of the first stage of the VITAL-CML trial, comprising the first 8 patients. This marks an important milestone in the development of the company's lead product vididencel in chronic myeloid leukemia (CML).

"The progress of our CML program is a crucial pillar of our expanding clinical development strategy, positioning vididencel as a safe and robust immunotherapy across multiple myeloid malignancies", commented Mendus Chief Medical and Scientific Officer Professor Tariq Mughal. "Enabling more people with CML to safely discontinue TKI treatment and achieve functional cure is the ultimate goal of developing vididencel in this indication. We are indebted to the patients and investigators participating in the VITAL-CML trial for their commitment to addressing this important and increasing unmet clinical need."

VITAL-CML is a Phase 1b trial ([NCT07651878](#)) that evaluates vididencel immunotherapy in CML chronic phase (CP) patients with a suboptimal response to tyrosine kinase inhibitors (TKIs), who are therefore not eligible for treatment-free remission (TFR). The trial is led by [Professor Bjørn Tore Gjertsen](#) (University of Bergen & Haukeland University Hospital, Norway). The objective of the trial is initially to establish safety and tolerability of vididencel in CML patients. Subsequently, the trial will evaluate whether vididencel can induce immune-mediated deepening of molecular remissions, converting suboptimal responders into optimal responders that would then qualify for TFR. Mendus announced enrollment for VITAL-CML in April 2026 and now reports the successful completion of the first stage comprising 8 patients. The trial is expected to recruit an additional 16 patients. Milestone data based on safety and early molecular responses from the first stage of the trial are anticipated in the second half of 2026.

Positive initial safety assessment from the VITAL-CML trial will also enable the initiation of VITAL-TFR2, a Phase 2a trial evaluating whether vididencel immunotherapy can increase the likelihood of durable TFR in CML CP patients with a previously failed TFR attempt.

About CML

Chronic myeloid leukemia (CML) is a clonal myeloproliferative neoplasm originating in hematopoietic stem cells affecting around 300,000 people in Europe and the US. It is commonly associated with the Philadelphia chromosome translocation, resulting in activation of the BCR::ABL1 oncoprotein, with or without additional mutations in myeloid associated genes that fuel cancer growth in the blood and bone marrow, disrupting the production of healthy blood cells. CML is commonly treated with tyrosine kinase inhibitors (TKIs) that inhibit the BCR::ABL1 kinase activity. Overall survival of CML patients on TKI treatment is similar to that of the general

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population and treatment goals of CML have therefore shifted to quality of life and, ultimately, functional cure without continued TKI treatment called “treatment-free remission” (TFR). Today, less than 25% of patients accomplish durable TFR due to relapse after TKI treatment is stopped.

About vididencel

Vididencel is an active immunotherapy designed to improve long-term outcomes in the treatment of myeloid malignancies. Phase 2 proof-of-concept data in acute myeloid leukemia (AML) demonstrated durable clinical remissions associated with vididencel-induced immune responses in patients with persistent measurable residual disease following first-line therapy. Mendus’ clinical development strategy aims to position vididencel broadly as a post-remission therapy to improve relapse-free and overall survival in AML and to apply the same principle of durable disease control to support treatment-free remission (TFR), considered the ultimate therapy goal in CML.

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About Mendus AB (publ)

Mendus is a clinical-stage biopharmaceutical company dedicated to developing novel immunotherapy options for myeloid malignancies. Based in Sweden and the Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST.
<https://www.mendus.com/>