

MENDUS REPORTS POSITIVE READ-OUT FOR FIRST STAGE VITAL-CML TRIAL

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced a positive read-out of the first safety and tolerability stage of the VITAL-CML trial, following a review by the Data Safety Monitoring Board (DSMB).

VITAL-CML is a pivotal trial to evaluate the safety and potential efficacy of vididencel in chronic-phase (CP) chronic myeloid leukemia (CML) patients with suboptimal responses to current standard-of-care treatment with tyrosine kinase inhibitors (TKIs). In July, Mendus announced complete enrollment of the first safety and tolerability stage of the trial. The company now reports that a review by the DSMB concluded that the combination of vididencel and TKI treatment did not raise any safety or tolerability concerns, based on 8 patients who completed 4 doses of vididencel.

"The DSMB review of the first stage of the VITAL-CML trial is an important milestone for our CML program and provides further support for the excellent safety and tolerability profile of vididencel," commented Mendus Chief Medical and Scientific Officer Prof Dr Tariq Mughal.

"Enabling more people with CML to safely discontinue TKI treatment and experience treatment-free remission (TFR) is the ultimate goal of developing vididencel in this indication. The positive safety and tolerability assessment will allow us to advance the VITAL-CML trial in patients who remain ineligible for TFR despite ongoing TKI therapy, while continuing preparations for the VITAL-TFR2 trial which will evaluate vididencel in TFR-eligible patients."

VITAL-CML is a Phase 1b trial ([NCT07651878](#)) that evaluates vididencel immunotherapy in CML chronic phase (CP) patients with a suboptimal response to TKIs, who are therefore not eligible for TFR. The trial is led by [Prof Dr Bjørn Tore Gjertsen](#) (University of Bergen & Haukeland University Hospital, Norway). The initial objective of the trial is to establish the 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 who may then qualify for TFR. The trial has recruited 12 patients to date and will recruit a total of 24 patients. Additional read-outs from the VITAL-CML trial are expected in Q4 2026, with initial topline data from all 24 patients expected mid-2027.

The 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, scheduled to start in Q4 2026.

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.

Press Release

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

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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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