Press Release
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MENDUS ANNOUNCES COLLABORATION WITH THE SOUTH AUSTRALIAN HEALTH AND MEDICAL RESEARCH INSTITUTE (SAHMRI) TO SUPPORT PREPARATION OF THE VITAL-TFR2 TRIAL IN CHRONIC MYELOID LEUKEMIA (CML)

- *SAHMRI, a leading Australian medical research institute, will support preparations for the Phase 2a VITAL-TFR2 trial in CML*
- *The VITAL-TFR2 trial will evaluate whether vididencel immunotherapy can increase the likelihood of achieving durable treatment-free remission (TFR) in patients who have previously failed a TFR attempt*
- *Progress in VITAL-TFR2 builds on the ongoing VITAL-CML trial, with initial data from the safety and tolerability stage of the VITAL-CML trial expected in H2 2026*

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced that it has signed an agreement with SAHMRI to support preparations for the Phase 2 VITAL-TFR2 trial with the company's lead product vididencel in chronic myeloid leukemia (CML). SAHMRI is a leading Australian medical research institute, and home to internationally recognized experts in hematology and cancer research.

VITAL-TFR2 is a Phase 2a trial to be led by Professor Timothy Hughes (SAHMRI and Adelaide University, Australia) and Associate Professor David Ross (SAHMRI and Royal Adelaide Hospital, Australia), two renowned clinical experts in the aspects of TFR in CML.

"Evidence that the immune response is central to the success of TFR has accumulated over the past decade, but we have lacked therapies to safely harness an effective immune response. Vididencel may provide a safe means to achieve the immune stimulation required to achieve TFR in this challenging group of patients. We are excited to collaborate with Mendus to test this novel approach" said Professor Hughes.

The development of tyrosine kinase inhibitors (TKIs) has transformed CML into a manageable chronic disease for most patients. As a result, focus has shifted toward quality of life and the attainment of treatment-free remission (TFR), which allows patients to safely stop taking daily TKIs. However, TFR remains elusive for many CML patients due to two key challenges. First, many patients do not achieve the deep and sustained molecular responses required to qualify for a TFR attempt. The ongoing VITAL-CML trial aims to address this by converting suboptimal responses into sustained deep molecular responses that enable TFR eligibility. Second, relapse after TKI discontinuation remains a major obstacle to durable TFR success. Approximately half of patients relapse after stopping treatment and must restart TKI therapy, with failure rates even higher for subsequent TFR attempts. VITAL-TFR2 will evaluate whether vididencel can support durable, immune-mediated remission and improve long-term TFR success in patients with a previous relapse following a TFR attempt.

As preparations for VITAL-TFR2 advance, Mendus will work with SAHMRI and the study team to support key trial planning and start-up activities. "Effective collaboration between researchers, clinicians and trial specialists is critical to advancing innovative therapies and delivering high-quality clinical research. We are delighted to support preparations for the VITAL-TFR2 trial alongside Mendus and the study team," said Emma Heath, Head of the Clinical Trials Platform at SAHMRI.

Mendus recently announced completion of enrollment of the first safety and tolerability stage of the VITAL-CML trial in Bergen, Norway. Positive initial data from the VITAL-CML trial, expected in the second half of 2026, will lay the foundation for two parallel development paths with vididencel in CML. One path is focused on improving TFR eligibility for suboptimal TKI responders through the VITAL-CML trial, while the other seeks to support TFR success through the VITAL-TFR2 trial.

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 the general 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).

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. Based on these results, 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 establish 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 transforming immunotherapy 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/