

MENDUS ANNOUNCES FIRST PATIENT ENROLLED IN THE VITAL-CML TRIAL

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced that the first patient has been enrolled in the VITAL-CML trial, which evaluates Mendus' lead product vididencel in chronic myeloid leukemia (CML).

Following recent regulatory approval, the first patient has now been enrolled into the company-sponsored phase 1b trial. The VITAL-CML trial is led by Prof Dr Bjørn Tore Gjertsen (University of Bergen and Haukeland University Hospital, Norway) and evaluates vididencel in chronic phase CML patients with a sub-optimal response to currently approved tyrosine kinase inhibitors (TKIs).

The VITAL-CML trial will recruit up to 24 patients, with initial topline safety and early molecular response data based on the first 8 patients treated expected in the second half of 2026. If positive, this will trigger the onset of the VITAL-TFR2 Phase 2a trial to assess the role of vididencel to improve TFR rates in patients who failed an earlier TFR attempt.

About CML

Chronic myeloid leukemia (CML) is a clonal myeloproliferative neoplasm originating in hematopoietic stem cells. 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. Because these treatments are effective, overall survival of CML patients is similar to that of the general population and attention in the treatment of CML has shifted to quality of life and, ultimately, treatment-free remission (TFR). Today, an estimated number of > 300,000 people live with CML in Europe and the US only, with a global estimate of around 5 million and a prevalence plateau that may reach as many as 10 million people affected by the disease.

About vididencel

Vididencel is an off-the-shelf, active immunotherapy designed to stimulate immune control of residual disease and improve disease-free and overall survival following first-line treatment of tumors with a high recurrence rate including myeloid blood cancers. Vididencel comprises irradiated leukemic-derived dendritic cells that are administered via intradermal injection. Vididencel has demonstrated an excellent safety profile in multiple clinical trials, with temporary local injection site reactions as the main side effect and no serious product-related side effects reported to date. The product is manufactured using a proprietary cell line and a scalable manufacturing process that does not require patient material or genetic engineering. Vididencel has a strong regulatory dossier including an EMA ATMP Manufacturing Certificate, Orphan Drug and Fast Track Designations.

Press Release

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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 under the ticker IMMU.ST. <https://www.mendus.com/>