Press Release
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MENDUS ANNOUNCES START OF CLINICAL PROGRAM IN CML

Mendus AB ("Mendus" publ; IMMU. ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced that it has completed preparations and received all regulatory approvals for the VITAL-CML trial, marking the start of clinical development with the company's lead product vididencel in chronic myeloid leukemia (CML).

The VITAL-CML trial evaluates vididencel in chronic phase CML patients with a sub-optimal response to currently approved tyrosine kinase inhibitors (TKIs). The company-sponsored Phase 1b trial will be led by Prof Dr Bjørn Tore Gjertsen (Professor of Hematology, University of Bergen, Norway, and Senior Consultant Hematologist at Haukeland University Hospital) and investigate vididencel in patients with molecular disease levels indicating a sub-optimal response to TKIs. Mendus has now completed preparations and received all necessary approvals to open the trial for recruitment. The primary objective of the VITAL-CML trial is to establish safety and feasibility of vididencel as an active immunotherapy in CML, with the ultimate goal to allow patients to stop their medication safely and effectively, described as 'treatment-free remission' (TFR).

"With regulatory approvals in place, we are excited to initiate the VITAL-CML trial and thereby start the development of vididencel as an active immunotherapy in our quest to deliver the best clinical care in CML across the world", says Mendus Chief Medical and Scientific Officer Prof Dr Tariq Mughal. "Despite the successful development of selective and more potent TKIs, long-term TFR success remains limited. We are now in a position to address this huge unmet medical need by assessing if vididencel can stimulate the patient's own immune system to reduce relapse risk and offer functional cure without life-long TKI therapy."

Vididencel has been studied as a safe and active immunotherapy in acute myeloid leukemia (AML), demonstrating durable clinical remissions associated with vididencel-induced immune responses in the ADVANCE II Phase 2 proof-of-concept trial. As part of its updated clinical development strategy communicated end of 2025, Mendus will broaden the positioning of vididencel as a first-line post-remission treatment in AML and expand clinical development to include CML as an additional indication.

"Following the successful treatment of AML patients as part of the ADVANCE II trial, we are looking forward to explore the application of vididencel in CML", comments Prof Dr Bjørn Tore Gjertsen. "The main struggle for chronic phase CML patients is the burden of life-long medication and the side effects associated with TKIs. The VITAL-CML trial focuses on a partly forgotten but increasing group of patients with adverse effects - often younger adults facing decades or life long TKI therapy. As a next step, we will explore the use of vididencel to allow more patients to stop TKI treatment safely and successfully."

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 are 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-fee 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.

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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 that 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/