Press Release
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MENDUS ANNOUNCES UPDATED CLINICAL STRATEGY AND OPERATIONAL FOCUS

Vididencel to be developed as a post-remission therapy across AML risk categories and in CML

Mendus AB ("Mendus" publ; IMMU. ST), a biopharmaceutical company focused on immunotherapies targeting tumor recurrence, today announced an update of the late-stage clinical development strategy with its lead product vididencel in myeloid malignancies. The update is based on continued positive data with vididencel in acute myeloid leukemia (AML) and follows the recent appointment of Tariq Mughal as Chief Medical Officer. The company also announced development of vididencel as an active immunotherapy for chronic myeloid leukemia (CML) and its dedicated focus on the clinical development of vididencel, including organizational changes to offset new clinical trial expenses.

- *Vididencel continues to demonstrate unprecedented long-term overall survival in the ADVANCE II Phase 2a trial in high-risk AML, with the majority of patients remaining alive and five patients having passed 5-year survival at median follow-up of 48 months*
- *Acceleration of recruitment of patients in AMLM22-CADENCE, a randomized phase 2b post-remission combination trial with oral azacitidine*
- *New clinical trial in AML to focus on patients treated with azacitidine plus venetoclax*
- *Clinical strategy in place to develop vididencel as an active immunotherapy for chronic myeloid leukemia (CML) as a second blood-borne tumor indication*
- *Cost savings realized by corporate reorganization, offsetting new trial costs anticipated for 2026*

AML Program
Mendus has reported long-term proof-of-concept data from the Phase 2a ADVANCE II trial in AML patients with measurable residual disease (MRD), showing durable remissions and confirming vididencel's mechanism as an active immunotherapy. With 48 months median follow-up, 13 of 20 patients remain alive, and 5 have surpassed 5-year survival. Vididencel is currently under evaluation in the randomized Phase 2b AMLM22-CADENCE trial, combining vididencel with oral azacitidine in both MRD-positive and -negative patients post high-intensity chemotherapy. The trial is supported by the Australasian Leukaemia and Lymphoma Group and since February 2025, 12 patients have been enrolled, with a goal of 20 in Q1 2026. Based on CADENCE outcomes, Mendus will pursue broader positioning of vididencel beyond MRD-positive patients, significantly expanding its target population. Additionally, Mendus has prepared a Phase 1b trial (N=24) to evaluate vididencel post-remission in AML patients unfit for intensive chemotherapy, following promising preclinical data showing synergy with azacitidine and venetoclax (aza+ven) presented at the ASH 2024 conference. The trial will be led by Prof Andrew Wei, also a lead investigator of CADENCE. Initial topline data from both trials are expected mid-2026 and will guide the go-to-market strategy in AML.

In the third quarter of 2025, Mendus has also entered into a preclinical research collaboration with an international biopharmaceutical company to study vididencel in combination with targeted therapy in AML.

“Rather than focusing on a limited patient population, our updated late-stage clinical development strategy in AML addresses the full spectrum of post-remission therapy in AML,” said Mendus Chief Medical Officer Prof Tariq Mughal. “As an immunotherapy, vididencel acts across different subtypes of AML and independent of specific AML mutations. With a stellar safety profile and supported by robust preclinical research data, vididencel can be combined with current and upcoming AML backbone therapies. This will allow us to broaden the addressable patient population and next decide the optimal path towards market entry, validated by input from the medical-scientific community and industry feedback.”

CML program
Building on positive AML data and preclinical results presented at ASH 2024, vididencel shows potential to enhance the safety and efficacy of treatment in chronic-phase CML patients receiving tyrosine kinase inhibitors (TKIs). While TKIs have transformed CML into a manageable chronic condition, most patients require life-long therapy, which carries risks of toxicity, serious adverse events, and expensive treatment. Given evidence suggesting immune mechanisms contribute to controlling residual disease post-TKI, Mendus is initiating a clinical strategy to evaluate vididencel in CML. The goal is to improve immune-mediated control and support durable TKI treatment-free remission (TFR). A Phase 1a/1b trial led by Prof Bjørn-Tore Gjertsen (University of Bergen, Norway) will assess safety and feasibility, with first data expected mid-2026. If successful, a Phase 2a trial led by Prof Timothy Hughes (University of Adelaide, Australia) will evaluate vididencel’s role in improving TFR rates in patients who previously failed TFR attempts.

Corporate reorganization
Mendus will reduce its staff from 28 to 19, including an adjustment of the company’s executive management team from 5 to 3 members. With the large-scale production process and manufacturing alliance with NorthX Biologics accomplished, Chief Technology Officer Leopold Bertea will step down from the management team after a short transition period. Chief Scientific Officer Alex Karlsson-Parra will also step down and continue to act as adviser to Chief Medical Officer Tariq Mughal, who will take on the combined position of Chief Medical and Scientific Officer. Erik Manting and Lotta Ferm will remain Chief Executive Officer and Chief Financial Officer, respectively. The cost savings realized by the corporate reorganization are estimated to offset the extra trial costs anticipated for 2026.

“The positive long-term follow-up data of the ADVANCE II trial and the momentum of the CADENCE trial underscore the potential of vididencel as a post-remission therapy following high-intensity chemotherapy in AML”, commented Mendus CEO Erik Manting. “The goal of our clinical strategy is to further broaden the positioning of vididencel in the AML treatment landscape and in CML as a new indication. The execution of this clinical development plan requires operational focus, and we will therefore reduce our R&D activities to what is required to support our clinical programs. We are thankful to those colleagues who are leaving the company and the entire team for their contributions and commitment to the realization of these objectives.”

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For more information, please contact:
Erik Manting
Chief Executive Officer
E-mail: ir@mendus.com

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/