Press Release
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MENDUS ANNOUNCES INITIATION OF THE DIVA TRIAL

Mendus AB ("Mendus" publ; IMMU. ST), a biopharmaceutical company focused on immunotherapies for myeloid blood cancers, today announced the initiation of the DIVA trial evaluating vididencel in combination with less-intensive first-line treatment in patients with acute myeloid leukemia (AML).

- DIVA will evaluate vididencel in combination with venetoclax and azacitidine (Ven+Aza) in newly diagnosed AML patients with MRD considered unfit for intensive induction chemotherapy.
- The study is led by Professor Andrew Wei at Peter MacCallum Cancer Centre and supported by Olivia Newton-John Cancer Research Institute (ONJCRI).
- A first safety read-out (N=6) is expected in H1 2027, with initial topline data (N=24) expected in H2 2027.

The DIVA Phase 1b trial will evaluate vididencel in newly diagnosed AML patients with measurable residual disease (MRD) following treatment with venetoclax and azacitidine (Ven+Aza). To support the trial, Mendus entered into an agreement with the Olivia Newton-John Cancer Research Institute (ONJCRI), a leading Australian cancer research institute, in Q1 2026. Today, the company announces that trial preparations have been completed and all regulatory approvals have been obtained. The DIVA trial broadens the positioning of vididencel as a post-remission treatment in AML to include patients considered unfit for intensive induction chemotherapy (IC).

“A major challenge in the treatment of AML is the elimination of leukemia stem and progenitor cells (LSCs), therapy-resistant cells that persist after induction and are considered a principal cause of relapse. There is evidence that LSCs can be targeted and eliminated by the immune system and we are therefore excited to see the DIVA trial commence, further broadening the positioning of vididencel as a post-remission immunotherapy in AML,” said Mendus Chief Medical and Scientific Officer Professor Tariq Mughal. “An ongoing randomized phase 2b study (AMLM22-CADENCE), led by Professor Andrew Wei (Peter MacCallum Cancer Centre, Melbourne, Australia), is evaluating vididencel in combination with oral azacitidine for patients in complete remission following IC. The DIVA trial, also led by Professor Wei, is particularly important given the increasing number of patients in remission after less-intensive approaches since the approval of venetoclax in 2018. We are grateful to Professor Andrew Wei and his team and to ONJCRI for the timely execution of the preparations for the DIVA trial.”

The DIVA (Dendritic cell Immune activation combined with Venetoclax and Azacitidine) trial is a Phase 1b single-arm study (N=24) of vididencel in newly diagnosed, transplant-ineligible, MRD+ AML patients in first complete remission (CR1) or partial CR1 (CRh or CRi) within 120 days of commencing VEN+AZA. The primary objectives of the trial are to confirm safety, assess immune activity and to demonstrate a reduction in MRD. A first safety read-out (N=6) is expected in H1 2027 with initial topline data (N=24) expected in H2 2027. The trial is designed to deliver proof-of-

concept that vididencel can safely and effectively be combined with Ven+Aza, complementing the ongoing development of vididencel in the post-IC setting and demonstrating the utility of vididencel in the post-remission setting to augment immune activation and reduce the risk of relapse in AML.

About venetoclax
Venetoclax is a targeted drug that inhibits the BCL-2 protein needed for the survival of leukemic cells, thereby helping to kill and reduce the number of cancer cells in AML. The combination treatment of venetoclax plus azacitidine has been approved as a first-line treatment for patients 75 years or older as well as for patients who are deemed ineligible to receive intensive induction chemotherapy. Emerging clinical evidence suggests that venetoclax combined with azacitidine or other hypomethylating agents may benefit a broader AML patient population, including patients eligible for induction chemotherapy.

About vididencel
Vididencel is an active immunotherapy designed to improve disease-free and overall survival following first-line treatment, by stimulating immune control of residual disease. In AML patients with measurable residual disease (MRD), durable clinical remissions were associated with vididencel-induced immune responses in the Phase 2a ADVANCE II trial. Vididencel is administered as a single course of intradermal injections and has demonstrated an excellent safety profile, with no product-related serious adverse events reported to date. Vididencel has a strong regulatory dossier including a European Medicines Agency (EMA) Advanced Therapy Medicinal Product (ATMP) Manufacturing Certificate, Orphan Drug Designations (EU + US) and Fast Track Designation (US). The product is derived from a proprietary cell line, using a scalable production process that does not require patient material or genetic engineering and is stored frozen, allowing for centralized manufacturing and on-demand delivery to hospitals.

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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.
https://www.mendus.com/