FDA AND EMA FEEDBACK ENDORSES VIDIDENCEL REGISTRATION TRIAL PREPARATIONS

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, announces a summary of the feedback received from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) in the fourth quarter of 2024. The feedback is supportive of the preparations for a registration trial with Mendus' lead program vididencel in acute myeloid leukemia (AML).

Following positive updated Phase 2 survival data from the ADVANCE II trial reported last December at the annual American Society of Hematology (ASH) conference, Mendus continues to focus on preparing the lead program vididencel for a registration trial in AML. As part of that exercise, Mendus had announced it would seek advice from FDA and EMA in the fourth quarter of 2024 and now provides a summary of the feedback received during an end-of-Phase 2 ("Type B") meeting held with the FDA and the Scientific Advice received from the EMA Committee for Medicinal Products for Human Use (CHMP). Both FDA and EMA supported the trial design, patient population, reference therapy, primary and secondary endpoints and statistical analysis strategy, as proposed by Mendus. The Phase 3 study design was considered appropriate to demonstrate efficacy in the intended patient population. Both agencies also agreed to the development steps taken by Mendus towards establishing large-scale manufacturing of vididencel, including the required comparability protocol.

"*The feedback obtained from FDA and EMA endorses our registration trial preparations for vididencel in AML*," **said Jeroen Rovers, CMO of Mendus**. "*It confirms that we are on the right track in addressing the main clinical, regulatory, and quality & control challenges related to trial design, manufacturing and regulatory considerations. We are committed to working towards market registration of vididencel as a novel treatment for AML patients in need of maintenance therapy, in order to improve disease-free and overall survival following initial treatment success*."

During the ASH conference held in December 2024, Mendus presented positive updated survival data from the ADVANCE II Phase 2 trial addressing AML patients with measurable residual disease (MRD). The data showed that 13 out of 20 patients treated with vididencel were alive and 11 patients were still in first complete remission at a median follow-up of 41.8 months. Based on the positive Phase 2 data, Mendus is expanding clinical development and preparing for a registration trial with vididencel in AML. To support late-stage clinical development and commercialization of vididencel, Mendus has established a manufacturing alliance with NorthX Biologics, which is expected to be ready for large-scale GMP production of vididencel by mid-2025.

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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/**