Press Release

Stockholm, Sweden, September 8, 2023

Mendus receives U.S. FDA Fast Track Designation for vididencel in Acute Myeloid Leukemia (AML)

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, today announced that it has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the Company's lead program, vididencel, for the treatment of Acute Myeloid Leukemia (AML) in complete remission with residual disease. Advantages of the Fast Track Designation include close and early interactions with the FDA to support accelerated approval, as well as the possibility of a "rolling review" for a subsequent market application.

The FDA's decision was based on the previously communicated results from the ADVANCE II clinical trial, which delivered promising survival read-outs and underpinned the safety of vididencel as a monotherapy in AML. Vididencel had already been assigned Orphan Drug Designation for treatment of AML in the US and Europe. Additionally, Mendus had recently been granted an Advanced Therapy Medicinal Product (ATMP) certificate by the European Medicines Agency (EMA) following a review of manufacturing quality and non-clinical data for its lead pipeline program vididencel.

"As part of the preparations for continued clinical development of vididencel in AML, we continue to strengthen the program in all product-relevant aspects, including on the regulatory front," commented Jeroen Rovers, MD PhD, Chief Medical Officer of Mendus. "The Fast Track Designation granted by the FDA adds substantial regulatory value to the vididencel program in the most important healthcare market worldwide. As Mendus advances vididencel into the next phase of clinical development in AML maintenance, the Fast Track Designation will allow the Company to engage more frequently with the FDA to optimally align its development plan."

Vididencel is currently being evaluated in AML and ovarian cancer as a potential maintenance therapy to reduce or prevent tumor recurrence. Vididencel is an off-the-shelf, intradermal vaccine derived from the Company's proprietary DCOne leukemic cell line. In December 2022, the Company presented positive results from the ADVANCE II study in AML at the American Society of Hematology (ASH) Annual Meeting. The analysis demonstrated the potential of vididencel to control measurable residual disease (MRD) and induce durable relapse-free survival in the majority of patients. Mendus expects to present a next survival update in the fourth quarter of 2023. Additionally, Mendus anticipates to start a new Phase 2 clinical trial evaluating a combination of vididencel with oral azacitidine (Onureg®, the current standard of care in AML maintenance) in H2 2023, as a step-up to pivotal-stage development.

ABOUT MENDUS AB (PUBL)

Mendus is dedicated to changing the course of cancer treatment by addressing tumor recurrence and improving survival outcomes for cancer patients, while preserving quality of life. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based 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. http://www.mendus.com/

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