Press Release

Stockholm, Sweden, December 22, 2023

Mendus announces clinical pipeline update

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, announced an update on the status and outlook of its clinical pipeline programs.

Mendus reports completion of the long-term follow up of the MERECA trial studying the intratumoral immune primer **ilixadencel** in metastatic renal cell carcinoma (mRCC). The long-term follow up data confirmed the observations previously reported, with no significant survival difference between the ilixadencel plus sunitinib treatment arm versus the sunitinib-only control arm of the trial. The final results of the MERECA trial confirm the decision not to pursue mRCC as a possible indication for ilixadencel. Mendus continues to explore the clinical development of ilixadencel in soft tissue sarcomas (STS) in the first half of 2024, versus earlier guidance of starting a trial before 2023YE.

"The data from the MERECA trial do not support continued development in renal cell carcinoma. However, ilixadencel remains a promising product candidate for difficult-to-treat solid tumors, such as soft tissue sarcomas", said Erik Manting, CEO of Mendus.

Mendus also confirms that the Phase 1 ALISON trial with its cancer maintenance therapy **vididencel** in ovarian cancer is now fully recruited (17 patients). Mendus had earlier reported initial positive interim data from the ALISON trial, based on the induction of immune responses against tumor antigens previously shown to be relevant for ovarian cancer and confirming a strong safety profile for vididencel in this indication. Mendus expects further read outs of the trial in 2024, including a survival analysis in 2024H2.

Mendus recently announced positive data from the Phase 2 ADVANCE II trial with its lead product vididencel in acute myeloid leukemia (AML). The data presented on December 11, 2023 at the American Society of Hematology Annual Meeting (ASH 2023), demonstrated durable clinical remissions in AML patients diagnosed with measurable residual disease (MRD).

"The data with our lead product vididencel recently reported at ASH demonstrated durable clinical benefit in AML, an indication with very high unmet medical need. Mendus therefore remains focused on the regulatory path and increasing the development efforts for vididencel in AML", Erik Manting added.

As a next step in the development of vididencel in AML, Mendus has announced a collaboration with the Australasian Leukaemia and Lymphoma Group (ALLG) to study vididencel in combination with the current standard of care in AML maintenance treatment, oral azacitidine, in a 2-stage, control-arm trial including up to 140 patients.

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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/

About the MERECA trial

The completed Phase 2 MERECA trial (NCT02432846) was an international, multicenter, open-label, randomized, controlled study evaluating the safety and efficacy of ilixadencel in metastatic renal cell carcinoma (mRCC). A total of 86 metastatic mRCC patients were treated, of which 56 were given ilixadencel as an intratumor administration, followed by surgery to remove the kidney tumor and standard treatment with sunitinib, and 30 patients were treated with sunitinib only. Results from the MERECA trial published earlier demonstrated that the primary endpoint of 18 months survival showed no significant differences between the ilixadencel arm and control group. Median OS was 35.6 months for the ilixadencel arm, as compared to 25.3 months in the control group[1]. At completion of the long-term follow-up period of 5 years post-treatment of last patient enrolled, there was no significant survival difference between the two treatment arms, with 32.1% of patients alive in the ilixadencel arm, as compared to 26.7% in the control arm. The MERECA trial data do not support the development of ilixadencel in mRCC.

1. Lindskog *et al*., European Urology Open Science 40 (2022) 38–45

About the ALISON trial

The Phase 1 ALISON trial (NCT04739527) is a single-center, open-label study evaluating safety and efficacy of vididencel (DCP-001) in high-grade serous ovarian cancer (HGSOC) patients. The ALISON trial evaluates the use of vididencel as a maintenance immunotherapy, aimed to prolong disease-free survival following primary treatment comprising debulking surgery and chemotherapy. The primary endpoint of the trial is the number of patients with vididencel-induced antigen-specific T cells responses in peripheral blood after treatment. Key secondary endpoints include safety and tolerability after repeated vididencel dosing, as well as recurrence free survival (RFS) and overall survival (OS) during a 2-year follow-up period. Patient enrolment (17) has been completed and further analysis of vididencel-induced immune responses, safety and potential survival benefit will continue in 2024.

About the ADVANCE II trial

The Phase 2 ADVANCE II trial (NCT03697707) is an international, multicenter, open-label study evaluating safety and efficacy of vididencel (DCP-001) in acute myeloid leukaemia (AML). Patients were in remission following chemotherapy, but diagnosed with persistent measurable residual disease (MRD). Patients received four biweekly doses of vididencel, followed by additional booster administrations at weeks 14 and 18. Blood and tissue samples were collected for assessments of MRD and immune response monitoring. The active study phase comprising a 70-week follow-up period from the start of vididencel treatment was completed and patients are now in long-term follow up. As per the most recent read-out November 24, 2023, the median follow-up for the entire study population was 31.6 months. Median RFS stood at 30.4 months and median OS was not reached, with 14/20 patients still alive and 11 still in remission at the cut-off date. The RFS at 2 years was 56%, and the estimated 2-year and 3-year OS stood at 74.9% and 64.7%, respectively. Reduction in MRD and induction of immune responses was associated with RFS and OS benefit, confirming the vididencel mechanism of action as an immunotherapy which improves immunity against residual cancer cells. Vididencel treatment was generally well-tolerated and safe, with drug-related adverse events limited to injection-site reactions and no reported drug-related serious adverse events. The positive ADVANCE II data support the continued development of vididencel in AML.