

## Press Release

Stockholm, Sweden, December 12, 2022

### **Mendus presents positive survival data from the ADVANCE II trial evaluating DCP-001 as a maintenance therapy in AML at the American Society of Hematology (ASH) meeting**

**MENDUS TO HOST A WEBCAST TO DISCUSS THE ASH DATA ON TUESDAY, DECEMBER 13, 2022 AT 8.00AM ET/2.00PM CET**

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, presented survival data based on the completed active study period and long-term follow-up to date from the Company's ADVANCE II clinical trial at the 64th American Society of Hematology Annual Meeting (ASH). ADVANCE II is a Phase 2 monotherapy trial evaluating DCP-001 as a maintenance therapy in acute myeloid leukemia (AML) for patients brought into complete remission through chemotherapy, but with measurable residual disease (MRD).

The ADVANCE II trial has completed the 70-week follow-up period after start of DCP-001 treatment, and patients are now in long-term follow up. Median follow-up for the entire study population at the data cut-off for ASH on 22<sup>nd</sup> of November was 19.4 months. Median relapse-free survival (RFS) was not yet reached, with 12 out of 20 patients still in complete remission, ranging from 16 to 47 months after start of treatment. Median overall survival (OS) currently stands at 30.9 months.

The only drug approved for AML maintenance therapy is oral azacitidine, which in MRD positive patients led to a median relapse free survival (RFS) of 7.1 months versus 2.7 months in the placebo arm and an overall survival (OS) of 14.6 months versus 10.4 months in the placebo arm of the registration trial<sup>1</sup>.

"The survival data from the ADVANCE II trial show the potential of DCP-001 to bring a meaningful improvement as compared to current standard of care, particularly for patients with measurable residual disease," said Dr. Arjan van de Loosdrecht, Principal Investigator of the ADVANCE II trial "Considering the limited options currently available for AML maintenance therapy, new treatments are clearly needed, and novel therapies designed to activate the patient's immune system such as DCP-001 could become an important approach."

Increased immune responses against tumor-associated antigens were seen in 17 out of 20 patients following DCP-001 administration, with a significantly higher number of immune responses observed in patients with an MRD response.

As reported earlier, treatment with DCP-001 resulted in an MRD response in 7 out of 20 evaluable patients, with 5 patients converting to MRD negativity and 2 patients with a decline in MRD of at least 10-fold. Patients converting to MRD negativity following DCP-001 treatment continue to have a significantly better overall survival, with all still being alive to date.

Longer-term follow up confirms the excellent safety profile of DCP-001, with no drug-related serious adverse events reported and injection-site reactions as the most common drug-related adverse events.

"These results from the ADVANCE II trial provide clinical proof of concept of DCP-001 as an effective maintenance treatment for patients with AML, reducing residual disease and prolonging disease-free and overall survival," said Jeroen Rovers, MD PhD, CMO of Mendus. "This provides the basis for further studies in AML patients with residual disease, either after initial treatment with high-dose chemotherapy or other regimens, or following hematopoietic stem cell transplantation."

"Residual disease and tumor recurrence is what causes most cancer-related deaths. We could not be more pleased with the data from the ADVANCE II trial studying DCP-001 in a very challenging

<sup>1</sup>(Roboz et al. (April 2022) Blood; volume 139(4):2145)

patient population, with MRD being associated with fast relapse in AML,” said Erik Manting, PhD, Chief Executive Officer of Mendus. “The survival data reported at ASH, combined with the immunomonitoring results and earlier reported MRD data, confirm that DCP-001 could have a large therapeutic potential as a maintenance therapy in AML and possibly in additional indications where residual disease poses a threat to patients.”

Mendus will host a webcast to discuss the data presented at ASH.

#### **Mendus ASH 2022 Clinical Results – Webcast Details**

DATE: Tuesday, December 13, 2022

TIME: 8.00am ET/2.00pm CET

To register and access the live webcast: <https://edge.media-server.com/mmc/p/fbg3u4we>

To register for the audio conference call:

<https://register.vevent.com/register/BI1a086aa18ea8491c8dd34eb1f5d0fe59>

Following the live webcast, a replay will be available under the “Events and Webcasts” section on the Investor page of the Company’s website: <https://mendus.com/investors/events-presentations/>

This information is such information that Mendus AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (No. 596/2014). The information was submitted for publication through the agency of the contact persons set out below on 12 December 2022, at 19:00 CET.

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#### **ABOUT THE ADVANCE II STUDY**

The international, multi center, open-label Phase 2 trial ADVANCE II enrolled AML patients in complete remission (CR) following chemotherapy induction, but who remained MRD positive and were therefore deemed to be at elevated risk of relapse. Patients received four biweekly doses of DCP-001, followed by additional booster administrations at weeks 14 and 18. MRD responses were recorded at 14, 20, and 32 weeks and patients were followed for up to 70 weeks after first administration. The primary endpoint of the study is MRD response, and the secondary endpoints of relapse free survival (RFS) and overall survival (OS). For more information about the Phase 2 ADVANCE-II clinical trial of DCP-001, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov), (Identifier: [NCT03697707](https://clinicaltrials.gov/ct2/show/study/NCT03697707)).

#### **ABOUT DCP-001**

DCP-001 is a cancer relapse vaccine derived from Mendus’ proprietary DCOne leukemic cell line. DCP-001 is being developed as a potential novel AML maintenance therapy, in order to reduce the incidence of relapse and improve disease-free and overall survival. Mendus received Advanced

Therapy Medicinal Product Classification from the EMA for DCP-001 in June 2021 and has orphan drug status for DCP-001 with both the FDA and EMA.

**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/>