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## Press Release

Stockholm, Sweden, May 16, 2022

### Immunicum Announces Positive Interim Results from ADVANCE II Study in AML Maintenance Treatment

- Analysis of primary study endpoint was completed with 7 patients showing a measurable residual disease (MRD) response, of which 5 patients converted from MRD+ to MRD- and 2 patients showed a substantial, at least 10-fold reduction in MRD following treatment with DCP-001
- After a median follow-up period of 14.3 months, median relapse-free survival (RFS) and overall survival (OS) have not yet been reached
- The estimated 6-month RFS based on the currently available data is 83.7% and the estimated 6-month OS is 97.0%
- Immunicum plans to present further updates on survival data including RFS and OS, as well as immunomonitoring data in Q4 2022
- Company to host conference call and webcast today at 14:00 CET (8am ET, 1pm GMT)

Immunicum AB (“Immunicum” publ; IMMU.ST), a biopharmaceutical company focused on therapies addressing tumor recurrence and hard-to-treat established tumors, announced today updated interim results from the ongoing ADVANCE II clinical trial evaluating the company’s lead development program DCP-001, a novel therapeutic option for acute myeloid leukemia (AML) maintenance therapy in patients with measurable residual disease (MRD). The analysis demonstrates the therapeutic potential of DCP-001 to control MRD based on the complete read-out of all 20 evaluable patients. In addition, the interim survival data provides for a first strong indication on how the effects of DCP-001 vaccination observed on MRD translate into relapse-free and overall survival benefits for this patient population. The previously reported clean safety and tolerability profile of DCP-001 was confirmed.

“The clinical data for our lead pipeline project DCP-001 have matured and are shaping up very positively, delivering a successful outcome on MRD conversions and control as the primary study endpoint. With the majority of patients still relapse-free at the moment of this read-out, this update provides for a first clear signal that MRD responses following DCP-001 vaccination translate into relevant survival benefit,” commented Erik Manting, PhD, Chief Executive Officer of Immunicum. “In addition, DCP-001 continues to demonstrate excellent safety in the clinic and the preclinical studies which we presented at medical and scientific conferences confirm its combination potential with standard-of-care AML therapies. This provides the basis for a highly competitive product profile in AML maintenance.”

“With only one sole drug specifically approved for post-remission AML maintenance treatment, AML patients in remission have historically been underserved with respect to solutions prohibiting or at least delaying cancer recurrence. The achievement of MRD conversions after DCP-001 treatment, coupled with a compelling safety profile, is an exciting step forward for Immunicum and the AML patient population with continued unmet need,” commented Jeroen Rovers, PhD, M.D., Chief Medical Officer of Immunicum. “The ADVANCE II data contribute to the growing body of evidence that reducing MRD directly correlates with a relapse-free and overall survival benefit for patients. We are confident that the outcome of the ADVANCE II study will provide a strong rationale for continued evaluation of DCP-001 in a larger clinical trial.”

“MRD as the primary endpoint in Phase II studies is of increasing importance for predicting relapse-free and overall survival. The ADVANCE II study shows that DCP-001 induces sustained MRD conversion in a subset of patients with AML and hence with prolonged RFS and OS as compared to those who did not achieve MRD conversion. These data confirm the power of MRD as primary endpoint as well as the immunotherapeutic potential of DCP-001,” commented Prof. Dr. Arjan Van

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De Loosdrecht, Principal Investigator of the ADVANCE-II study and lead-scientist in MDS/AML at Amsterdam University Medical Center/VUmc.

The international, multi center, open-label Phase II study 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 in the ADVANCE II trial were divided into two cohorts of 10 patients each, administered with two different dose levels of DCP-001, 25 and 50 million cells/vaccination. Patients in each cohort 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. Median follow up of patients at the cut-off date for the interim analysis was 14.3 months. The primary endpoint of the study is MRD response, and the secondary endpoints of relapse free survival (RFS) and overall survival (OS).

At the cut-off date for the interim analysis, 7 patients out of twenty showed a MRD response, with 5 patients converting from MRD+ to MRD-, and 2 patients achieving a substantial, at least 10-fold reduction in MRD throughout the course of the trial. Patients who converted from MRD+ to MRD- over the course of the trial demonstrated an improved survival over those not having fully converted. An additional seven patients remained in complete remission (CR) with stable MRD levels and only six patients encountered relapse. Intradermal injections of DCP-001 were well tolerated, with only limited drug related side effects. No serious adverse events were reported in conjunction with DCP-001.

To date, with a median follow-up on study of 14.3 months, the median RFS and OS have not yet been reached. The estimated 6-month RFS based on the data available to-date is 83.7%, with an estimated 6-month OS of 97.0%.

The trial is continuing follow-up of patients to assess RFS and OS and Immunicum expects to report on the status of these endpoints and immunomonitoring data in Q4 2022.

### **Conference Call and Webcast**

Immunicum will host a conference call and webcast today at 14:00 CET (8am ET, 1pm GMT) to discuss the interim results from the ADVANCE II study. To access the webcast, please use the following link: <https://edge.media-server.com/mmc/p/ik922ghk>. An archived replay of the webcast will be available in the Events and Presentations section of the Immunicum website at [www.immunicum.se](http://www.immunicum.se) for approximately 30 days following the presentation.

### **FOR MORE INFORMATION, PLEASE CONTACT:**

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**ABOUT IMMUNICUM AB (PUBL)**

Immunicum is a biopharmaceutical company focused on therapies addressing tumor recurrence and hard-to-treat established tumors, two key challenges in oncology. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based therapies for blood-borne and solid tumors. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. [www.immunicum.com](http://www.immunicum.com)

**ABOUT DCP-001**

DCP-001 is a cancer relapse vaccine derived from Immunicum's proprietary DCOne® leukemic cell line. With positive tolerability and efficacy data from recent Phase I and Phase II AML trials, DCP-001 is being developed as potential novel AML maintenance therapy, in order to reduce the incidence of relapse and improve disease-free and overall survival. Immunicum 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.