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## Press Release

22 February 2021

### Immunicum Announces Encouraging Signs of Survival Benefit in Phase II MERECA Trial of Ilixadencel in Kidney Cancer

– Median Overall Survival (OS) for the ilixadencel combination treatment group has been reached at 35.6 months, as compared to 25.3 months for the sunitinib control group, indicating a potential survival benefit for patients in the ilixadencel combination group

Immunicum AB (publ) today announced updated survival data from the Company's randomized Phase II MERECA trial evaluating its off-the-shelf immune primer, ilixadencel, in combination with sunitinib in the first-line treatment of newly diagnosed patients with metastatic renal cell carcinoma (mRCC). In the MERECA study, 88 patients were randomly assigned to the ilixadencel combination group, or sunitinib control group, and subsequently followed for survival. As previously reported in August 2020, the co-primary endpoint of median OS was reached at 25.3 months in the sunitinib control group, while the median OS in the ilixadencel treatment group has now been reached at 35.6 months.

"The observed difference of 10 months in median OS for the ilixadencel combination group versus the control group is substantial and clinically meaningful," stated Peter Suenart, M.D., Ph.D., Chief Medical Officer at Immunicum. "Although the randomized, controlled study was not statistically powered for the OS endpoint, the data announced today suggests that ilixadencel has the potential to become a promising treatment option for these patients by improving survival outcomes when combined with standard-of-care cancer therapies."

"These updated results from the Phase II MERECA trial underscore the positive impact on overall survival that ilixadencel may achieve for kidney cancer patients," commented Sven Rohmann, M.D., Ph.D., CEO at Immunicum. "With today's longer follow-up data, the encouraging signal observed has matured and builds our conviction to bring ilixadencel to patients in need. With our ongoing evaluation of ilixadencel, we are working to provide further clinical evidence supporting our conviction."

Updated data as of February 2021 demonstrate a separation in Kaplan-Meier survival curves in favor of the ilixadencel combination treatment, in line with the projected separation from August 2020. The median OS was 35.6 months for the ilixadencel combination group, as compared to 25.3 months in the control group. The proportion of patients alive was 41% (23 out of 56) in the ilixadencel combination treatment group, compared to 30% (9 out of 30) in the control group. All five patients with complete tumor response as best response in the ilixadencel combination treatment group are still alive in this follow-up, as compared to the one with complete response in the control group who had died during the first follow-up period. Moving forward, survival updates for patients in the MERECA study will be announced for each consecutive 12-month follow-up period.

The corporate presentation, which contains the updated survival results and survival curves, is available on Immunicum's website: <https://immunicum.se/>

#### About MERECA

MERECA was an exploratory, international, randomized, controlled and open-label Phase II clinical trial in which a total of 88 newly diagnosed, intermediate and poor risk metastatic renal cancer patients were enrolled. Based on a 2-to-1 randomization, patients received either two intratumoral doses of ilixadencel before nephrectomy (surgical removal of the tumor-affected kidney) and subsequent treatment with sunitinib or sunitinib therapy alone post-nephrectomy. The primary objectives of the study are to evaluate median OS and 18-months survival rates. Secondary

objectives include evaluation of safety and tolerability, tumor response and immunological profiling including T cell infiltration.

#### **About renal cell cancer / carcinoma**

There are approximately 273,000 new cases of Renal Cell Cancer diagnosed worldwide each year, representing approximately two percent of all cancers. The therapeutic effect of targeted therapies has often been of short duration, but therapeutic combinations with novel immunotherapies called checkpoint inhibitors have led to recent approvals due to the increased tumor response and survival duration. There remains a relatively large unsatisfied medical need for new treatments that lead to deeper and more durable responses, and have less unwanted side effects.

#### **About ilixadencel**

Ilixadencel is an off-the-shelf cell-based cancer immunotherapy developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Injection of these cells in the patient's tumor generates an inflammatory response which in turns leads to tumor-specific activation of the patient's cytotoxic T cells. To-date ilixadencel has been tested in a range of clinical trials in various solid tumor indications including metastatic Renal Cell Carcinoma (mRCC), hepatocellular carcinoma (HCC) and gastrointestinal stromal tumors (GIST) and in combination with several standard-of-care cancer therapies such as the tyrosine kinase inhibitors Sutent® (sunitinib) and Stivarga® (regorafenib), and the checkpoint inhibitor Keytruda® (pembrolizumab). Ilixadencel has consistently maintained a positive safety and tolerability profile and demonstrated initial signs of efficacy as seen in the randomized Phase II MERECA trial.

*The information is such information that Immunicum is obliged to make public pursuant to EU Market Abuse Regulation. The information was released for public disclosure through the contact persons detailed below on 22 February 2021 at 8.00 am CET.*

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#### **ABOUT IMMUNICUM AB (PUBL)**

Immunicum is leveraging its unparalleled expertise in dendritic cell biology to develop novel, off-the-shelf, cell-based therapies for solid and blood-borne tumors. With complementary therapeutic approaches in Phase II clinical development that are based on intratumoral priming and cancer relapse vaccination, the company aims to improve survival outcomes and quality of life for a broad population of cancer patients. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. [www.immunicum.com](http://www.immunicum.com)