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## Press Release

18 August 2020

### Immunicum AB (publ) Announces Update on Survival Data from Phase II MERECA Trial of Ilixadencel in Kidney Cancer

– Median Overall Survival (OS) was reached at 25 months in the control group treated with sunitinib, while the final median OS value in the ilixadencel treatment group has not yet been reached, indicating a survival benefit in the study's co-primary endpoint –

– August 2020 data continue to show a separation in survival curves in favor of the ilixadencel group as projected by the Kaplan-Meier curves in the previous survival follow-ups –

Immunicum AB (publ) announced today an update on survival data from the randomized Phase II MERECA trial evaluating its off-the-shelf immune primer, ilixadencel, in combination with Sutent® (sunitinib) first-line treatment regimen in newly diagnosed patients with metastatic renal cell carcinoma (mRCC). During the trial, 88 patients were randomly assigned in a two-to-one ratio to the ilixadencel combination treatment group or sunitinib control group, and subsequently followed for survival. Based on the updated survival data, the final median OS value was reached in the sunitinib control group, while the median OS has not yet been reached in the ilixadencel treatment group. Follow-up on survival data will be collected and updated continuously at 6-month intervals, with the next update expected in Q1 2021.

“As our largest and longest study, the Phase II MERECA trial continues to give us insight into the potential efficacy of ilixadencel in combination with standard-of-care in patients with metastatic tumors. As such, we are encouraged that the data at this stage show that only two injections of ilixadencel continue to have an impact on survival of patients as the median Overall Survival of that group has not yet been reached,” commented Associate Professor Alex Karlsson-Parra, CSO and Interim CEO of Immunicum. “As the data continue to mature, we are able to further analyze which patients most benefit from ilixadencel and design our future studies to maximize our understanding of therapeutic potential for patients.”

Updated data as of August 2020 continue to show a separation in Kaplan-Meier survival curves and indicate a difference in the median OS in favor of the ilixadencel treatment group. The median OS, which is the co-primary endpoint of the study, is defined as the time from randomization at which 50% of patients in each group are still alive. The median OS value was reached in the control group at 25.3 months, while the median OS for the ilixadencel treatment group is not reached yet as the data is not mature. The proportion of patients alive was 43% (24 out of 56) of patients in the ilixadencel treatment group compared with 33% (10 out of 30) of patients in the control group. All five Complete Responders (CRs) in the ilixadencel treatment group are still alive in this follow-up, while, as previously reported, the one CR in the control group died during the first follow-up period.

Earlier this year, ilixadencel received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) based on the previously communicated results from the Phase II MERECA clinical trial. Immunicum will continue these discussions with regulatory authorities and preparations to determine the next set of priorities and objectives for ilixadencel.

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

#### About MERECA

MERECA is 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

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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-month 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 existing treatments, called targeted therapies, is often of short duration, with limited survival gain. With no alternatives to these therapies, there exists a relatively large unsatisfied medical need for new treatments that are effective, more cost-efficient 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. Ilixadencel is currently moving towards late-stage clinical development.

*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 18 August 2020 at 8.00 am CEST.*

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**ABOUT IMMUNICUM AB (PUBL)**

Immunicum is establishing a unique immuno-oncology approach through the development of allogeneic, off-the-shelf cell-based therapies. Our goal is to improve survival outcomes and quality of life by priming the patient's own immune system to fight cancer. The company's lead product ilixadencel, consisting of pro-inflammatory allogeneic dendritic cells, has the potential to become a backbone component of modern cancer combination treatments in a variety of solid tumor indications. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II MERECA study in kidney cancer and the Company is moving towards late-stage clinical development. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. [www.immunicum.com](http://www.immunicum.com)