Press Release

6 February 2020

Immunicum AB (publ) Presents Updated Data from Phase II MERECA Trial of Ilixadencel in Kidney Cancer at ASCO-SITC Clinical Immuno-Oncology Symposium

-- December 2019 data confirm the separation in survival curves in favor of the ilixadencel group that was projected by the Kaplan-Meier curves in the previous update from July 2019, while final median Overall Survival (OS) values were still not reached in either of the two study groups —

-- Survival as of December 2019 was 54% in the ilixadencel treatment group compared with 37% of patients in the control group treated with sunitinib monotherapy —

-- Confirmed Objective Response Rate (ORR) was 42% in the ilixadencel treatment group and 24% in the control group —

Immunicum AB (publ) announced today updated results from the randomized Phase II MERECA trial testing its off-the-shelf immune primer ilixadencel in combination with Sutent® (sunitinib) first-line treatment regimen in newly diagnosed metastatic renal cell carcinoma (mRCC) patients. December 2019 data confirm the separation in survival curves in favor of the ilixadencel group that was projected by the Kaplan-Meier curves in the previous update from July 2019, while final median OS values were still not reached. Extended analysis of available data showed that compared to sunitinib monotherapy, combined treatment with ilixadencel demonstrated a nearly two-fold higher confirmed ORR. The results were presented in an oral podium presentation at the ASCO-SITC Clinical Immuno-Oncology Symposium on February 6th in Orlando, Florida.

The MERECA study evaluated intratumoral ilixadencel administration prior to kidney removal of the primary tumor-affected kidney followed by sunitinib treatment compared with kidney removal, without prior ilixadencel treatment, followed by sunitinib alone as first-line systemic therapy in patients with mRCC. Over a three-year period, 88 patients were randomly assigned in a two-to-one ratio to the ilixadencel combination treatment group or sunitinib control group.

Updated data as of December 2019 demonstrates a separation in Kaplan-Meier survival curves in favor of the ilixadencel treatment group, in line with the projected separation from July 2019. The proportion of patients alive was 54% (30 out of 56) of patients in the ilixadencel treatment group compared with 37% (11 out of 30) of patients in the control group. The median OS value cannot be calculated yet in either group as the data is not mature. Based on data on best overall response and the Duration of Response, Immunicum requested a post-study analysis by the contract research organization of confirmed ORR (a tumor response that is confirmed by a follow-up scan, per RECIST 1.1 criteria). The confirmed ORR for the ilixadencel treatment group was 42.2 % (19/45) versus 24.0% (6/25) for the sunitinib control group.

“The updated data emphasize that both tumor responses and the durability of patient response with ilixadencel treatment as part of a combination regimen were better compared to sunitinib alone. The addition of ilixadencel did not increase either the frequency or the severity of side effects. However, longer follow-up is required before we with certainty can comment on any differences in long-term survival,” stated Associate Professor Magnus Lindskog, clinical oncologist at Uppsala University Hospital, Sweden and principal investigator in the MERECA study who presented the results.

“The fact that ilixadencel, when combined with subsequent suntinib treatment, induces a nearly 2-fold increase in the confirmed Objective Response Rate and more complete responses when compared to sunitinib monotherapy, is of course highly encouraging. Additionally, the favorable early separation of the Kaplan-Meier curves that now has been confirmed and the long-term survival projections are clearly interesting,” commented Associate Professor Alex Karlsson-Parra,

CSO and Interim CEO of Immunicum. "We continue our discussions with regulatory bodies to define the next step in the development of ilixadencel as a treatment for a range of solid tumors."

The updated results including survival curves are available as part of the ASCO-SITC presentation and company presentation on Immunicum's website.

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-prognosis 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-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 6 February 2020 at 7.40 pm CET.

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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