Press Release

29 August 2019

Immunicum AB (publ) Announces Positive Phase II MERECA Topline Results Including Complete Tumor Responses in Metastatic Renal Cell Carcinoma Patients

--Ilixadencel in combination with Sutent® (sunitinib) achieved complete tumor responses in 5 out of 45 evaluable metastatic kidney cancer patients (11%) in contrast to 1 out of 25 in the sunitinib monotherapy control arm (4%)—

--Due to extended patient survival above 60% in both the treatment and control arms at 18 months, median overall survival has not yet been reached—

--Number of complete responses and favorable safety profile firmly validate the continued clinical development of ilixadencel as an immune primer in solid tumors--

Immunicum AB (publ) announced today the topline results from the global, exploratory, Phase II Metastatic Renal Cell Carcinoma (MERECA) clinical trial. The study's objective was to evaluate the therapeutic impact of combining ilixadencel with Sutent® (sunitinib). The most important outcome was achieving 5 complete responses, defined as eradication of the cancerous tumor and no further evidence of disease, without ilixadencel adding toxicity. Due to a high rate of overall survival in both study arms, median overall survival has not yet been reached. The results strongly support the continued clinical development of ilixadencel in kidney cancer as well as other solid tumor indications.

“As a clinical oncologist specialized in treating kidney cancer patients, the prospect of an immune primer that can support the achievement of complete responses in advanced-stage patients with a positive tolerability and safety profile is extremely exciting, especially in an indication in which complete responses are rare,” commented Dr. Magnus Lindskog, Associate Professor at Uppsala University Hospital and MERECA investigator. “If this response rate can be confirmed in a larger pivotal trial, it would represent a major step forward for the treatment of kidney cancer patients.”

“Our main objective for MERECA was to explore the therapeutic benefit of ilixadencel in combination with a standard treatment regimen. The surprising number of complete responses in advanced-stage cancer patients is particularly encouraging and highly supportive of our vision for ilixadencel as a backbone therapy in modern cancer treatment regimens,” said Carlos de Sousa, CEO of Immunicum. “We are eager to conduct the full analysis of the data and use that to refine and accelerate ilixadencel’s clinical development.”

Study Design

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. The primary objectives of the study were to evaluate median overall survival (OS) and 18-month survival rates. 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. Secondary objectives included evaluation of safety and tolerability, tumor response and immunological profiling including T cell infiltration.

Results

Of the 88 patients enrolled, 70 patients were evaluable for overall response as per RECIST v1.1 using a central blinded review (45 patients in the ilixadencel treatment group, 25 patients in the control group). Complete tumor response was seen in 5 out of 45 patients who received ilixadencel (11%) and 1 out of 25 patients in the control group (4%). Median overall survival has not yet been reached in either group. The 18-month survival rates were similar being 63% in the ilixadencel treatment group and 66% in the control group and additional survival data will be collected from these patients. Median Progression Free Survival (PFS) and Time To Progression (TTP) were similar in the two treatment arms. The immunological profiling including T cell infiltration data need further analysis.

The overall safety and tolerability results were similar in the two treatment groups and in line with previous positive safety data for ilixadencel in clinical trials.

Conclusions

Ilixadencel together with sunitinib produced a surprisingly high number of complete responses in this patient population without added toxicity from ilixadencel. The available topline data from the MERECA study provides a solid foundation for further clinical development of ilixadencel as an effective immune primer in solid tumors. Moving forward, the data gathered from this study will be further examined and published in a peer-reviewed journal or presented at a scientific conference.

“Immuno-oncology has changed cancer therapy outcomes by making complete responses more possible and the data seen in the MERECA trial support ilixadencel’s potential for increasing the number of patients who can hope for such an outcome,” added Peter Suenaert, MD, PhD, Chief Medical Officer at Immunicum

The company will hold a webcast to discuss the results and take questions in a live forum on Thursday, August 29th at 10.00 am CEST. To submit questions prior to the start of the webcast, send them to ir@immunicum.com. The presentation will be accessible at the following link: https://www.redeye.se/live/1963

About ilixadencel

Ilixadencel, a cell therapy product, is an off-the-shelf cancer immune primer, developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Intratumoral injection of these cells generates an inflammatory response which in turn leads to tumor-specific activation of the patient's cytotoxic T-cells.

About renal cell cancer / carcinoma

There are approximately 273,000 new cases of Renal Cell Cancer (RCC) 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.

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 29 August 2019 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. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com