Press Release

25 September 2019

Immunicum AB (publ) Announces Complete Topline Data Analysis from Phase II MERECA Trial

--Survival as of July 2019 was 57% (32 out of 56) of patients treated with ilixadencel compared with 43% (13 out of 30) of patients who did not receive ilixadencel; the median Overall Survival final value cannot yet be calculated in either group as the data is not mature enough--

--The Objective Response Rate (ORR), measured in all patients receiving sunitinib was 44% (20 out of 45 patients) in the ilixadencel combination group and 48% (12 out of 25 patients) in the sunitinib monotherapy group, while the number of Complete Responders was 11% (5 out of 45) and 4% (1 out of 25) in the respective groups--

--The median Duration of Response was 7.1 months for the ilixadencel combination group versus 2.9 months in the sunitinib monotherapy group over the 18 months study period—

--The overall safety data was similar in both treatment groups, meaning ilixadencel did not add toxicity, which supports ilixadencel's favorable safety profile--

Immunicum AB (publ) announced today the complete analysis of the topline data from the exploratory Phase II MERECA clinical trial. The study evaluated the therapeutic impact of the Company's lead candidate, ilixadencel, in combination with Sutent® (sunitinib) in metastatic Renal Cell Carcinoma (RCC) patients. The topline data on survival benefit in all patients showed that a higher percentage of ilixadencel patients were alive as per data cut-off in July 2019. Among the responders, meaning the patients with Complete Responses (CR) and Partial Responses (PR), the addition of ilixadencel to sunitinib induced stronger and more durable tumor responses. These results indicate that ilixadencel provided a systemic therapeutic benefit while maintaining a positive safety and tolerability profile. Overall the data supports the continued clinical development of ilixadencel as an immune primer in RCC and other solid tumors. Portions of this data were previously communicated on August 29, 2019.

"The purpose of the MERECA trial was to gain the first set of comparative data on what effect ilixadencel has on patients when combined with a standard treatment. The results indicate that ilixadencel benefits patients by clearing tumors at a higher rate and for a longer time than sunitinib alone," commented Carlos de Sousa, CEO of Immunicum. "The results support the continued clinical development of ilixadencel for the benefit of cancer patients, and we look forward to starting the preparations for the pivotal study in RCC."

Results

A total of 88 patients were enrolled and randomly assigned 2-to-1 (in groups of 3 patients) to receive either ilixadencel before surgical removal of the tumor-affected kidney and subsequent treatment with sunitinib or surgery and sunitinib therapy alone.

The patient disposition is as follows:

Patient Distribution			
	Ilixadencel group	Sunitinib only group	Total
Patients enrolled	58	30	**88**
Patients treated with ilixadencel	56	0	**56**
Patients evaluable for Survival and Safety	56	30	**86**
Patients treated with sunitinib and evaluable for Tumor Response	45	25	**70**

Overall Survival (OS)
As of July 2019, 57% (32 out of 56 patients) in the ilixadencel treatment group were alive compared with 43% (13 out of 30 patients) in the control group. The median Overall Survival final value cannot yet be calculated in either group as the data is not mature enough.

As previously communicated, and based on Kaplan-Meier probabilities, the 18-month OS rate is 63% in the ilixadencel combination group and 66% in the sunitinib monotherapy group.

Follow up on survival data will be collected and updated continuously at 6-month intervals, with the first update expected in January 2020. Based on this ongoing follow-up, Immunicum will communicate the median OS values once the data becomes more mature. Detailed information on Overall Survival will be presented during the webcast.

Tumor Response
The Objective Response Rate (ORR) is the proportion of patients with Complete Responses (CR) or Partial Responses (PR), measured by CT scan within the 18-month follow-up. The ORR was similar in the two groups with 44% (20 out of 45 patients) in the ilixadencel combination group and 48% (12 out of 25 patients) in the sunitinib monotherapy group (See Table 1). However, as previously communicated, the number of Complete Responders was higher in the ilixadencel combination group with 11% (5 out of 45 patients) compared to 4% (1 out of 25 patients) in the sunitinib monotherapy group.

Furthermore, as summarized in Table 2, the ilixadencel combination group showed:
- a longer median Duration of Response (7.1 months versus 2.9 months in the sunitinib monotherapy group) within the 18-months follow-up;
- a higher percentage of responses ongoing at the 18-months follow-up, 60% (12 out of 20 patients) versus 33% (4 out of 12 patients) in the sunitinib monotherapy group;
- a higher percentage of Responders alive at last patient contact, 85% (17 out of 20 patients) versus 58% (7 out of 12 patients) in the sunitinib monotherapy group.

All Complete Responders in the ilixadencel combination group were still alive at last patient contact (5 out of 5 CRs), while the Complete Responder in the sunitinib monotherapy group had died at the latest point of follow-up.

Tumor Infiltration
Tumor tissue from the surgically removed kidney tumors was available from post-ilixadencel treatment patients and non-treatment control patients. The analysis was performed on a tissue section from each tumor placed on a slide and immuno-stained with anti-CD8 antibodies. Tumor infiltration of CD8+ T cells was then assessed on the entire slide by a new methodology including a customized and validated computer algorithm software to quantify the CD8-stained area as a percentage of the total tumor area.

This analysis showed a median stained area of 1.08% in the ilixadencel group as compared to 0.84% in the untreated control group, at time of kidney surgery. The high variability of CD8-stained area in the tumors within the treatment groups, between different samples taken from the same

tumor and also within Complete Responders, indicate that the intratumor infiltration of CD8+ T cells by itself, without considering CD8+ T cell specificity and functionality, does not explain the systemic therapeutic impact of ilixadencel when combined with sunitinib.

Safety and Tolerability
The overall safety and tolerability data was similar in both treatment groups, meaning that the addition of ilixadencel to sunitinib did not add toxicity. This confirms ilixadencel's favorable safety profile from previous studies and supports that ilixadencel is well-suited for combination therapies.

"The results from Immunicum's MERECA study indicate that ilixadencel treatment combined with sunitinib provided a stronger and more durable anti-tumor response, which is exciting and positive. The findings from this study are also in line with other successful and recently published immuno-oncology studies in RCC patients. The achievement of complete and durable responses in patients with advanced-stage cancer and with a positive tolerability and safety profile is what we as practicing physicians strive to achieve for our patients," added Prof. Börje Ljungberg, Professor of Urology at Umeå University and Primary Investigator of the MERECA study.

A presentation by Immunicum's CEO, Carlos de Sousa, will be available on Immunicum's website. The presentation provides a more detailed description of the information in the press release.

Table 1
Objective Response Rates

	Ilixadencel/sunitinib n=45	Sunitinib n=25
ORR (Complete and Partial Response)	20 (44%)	12 (48%)
Complete Response	5 (11%)	1 (4%)

Table 2
Duration of Response

	Ilixadencel/sunitinib n=20	Sunitinib n=12
Duration of Response during the 18 months follow-up	7.1 month	2.9 months
Patients with Ongoing Response at 18 months follow-up	12 (60%)	4 (33%)
Responders alive at last patient contact	17 (85%)	7 (58%)

Appendix A
The graphs included on immunicum.com provide details on the survival status of all patients in each study arm (56 in the ilixadencel Treatment Groups and 30 in the Control Group), as of the last follow-up in July 2019. Patients will continue to be followed on a six-month basis.

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 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 overall survival (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 (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 25 September 2019 at 12.00 pm 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**