29 August 2019

Information on MERECA

Click below to access the full press release:
Immunicum AB (publ) Announces Positive Phase II MERECA Topline Results Including Complete Tumor Responses in Metastatic Renal Cell Carcinoma Patients

> "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."

Link to Company webcast on 29. August 2019 at 10.00 am CEST:
https://www.redeye.se/live/1963

Background on the Clinical Development of MERECA:

Phase I/II Clinical Trial
The Phase I/II of the study was initiated in 2012 and included twelve patients with newly diagnosed metastatic renal cell carcinoma (mRCC). The last patient was treated in August 2013 and in March 2014 the concluding report was presented. No treatment-related serious adverse events had been noted. The immunology data showed clear signs of tumor specific immune activation. The study showed strong infiltration of CD8+ T cells in the treated tumors, but also in distant metastasis, which indicates that the activated immune system is also able to identify and target cancer cells in other parts of the body after injection of ilixadencel.

Follow-Up Data Published in Journal for ImmunoTherapy of Cancer
Immunicum published follow-up data from the Phase I/II study in the Journal for ImmunoTherapy of Cancer in June 2017, which contained data of patients up to December 2016. Updated survival time data, as per January 2018, from the Phase I/II study, showed that three out of eleven evaluable patients were alive. Three out of eleven evaluable patients surpassed the 5-year survival and the median overall survival time for the patient group as a whole was 48 months compared to the expected median survival time of 14 – 16 months based on historical data of newly diagnosed metastatic patients being treated with tyrosine kinase inhibitors, including Sutent® (sunitinib) and Votrient® (pazopanib). For the six patients with a poor prognosis (MSKCC high risk), the median overall survival time was 36 months, compared to the expected 9 months based on historical control.

Phase IIa Clinical Trial
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.

The primary purpose of the MERECA study was to investigate the clinical efficacy of treatment with ilixadencel in combination with sunitinib in newly diagnosed metastatic renal cell cancer patients. This Phase II study is primarily a proof of concept study and it will provide crucial input for planning

of future pivotal/confirmatory (i.e. Phase III) trials. In December 2016, Immunicum received clearance from FDA on its Investigational New Drug (IND) application and expanded the MERECA study into the US in the second quarter of 2017, which led to the first patient enrolled in August 2017. The last patient was recruited to the study in early 2018.

Peer-Reviewed Articles & Conference Presentations on MERECA:

Laurell et al. "Intratumorally injected pro-inflammatory allogeneic dendritic cells as immune enhancers: a first-in-human study in unfavourable risk patients with metastatic renal cell carcinoma.", J Immunother Cancer 2017
https://www.ncbi.nlm.nih.gov/pubmed/28642820

Karlsson-Parra et al. Intratumoral administration of pro-inflammatory allogeneic, off-the-shelf, dendritic cells in combination with anti-PD-1 or anti-CD137 has a synergistic anti-tumor effect. European Society for Medical Oncology (ESMO) Congress 2018
https://immunicum.se/wp-content/uploads/2019/01/ESMO-poster-2018.pdf

Pre-activated allogeneic dendritic cells as immune enhancers in therapeutic cancer vaccination
https://oncologypro.esmo.org/content/download/72511/1288857/file/ESMO-Preceptorhsip-on-Immunotherapy-of-Cancer-Lund-KARLSSON-PARRA.pdf

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Details on MERECA on clinicaltrials.gov
https://www.clinicaltrials.gov/ct2/show/NCT02432846?term=mereca&rank=1

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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