Press Release

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Immunicum Publishes Phase II MERECA Trial Results of Ilixadencel in Kidney Cancer in European Urology Open Sciences

Immunicum AB ("Immunicum" publ; IMMU.ST), a biopharmaceutical company focused on therapies addressing tumor recurrence and hard-to-treat established tumors, has published the results of the Phase II MERECA study evaluating ilixadencel in advanced kidney cancer in European Urology Open Sciences, a peer reviewed, open access journal. The MERECA study showed that the combination of ilixadencel with the tyrosine kinase inhibitor sunitinib was safe and associated with a positive trend for improved tumor response rate and overall survival, compared with sunitinib monotherapy (control group).

"The results of the MERECA study have further increased our understanding of the biology and therapeutic combination potential of ilixadencel with tyrosine kinase inhibitors such as sunitinib," commented Jeroen Rovers, M.D., Ph.D., Chief Medical Officer at Immunicum. "This will support the design of future clinical studies, including the Phase II trial which Immunicum is currently preparing to evaluate ilixadencel in combination with tyrosine kinase inhibitors in gastrointestinal stromal tumors (GIST)."

A total of 86 patients were treated within this study, of which 56 were given ilixadencel intratumorally, followed by surgery to remove the kidney tumor and standard treatment with sunitinib, and 30 patients were only given sunitinib after surgery. The published data show proof-of-concept for ilixadencel in kidney cancer with improved overall response rate (ORR) and overall survival (OS). The 18 months survival rate as primary endpoint of the study showed no significant differences between combination arm and control group. However, the median OS was 35.6 months for the ilixadencel + sunitinib combination arm, as compared to 25.3 months in the control group, showing an improved survival over time. Ilixadencel in combination with sunitinib was associated with a numerically higher confirmed response rate, including complete responses, compared with sunitinib monotherapy. Confirmed ORR was 42.2 % (19 out of 45) in the combination arm, including 3 patients with confirmed complete response (CR). Two additional patients in the combination arm developed a CR at the last follow-up CT scan at 18 months (non-confirmed CR). The ORR in the control group was 24.0% (6 out of 25) with no confirmed CR. One patient in the control arm had a CR observed at the last 18-months CT follow-up. The five patients who achieved a CR in the combination arm were all still alive at the latest survival follow up while the one patient with a non-confirmed CR in the control group had died. The addition of ilixadencel to sunitinib did not increase toxicity and the safety profile was consistent with previous experience with ilixadencel in combination with TKIs across a range of tumor types. The study continues to follow up patients for long-term survival.

The publication "*Ilixadencel, a cell-based immune primer, plus sunitinib versus sunitinib alone in metastatic renal cell carcinoma: A randomized phase 2 study*" is available on the European Urology Open Sciences website. For more, please click here.

ABOUT THE MERECA STUDY

MERECA is an exploratory, international, randomized, controlled and open-label Phase II clinical trial in which newly diagnosed, intermediate and poor risk 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-months survival rates. Secondary objectives include evaluation of safety and tolerability, tumor response and immunological profiling including T cell infiltration.

ABOUT ILIXADENCEL

Ilixadencel is an off-the-shelf cell-based cancer immunotherapy developed for the treatment of solid tumors. 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 demonstrated signs of efficacy and maintained a positive safety and tolerability profile. Immunicum's development plans for ilixadencel focus on evaluating ilixadencel in combination with tyrosine kinase inhibitors in gastrointestinal stromal tumors (GIST).

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is a biopharmaceutical company focused on therapies addressing tumor recurrence and hard-to-treat established tumors, two key challenges in oncology. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based therapies for blood-borne and solid tumors. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com