
Press Release

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Immunicum AB (publ) Announces Publication of Phase I/II Clinical Trial Results of Ilixadencel in Advanced Hepatocellular Carcinoma in *Frontiers in Oncology*

Immunicum AB (publ; IMMU.ST) announced today that the final data analysis from the exploratory clinical study of ilixadencel in patients with advanced hepatocellular carcinoma (HCC) has been published in the journal, *Frontiers in Oncology*. The data confirms previously communicated positive safety and tolerability of ilixadencel when administered both alone and in combination with current first-line standard of care, sorafenib. In addition, the data demonstrate an increased frequency of tumor-specific CD8+ T cells in circulating blood for a majority of evaluable patients, indicating a systemic immune response. The complete results provide further insight on ilixadencel's mode of action, signs of clinical activity and important information that will guide the next stage of clinical development.

As communicated in September 2017, the Phase I/II clinical study in 17 patients with unresectable and/or metastatic HCC and 1 patient with advanced cholangiocarcinoma (bile duct cancer) investigated the safety and tolerability of ilixadencel as a primary endpoint in this setting. The treatment regimen included three separate intratumoral injections of ilixadencel at approximately Day 1, 14 and 42 and patients were followed for at least 6 months after the last injection. Ilixadencel was administered either as a second-line therapy for patients not responding to previous treatment with sorafenib or as a first-line therapy alone or in combination with sorafenib.

The results of the study confirmed the safety of ilixadencel as a single agent or in combination with sorafenib and showed that ilixadencel produces immunological responses in advanced HCC as demonstrated by the induced expansion of tumor-specific CD8+ T cells in peripheral blood in 11 out of 15 evaluable patients. Regarding clinical impact, the data showed positive signals, in particular in the ilixadencel monotherapy group (11 patients), in which one patient's tumor responded to the treatment with a tumor regression (partial response), and 4 patients' tumors stopped progressing (stable disease) during the study. In the group of 6 patients receiving ilixadencel in combination with sorafenib in the first-line setting, the data showed no tumor responses and one patient with stable disease. This outcome in the sorafenib combination group is in line with recent preclinical data included in the publication, indicating that sorafenib's mode of action may not be an attractive combination with ilixadencel, in contrast to sunitinib and checkpoint inhibitors.

"With the broad potential of ilixadencel, it is important for us to gain insight on specific indications and treatment regimens. The clinical and biological information gathered through this trial has been invaluable to our understanding of safety, mechanism of action of ilixadencel and potential clinical activity in HCC, and we are pleased to have the results of the trial peer-reviewed and published in a well-reputed international scientific journal," said Peter Suenart, MD, PhD, Chief Medical Officer at Immunicum. "The safety profile of ilixadencel and the immune priming results corroborate our previously reported data and provide a firm foundation to continue exploring the potential of ilixadencel as part of combination treatment in liver cancer."

"We are most encouraged by the demonstration of a tumor-specific immune response in the majority of patients in the trial, all of whom were suffering from an advanced and severe form of a cancer that has very few treatment options," said Alex Karlsson-Parra, MD, PhD, Chief Scientific Officer of Immunicum. "Our objective is to continue investigating ilixadencel with different combination treatments to validate our approach of positioning ilixadencel as an backbone therapy for solid tumors."

The full publication titled "Phase I Trial with the Cell-Based Immune Primer Ilixadencel, Alone and Combined with Sorafenib, in Advanced Hepatocellular Carcinoma" can be accessed through the

current online version of the *Frontiers in Oncology* journal, specifically in the section “Cancer Immunity and Immunotherapy” and through the following link
<https://www.frontiersin.org/articles/10.3389/fonc.2019.00019/full>.

About hepatocellular carcinoma

Hepatocellular carcinoma (HCC) is one of the most common malignant tumors worldwide and the most common cause of death in people with liver cirrhosis. Progression is very rapid and prognosis is poor due to the inability to completely remove the tumor through surgery in most cases. Malignant transformation of liver cells may occur as a consequence of various origins, such as chronic viral hepatitis, alcohol and metabolic disorders.

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.

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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