
Press Release

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Immunicum Announces Positive Review by Data Safety Monitoring Board for Phase Ib Part of ILIAD Study

– Independent Data Safety and Monitoring Board (DSMB) issues positive opinion on safety for ilixadencel in combination with Keytruda® –

Immunicum AB (publ) today announced that the independent Data Safety and Monitoring Board (DSMB) for the Phase Ib/II ILIAD study completed its assessment of the Phase Ib part of the ILIAD trial, evaluating the Company's off-the-shelf, cell-based immune primer ilixadencel in combination with anti-PD1 checkpoint inhibitor Keytruda® (pembrolizumab), in different cancer indications. The positive opinion by the DSMB was based on the absence of material safety issues during the trial and is the first confirmation of safety for the use of ilixadencel in combination with a checkpoint inhibitor.

“The DSMB's positive recommendation reaffirms our confidence that ilixadencel is a safe compound with a good combination profile,” said **Jeroen Rovers, Chief Medical Officer at Immunicum**. “Following the combination with tyrosine kinase inhibitors in renal cell carcinoma in the MERECA trial, this is the first time we have received the validation of safety and feasibility of ilixadencel in combination with checkpoint inhibitors, specifically the PD-1 inhibitor pembrolizumab. Today's validation underscores the broad opportunities represented by our pipeline of innovative immuno-oncology approaches. We are looking forward to the longer-term results of the Phase Ib part which we expect later this year and will provide further guidance on our clinical development planning before the end of 2021.”

The Phase Ib/II ILIAD combination trial includes patients who are eligible for pembrolizumab therapy in its approved label by the FDA, which includes, among others, the tumor types head- and neck squamous cell carcinoma, melanoma, non-small cell lung cancer and gastric and gastroesophageal junction adenocarcinoma. In the Phase Ib portion, 21 patients were treated with four different dose-schedules of ilixadencel in combination with Keytruda®. No dose-limiting toxicities (DLTs) were observed, up to the highest dose of 20 million cells per injection.

No adverse events were reported which were life-threatening or led to death. Only two severe adverse events (grade 3) related to ilixadencel were reported, which were injection-related reactions. All other reported adverse events related to ilixadencel were mild to moderate.

All patients treated within this study suffered from advanced stages of their disease and were heavily pre-treated with several lines of treatments given, including previous exposure to checkpoint inhibitors in the majority of patients. Additional follow up of patients will assess responses to treatment, to be reported in the fourth quarter of 2021.

ABOUT ILIXADENCEL

Ilixadencel is an off-the-shelf cell-based cancer immunotherapy developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Injection of these cells in the patient's tumor generates an inflammatory response which in turns leads to tumor-specific activation of the patient's cytotoxic T cells. 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). More than 100 patients have been treated with ilixadencel at doses ranging from 3 – 20 million cells per injection. No adverse events leading to death or life-threatening events have been reported thus far and only limited numbers of related adverse events have been reported. Thus, ilixadencel has consistently maintained a positive safety and

tolerability profile and demonstrated initial signs of efficacy as seen in the randomized Phase II MERECA trial.

ABOUT ILIAD

Immunicum has named its multi-indication Phase Ib/II checkpoint inhibitor (CPI) combination trial ILIAD. The name represents ILIxadencel in combination with checkpoint inhibitors in ADvanced cancer patients. The trial will enroll patients with different cancer indications, including head and neck squamous cell carcinoma, non-small cell lung cancer and gastric and gastroesophageal junction adenocarcinoma.

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is leveraging its unparalleled expertise in dendritic cell biology to develop novel, off-the-shelf, cell-based therapies for solid and blood-borne tumors. With complementary therapeutic approaches in Phase II clinical development that are based on intratumoral priming and cancer relapse vaccination, the company aims to improve survival outcomes and quality of life for a broad population of cancer patients. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com