
Press Release

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Immunicum AB (publ) Announces Completion of Patient Recruitment for Phase Ib Portion of ILIAD Combination Clinical Trial

-- Topline results on safety and dosing from Phase Ib portion of trial expected during Q3 2021 --

-- Phase II portion of trial can initiate following selection of dose regimen from Phase Ib trial --

Immunicum AB (publ; IMMU.ST) announced today the completion of patient recruitment for the Phase Ib portion of the ongoing ILIAD (ILixadencel in combination with checkpoint inhibitors in ADvanced cancer patients) trial. The primary objective of the Phase Ib study is to evaluate the safety and tolerability as well as define the dose regimen for Immunicum's lead cell-based candidate, ilixadencel, in combination with the checkpoint inhibitor (CPI), Keytruda® (pembrolizumab), in a total of 21 patients. The follow-up period for the Phase Ib portion of the trial will include imaging of up to 6 months for evaluation of safety, dosing and signs of efficacy. Topline results of the Phase Ib trial are expected during the third quarter of 2021.

"Successfully finishing patient recruitment for the Phase Ib portion of the ILIAD trial stands as an important achievement, particularly during a year in which clinical trials, patient recruitment and standard operations have been impacted by the Covid-19 pandemic," commented Sven Rohmann, MD, Ph.D., CEO of Immunicum. "The completion of this milestone brings us one step closer to the topline data readout expected during Q3 next year, which will give us further insight into the potential of ilixadencel in a range of indications and in combination with checkpoint inhibitors. The Phase Ib/II ILIAD trial remains a critical piece of our clinical development strategy, and we look forward to continuing to provide updates on our newly expanded clinical pipeline."

The Phase Ib/II ILIAD combination trial includes patients who are candidates for pembrolizumab therapy in its approved label by the FDA, which includes, among others, the tumor types head and neck squamous cell carcinoma, non-small cell lung cancer and gastric and gastroesophageal junction adenocarcinoma. In terms of dosing, three patients were planned to receive two intratumoral doses of 3 million cells, six patients two doses of 10 million cells, six patients three doses of 10 million cells and the last six patients will receive one dose of 20 million cells followed by two doses of 10 million cells. Throughout the duration of the trial, the Dose Escalation Committee (DEC) has assessed ilixadencel's safety profile. The last update from the DEC in [October](#) confirmed there had been no dose-limiting toxicities. The Phase II portion of the ILIAD trial can subsequently continue with the selected dose regimen from the Phase Ib.

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). 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. Ilixadencel is currently moving towards late-stage clinical development.

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 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. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II MERECA study in kidney cancer and the Company is moving towards late-stage clinical development. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com