
Press Release

6 October 2020

Immunicum AB (publ) Announces Next Safety and Enrollment Update for Phase Ib/II ILIAD Combination Trial

Immunicum AB (publ; IMMU.ST) announced today that a total of 15 patients have now been enrolled in the ongoing Phase Ib/II ILIAD combination trial. In addition, ilixadencel has maintained a consistent safety profile in the study to-date and the Dose Escalation Committee (DEC) confirmed there were no dose limiting toxicities. The Phase Ib portion of the ILIAD trial will be evaluating the safety and tolerability of Immunicum's lead cell-based candidate, ilixadencel, in combination with the checkpoint inhibitor (CPI) Keytruda® (pembrolizumab) in a total of 21 patients.

In [June 2020](#), the Company announced that the non-staggered phase of the trial had started which enabled the recruitment and enrollment of patients to proceed more rapidly as the safety waiting period between patient enrollment was no longer necessary. Now, the DEC evaluated the safety profile for patients treated to date and recommended to continue treatment and open the last cohort to fully enroll the Phase Ib portion of the study.

“The patient enrollment progress we have achieved since the non-staggered phase opened is a positive development in this study and is ahead of the communicated timeline at the last safety update. Nonetheless, we maintain guidance that we expect the completion of patient enrollment for the Phase Ib portion of the trial in the first half of 2021,” commented Sven Rohmann, CEO of Immunicum. “The ILIAD trial is an important and exciting part of our core clinical development strategy in which we aim to evaluate ilixadencel in multiple solid tumor indications combined with a modern, standard of care treatment.”

The ILIAD 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. The Phase II part of the ILIAD trial will then continue with the selected dose regimen from the Phase Ib. Completion of the Phase Ib trial with longer duration of follow-up of patients for signs of efficacy is expected towards the second half 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 turn 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 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.

FOR MORE INFORMATION, PLEASE CONTACT:

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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