Press Release

15 June 2020

Immunicum AB (publ) Announces Advancement to a Non-Staggered Inclusion Phase in the Phase Ib/II ILIAD Combination Trial

Immunicum AB (publ; IMMU.ST) announced today that the sixth patient has completed the safety period in the ongoing Phase Ib/II ILIAD combination trial with ilixadencel, the Company's cell-based, off-the-shelf immune primer for the treatment of solid tumors. The Dose Escalation Committee (DEC) confirmed there were no dose limiting toxicities, therefore the study can move into the non-staggered inclusion phase.

The Phase Ib portion of the ILIAD trial is evaluating the safety and tolerability of Immunicum's lead candidate, ilixadencel, in combination with the checkpoint inhibitor (CPI) Keytruda® (pembrolizumab) in 21 patients. In the staggered part of the Phase Ib portion, the initial 3 patients received the dose level of 3 million cells of ilixadencel followed by 3 patients that received the dose level of 10 million cells of ilixadencel. The non-staggered phase will now allow the remaining 15 patients to proceed more rapidly as there will no longer be a safety waiting period between patient enrollment. However, due to the COVID-19 pandemic, the Company's ability to further accelerate enrollment with additional clinical centers may be impacted. The next safety update is therefore expected by the end of 2020, full enrollment of the Phase Ib part of the trial in the first half of 2021 and completion of the Phase Ib with longer duration of follow-up of patients for signs of efficacy towards the second half of 2021.

"To date, ilixadencel has demonstrated a favorable safety profile. As such, the confirmation of no dose limiting toxicities from the Dose Escalation Committee is an encouraging and validating step in the advancement of the ILIAD trial. Now, as we move into the next accelerated phase of testing, we will also be able to evaluate the effect of the different frequencies and dosing levels of ilixadencel. We look forward to announcing the next update on the advancement of enrollment and longer follow-up for potential signs of efficacy," commented Alex Karlsson-Parra, CEO of Immunicum.

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 have received two intratumoral doses of 3 million cells, six patients will receive 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.

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 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