
Press Release

Stockholm, Sweden, December 3, 2021

Immunicum Announces Completion of Phase Ib Portion and Early Closure of ILIAD Study

Immunicum AB (“Immunicum”, publ; IMMU.ST), a biopharmaceutical company focused on hard-to-treat established tumors and the prevention of cancer recurrence, announced today the completion of the Phase Ib portion of the ILIAD study evaluating the Company’s off-the-shelf, cell-based immune primer ilixadencel in combination with anti-PD1 checkpoint inhibitor (CPI) pembrolizumab (Keytruda®) in different cancer indications. All subjects in the Phase Ib portion have completed the initial follow-up period for safety and response evaluation, with a positive safety review by the Data Safety Monitoring Board reported last July. Responses to treatment were observed in patients previously treated with CPIs and not in CPI-naïve patients. As the latter was the intended patient population for the Phase II part of the study, the company has made the determination to close the study at this stage and not proceed with the Phase II portion.

The Phase Ib ILIAD combination trial included cancer patients eligible for pembrolizumab therapy based on its approved label by the FDA. A total of twenty-one subjects were enrolled: ten of those with types head- and neck squamous cell carcinoma (HNSCC), six with melanoma, two with gastroesophageal junction adenocarcinoma (GEJAC), one with non-small cell lung cancer (NSCLC), one with uterine carcinoma and one with cervical cancer. All patients treated within this study suffered from advanced stage disease and were heavily pre-treated with several lines of treatment. A total of sixteen patients were enrolled that had prior exposure to pembrolizumab and progressed on this checkpoint inhibitor, and five patients were enrolled without any prior exposure to pembrolizumab.

Among the ten HNSCC patients enrolled, a partial response was observed in two, with those two having been among a subgroup of six patients that tested negative for human papilloma virus (HPV) and had prior pembrolizumab exposure. Additionally, stable disease was observed in four subjects with prior pembrolizumab exposure. Of those stable disease subjects, one had HNSCC, one had melanoma, one had NSCLC and one had GEJAC. Observed responses in the CPI pre-treated patients will be further evaluated on a case-by-case basis. Of the five patients that were enrolled in the Phase Ib portion of the ILIAD study without any prior exposure to pembrolizumab, none had any observable response.

As previously reported, no dose-limiting toxicities were observed in the ILIAD study, up to the highest dose of 20 million cells per injection, and 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.

“The Phase Ib portion of the ILIAD study was purposefully intended to examine safety and tolerability of ilixadencel in a heterogeneous cancer patient population, which we completed successfully,” remarked Jeroen Rovers, CMO of Immunicum. “This phase of study was not designed to evaluate efficacy, particularly given the heterogeneity of the enrolled group overall and the small numbers in each subgroup or cancer indications. As such, the study does not provide enough support for the protocol-defined Phase II portion. The partial response and stable disease data in patients with prior exposure to Keytruda is however both meaningful and informative for further positioning of ilixadencel in combination with CPIs.”

“The ILIAD study has successfully demonstrated ilixadencel’s safety in combination with pembrolizumab as the leading CPI in the PD-1/PD-L1 pathway in a broad range of hard-to-treat tumors,” remarked Erik Manting, CEO of Immunicum. “The current cancer immunotherapy landscape requires novel combination therapies and a differentiated positioning of ilixadencel.

The data from the ILIAD study will further support our decision making around future clinical studies, on which we will provide an update in the first quarter of 2022.”

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 in mRCC, as seen in the randomized Phase II MERECA trial.

The information is such information that Immunicum is obliged to make public pursuant to EU Market Abuse Regulation. The information was released for public disclosure through the contact persons detailed below on December 3rd, 2021, at 8:00 am CET.

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is a biopharmaceutical company focused on hard-to-treat established tumors and the prevention of cancer recurrence, two key challenges in oncology. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based therapies for solid and blood-borne tumors. Based in

Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm.
www.immunicum.com