
Press Release

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Immunicum AB (publ) Announces Advancement to Next Dosage Group Level in Phase Ib/II ILIAD Combination Trial

Immunicum AB (publ) announced today an update from the Phase Ib/II ILIAD clinical trial examining the safety and tolerability of Immunicum's lead candidate, ilixadencel, in combination with the checkpoint inhibitor (CPI) Keytruda® (pembrolizumab). The Company has received confirmation from the Dose Escalation Committee (DEC) that ilixadencel showed a favorable safety profile with no serious adverse events in combination with Keytruda® in three patients dosed with two intratumoral injections of 3 million cells. Based on these data, further evaluation of ilixadencel in combination with Keytruda® is warranted and the trial will continue testing the next dosage level.

"These results confirm the safety of ilixadencel in the first cohort of the ILIAD clinical trial and will enable us to continue the study as planned with the next dose level of 10 million cells. They also add to an existing body of data that support ilixadencel's positive safety profile in various treatment combinations," said Carlos de Sousa, CEO of Immunicum.

Study Design

The ILIAD trial is divided into two parts. The first part, Phase Ib, will assess safety and define the optimal dose and schedule of ilixadencel administration in combination with a standard dose of the CPI, pembrolizumab (Keytruda®), in 21 patients with head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC) and gastric and gastroesophageal junction adenocarcinoma (GA/GEJ). The first 6 patients of the Phase Ib part of the trial are enrolled in a staggered manner, i.e. consecutively after each other after a safety follow-up period between the patients. Moving forward, the remainder of the patient enrollment in the Phase Ib trial will be conducted in a non-staggered manner, unless otherwise specified by the DEC.

The Phase II part will consist of three randomized, controlled studies in these indications conducted at centers in the United States and across Europe. These studies will further determine the safety and efficacy of ilixadencel when administered in combination with CPI therapy. Specifically, in NSCLC ilixadencel will be combined with pembrolizumab (Keytruda®) and in HNSCC and GA/GEJ it will be combined with avelumab (Bavencio®), which will be supplied by Merck KGaA, Darmstadt, Germany, and Pfizer under the existing collaboration agreement.

This trial design was based on input from clinical experts and EU regulatory authorities as well as guidance from the FDA.

About ilixadencel

Ilixadencel, a cell therapy product, is an off-the-shelf cancer immune primer, developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Intratumoral injection of these cells generates an inflammatory response which in turn leads to tumor-specific activation of the patient's cytotoxic T-cells.

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 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. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com