
Press Release

11 February 2019

Immunicum AB (publ) Announces First Patient Treated in Phase Ib/II ILIAD Combination Trial

Immunicum AB (publ; IMMU.ST) announced today that the first patient has been treated in the Phase Ib/II ILIAD clinical trial. The trial will evaluate the safety and efficacy of Immunicum's lead product in development, ilixadencel, in combination with checkpoint inhibitors (CPIs) in three cancer indications: head and neck cancer, non-small cell lung cancer and gastric cancer. The initial Phase Ib portion of the trial will be conducted at clinical centers in the United States.

"The start of the ILIAD clinical trial is a positive and important step in the development of ilixadencel, testing its ability to prime a patient's immune system to fight the cancer. This study will give us the opportunity to further evaluate its potential as a backbone component in combination therapies to treat solid tumors, and we look forward to exploring the synergistic effects of the immune activity of ilixadencel together with CPIs," said Peter Suenaert, Chief Medical Officer at Immunicum.

The ILIAD trial is an open-label multicenter study fully sponsored by Immunicum. The Principal and Coordinating Investigator for the study is Dr. J. Weiss, Associate Professor of Medicine at the School of Medicine at University of North Carolina-Chapel Hill.

"With the first patient starting treatment, we have achieved another key milestone for Immunicum," added Carlos de Sousa, CEO of Immunicum. "We will report after each dosing group is completed and we expect to have the first announcement related to the trial in the second half of 2019."

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 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 Phase II part, which will include up to 150 patients, 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 together 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 a collaboration agreement.

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