
Press Release

23 July 2018

Immunicum AB (publ) Announces Protocol Approval by the FDA Enabling the Initiation of Expanded Multi-indication Phase Ib/II Combination Trial

Immunicum AB (publ; IMMU.ST) announced today that the U.S. Food and Drug Administration (FDA) has approved the clinical trial protocol for its planned Phase Ib/II trial to evaluate the safety and efficacy of intratumorally-administered ilixadencel in combination with checkpoint inhibitors (CPI). The regulatory approval allows the company to start the process of patient enrollment. As previously communicated, Immunicum expects the trial to enroll the first patient in the second half of 2018.

The trial, abbreviated ILIAD, is an Immunicum-sponsored, randomized, open-label, multicenter Phase Ib/II study to evaluate the safety and efficacy of intratumorally-administered ilixadencel in combination with CPIs. It will test the combination in three indications: head and neck cancer, non-small cell lung cancer and gastric and gastroesophageal junction adenocarcinoma. The trial will be divided into two parts: Phase Ib and Phase II. The aim of the Phase Ib part of the study is to assess safety and define the optimal dose and schedule of ilixadencel administration in combination with standard doses of pembrolizumab (Keytruda®) in patients with any of these three types of cancers.

Importantly, the Phase Ib part of the study will now include 21 patients as compared to the 9 in the original draft protocol that was completed in the third quarter 2017. This development in trial design was based on input from clinical experts and EU regulatory authorities as well as guidance from the FDA. The expansion will contribute more data on dose levels and treatment schedules for use in the Phase II and has the potential to capture initial indications of efficacy. There will be an impact on the duration of the Phase Ib, which will also depend on the start and pace of patient enrollment.

The Phase II part of the trial will include up to 150 subjects randomly assigned in a 2:1 fashion to ilixadencel combined with a CPI versus a CPI alone. In this phase, the patients will be grouped by indication into three studies advancing in parallel. The aim of the Phase II study is to demonstrate a favorable impact of ilixadencel used in combination with CPIs. Each indication group will include enough patients to observe a statistically significant difference in clinical activity between the different treatment groups.

“It is a great accomplishment for Immunicum to have achieved the protocol approval and it will allow us to start the trial as planned. The larger number of patients in the Phase Ib will provide significant value as well as increase the potential to observe indications of clinical activity earlier in the trial,” said Carlos de Sousa, CEO of Immunicum. “As previously communicated, the company remains funded to the end of 2019 and we will provide updates on the Phase Ib progress during this year and over the course of 2019.”

“We appreciate the contributions of the clinical experts and investigators to the design of the protocol and value the positive interactions we have had with the regulatory authorities,” added Peter Suenaert, MD, PhD, Chief Medical Officer at Immunicum. “We look forward to start enrolling patients during the second half of 2018.”

About ILIAD

Immunicum has named its planned multi-indication Phase Ib/II CPI combination trial ILIAD. The name represents Ilxadencel in combination with checkpoint inhibitors in Advanced cancer patients. The trial will enroll head and neck cancer, non-small cell lung cancer and gastric and gastroesophageal junction adenocarcinoma patients at clinical centers in the United States and across Europe.

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.

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 23 July 2018 at 8.00 am CET.

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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