
Press Release

3 April 2018

Immunicum AB (publ) Provides Update on Ilixadencel Clinical Development Program

Immunicum AB (publ; IMMU.ST) provided today an update on planned, ongoing and previously completed clinical trials for its lead program, ilixadencel. Ilixadencel is a cell-based treatment with therapeutic potential as a component of combination regimens for a range of solid tumor cancers. It has been tested in more than 90 cancer patients to date.

“We proceed according to plan with our ongoing clinical trials for ilixadencel in kidney and gastrointestinal stromal cancer patients. In addition, over the last several months we have achieved important progress in the development of the study protocol for the multi-indication checkpoint inhibitor combination trial. We look forward to start enrolling patients in that trial this year,” said Carlos de Sousa, CEO of Immunicum. “Ilixadencel has broad potential as a key component of today’s innovative combination therapies to treat many different forms of solid tumor cancers. Our primary goal is to advance ilixadencel in indications with the greatest medical need and strategic potential.”

Trial in preparation

Multi-indication Phase Ib/II Checkpoint Inhibitor Combination Trial

Based on its mode of action and the preclinical proof-of-concept data announced in 2017, Immunicum sees significant potential for ilixadencel as an immune primer in combination with checkpoint inhibitors (CPIs). The Company conducted an in-depth analysis of solid tumor cancers with high unmet medical need and limited sensitivity to CPIs and selected head & neck cancer, gastric adenocarcinoma and non-small cell lung cancer. After meetings with external experts and health authorities, the study protocol is now in its final stages. Immunicum expects to submit the trial documentation first to the US Food and Drug Administration, followed by submission for ethical review, during the second quarter 2018. The Company plans to enroll the first patient during the second half of 2018. The Company will provide updates on the Phase Ib portion of the study. These updates are expected to start during the first half of 2019 and to continue over the course of the year.

“We are very excited about our progress preparing for this important study, which will be conducted primarily at clinics in the US, the most important market for cutting-edge immunology treatments,” added Peter Suenart, Chief Medical Officer of Immunicum.

Ongoing clinical trials

MERECAs Phase II Trial

As previously reported, patient recruitment has been completed and a total of 88 newly diagnosed mRCC patients have been randomized into the trial conducted at 28 centers in eight European countries and the US. The 18-month follow-up period for the last patient treated will be completed in mid-year 2019, which will allow communication of the main findings of the trial in the 3Q 2019. To iterate past communications, the study protocol does not permit interim data analysis. It is critical to the success of the trial and the integrity of the data for regulatory and corporate development purposes that Immunicum maintain the protocol and not invalidate the MERECAs data.

Gastrointestinal Stromal Tumors (GIST) Phase I/II Trial

The Company’s collaborators at the Karolinska University Hospital have enrolled a total of 5 patients in the clinical Phase I/II study with ilixadencel in patients with Gastrointestinal Stromal Tumors (GIST). GIST is a very rare and complex disease with only 200 cases diagnosed in Sweden every year. It remains a severe cancer indication in desperate need of new therapeutics. Immunicum expects to announce the analysis of primary outcome measures of safety and

tolerability, as well as initial secondary outcomes on efficacy, tumor response and progression-free survival in 2019.

Completed clinical trials

Hepatocellular Carcinoma (HCC) Phase I/II Trial

In September 2017, Immunicum announced the most important topline results from the completed Phase I/II safety and tolerability clinical trial of ilixadencel in 18 advanced liver cancer patients. Ilixadencel was shown to be safe and well tolerated in these patients when given both as a single treatment and in combination with the current first line standard treatment, sorafenib. In addition, the results provide evidence of tumor-specific immune activation in the majority of evaluable patients. Based on these positive data, Immunicum will continue to explore the potential of advancing to the next stage of clinical development in this indication based on different strategic and financial opportunities. The Company is preparing a manuscript describing the previously announced data in more detail for submission to a scientific journal for publication.

Renal Cell Carcinoma (mRCC) Phase I/II Trial

The trial initiated in 2012 tested ilixadencel in combination with standard of care in 12 newly diagnosed metastatic renal cell carcinoma (mRCC) patients. The last patient was treated in August 2013. Immunicum has followed the surviving patients over the course of the last 5 years and as of January 18, 2018, which is the final update, three of the 12 patients were still alive. The final median overall survival for the patients is 48 months, which compares favorably with published historical data of 15-16 months overall survival for newly diagnosed mRCC patients treated with sunitinib alone.

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.

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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