Press Release

7 December 2020

Immunicum AB (publ) Receives FDA Fast Track Designation for Ilixadencel in Gastrointestinal Stromal Tumors (GIST)

Immunicum AB (publ; IMMU.ST) announced today that it has received Fast Track Designation (FTD) from the U.S. Food and Drug Administration (FDA) for the Company's lead candidate, ilixadencel, a cell-based, off-the-shelf immune primer, for the treatment of the orphan indication, Gastrointestinal Stromal Tumors (GIST). The FDA's decision is based on results from the Phase I/II clinical trial in GIST, a rare and difficult-to treat cancer indication belonging to the group of cancers referred to as soft tissue sarcomas (STS). Fast Track Designation facilitates frequent communication with the FDA, related guidance on clinical trial design and can result in expedited review timelines to ensure novel therapies are available sooner for patients with serious illnesses.

"Having achieved Proof of Concept and RMAT designation for ilixadencel in Renal Cell Carcinoma, our next objective as a company is to move our lead program through clinical development and toward the market as rapidly as possible. As described in our clinical development strategy, GIST has been identified as one of the opportunities for pursuing commercialization of ilixadencel independently," said Sven Rohmann, MD, Ph.D., CEO of Immunicum. "The Fast Track Designation serves as a strong external validation of ilixadencel and will further accelerate our development timelines. We are eager to continue our preparations for the next clinical trial in this indication."

As defined by the FDA, Fast Track Designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions, thereby meeting an unmet medical need. As a novel therapy with a favorable safety profile and positive signs of therapeutic value in this indication, ilixadencel has already demonstrated potential benefits when combined with standard tyrosine kinase inhibitors (TKIs). As Immunicum advances ilixadencel into the next phase of clinical development in GIST with Fast Track Designation, the Company will be able to engage more frequently with the FDA to optimally align its development plan.

Immunicum announced positive topline results from the Phase I/II open-label, single arm clinical trial evaluating ilixadencel in combination with different TKIs in patients with GIST in June 2019. The latest results of the final data analysis from the clinical study were published in June 2020 in the journal, *Cancer Immunology, Immunotherapy*. The trial met the primary endpoint of safety showing that ilixadencel in combination with TKIs maintained a favorable safety profile with no treatment-related serious adverse events. In addition, analysis of the secondary clinical trial endpoints provided initial signals of clinical benefit in two out of six patients who experienced tumor shrinkage after adding ilixadencel treatment to TKI treatment despite previous tumor progression on the same TKI. The full publication titled, "Phase I Trial Evaluating Safety and Efficacy of Intratumorally Administered Inflammatory Allogeneic Dendritic Cells (ilixadencel) in Advanced Gastrointestinal Stromal Tumors" can be accessed through the current online version of *Cancer Immunology, Immunotherapy* and through the following link: https://bit.ly/37xQkVU

In May 2020, Immunicum received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for ilixadencel to be used for treatment of patients with metastatic Renal Cell Carcinoma.

For more information on Fast Track Designation refer to the following link: https://bit.ly/33tjvJ3

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 7 December 2020 at 8:00 am CET.

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). Ilixadencel has consistently maintained a positive safety and tolerability profile and demonstrated initial signs of efficacy as seen in the randomized Phase II MERECA trial. Ilixadencel is currently moving towards late-stage clinical development.

About Gastrointestinal Stromal Tumors

Gastrointestinal Stromal Tumors (GIST) is a common type of soft tissue sarcoma (STS) and is highly resistant to conventional radio- and chemotherapy. Although imatinib and other tyrosine kinase inhibitors (TKIs) have revolutionized the medical treatment of unresectable and/or metastatic GIST, TKI resistance still represents a major challenge as therapeutic options for advanced GISTs are limited when the disease progresses.

FOR MORE INFORMATION, PLEASE CONTACT:

Sven Rohmann, MD, Ph.D., CEO
Telephone: +46 8 732 8400
E-mail: info@immunicum.com

INVESTOR RELATIONS

Jonas Rodny and Carolin Wiken
Paues Åberg Communications
Telephone: +46 190 90 51
E-mail: ir@immunicum.com

MEDIA RELATIONS

Joanne Tudorica and Sophia Hergenhan, Ph.D.
Trophic Communications
Telephone: +49 171 351 2733
E-mail: ir@immunicum.com

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. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II MERECA study in kidney cancer and the Company is moving towards late-stage clinical development. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com