Press Release

31 December 2020

Immunicum AB (publ) Receives FDA Orphan Drug Designation for Ilixadencel as a Treatment for Hepatocellular Carcinoma (HCC)

Immunicum AB (publ; IMMU.ST) announced today that it has received Orphan Drug Designation (ODD) 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 Hepatocellular Carcinoma (HCC). The designation was based on data from a Phase I/II clinical trial of ilixadencel in patients with unresectable and/or metastatic HCC. The Orphan Drug Act was enacted in the United States to support the development of new drugs and biologics for rare diseases through financial incentives, such as partial tax credit for clinical trial costs, and up to seven years of market exclusivity upon regulatory product approval.

"Our efforts to secure the most advantageous conditions for the further clinical development of ilixadencel based on its broad potential in a range of solid tumor indications continue to be successful," said Sven Rohmann, M.D., Ph.D., CEO of Immunicum. "As we become a fully-integrated biopharmaceutical company and further define our plans for ilixadencel's path toward commercialization, it is valuable to complement this year's Fast Track and RMAT designations with today's FDA Orphan Drug Designation."

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. In December 2020, Immunicum announced that it received Fast Track Designation from the U.S. FDA for ilixadencel as a treatment for Gastrointestinal Stromal Tumors (GIST).

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 31 December 2020 at 2:00 pm 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 Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is a rare indication and yet the most common cause of death in people with liver cirrhosis. Progression is very rapid and prognosis is poor due to the inability to completely remove the tumor through surgery in most cases. Malignant transformation of liver cells may occur as a consequence of various origins, such as chronic viral hepatitis, alcohol and metabolic disorders.

FOR MORE INFORMATION, PLEASE CONTACT:

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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. 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