Press Release

26 January 2021

Immunicum AB (publ) Receives FDA Orphan Drug Designation for Ilixadencel as a Treatment of Soft Tissue Sarcoma (STS)

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 Soft Tissue Sarcoma (STS). The designation recognizes results from the Phase I/II clinical trial in Gastrointestinal Stromal Tumors (GIST), a rare and difficult-to treat cancer indication belonging to the group of cancers referred to as Soft Tissue Sarcoma.

"We continue to build recognition for ilixadencel's potential and are pleased to announce that in addition to designations for ilixadencel in Renal Cell Carcinoma and Hepatocellular Carcinoma, we have now received Orphan Drug Designation by the FDA for the treatment of Soft Tissue Sarcoma, which includes GIST," said Sven Rohmann, M.D., Ph.D., CEO of Immunicum. "GISTs are highly resistant to conventional radio- and chemotherapy and receiving the designation based on the positive data from our Phase I/II clinical trial provides additional momentum for our pipeline as well as encourages us to bring ilixadencel to patients as rapidly as possible."

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 in Gastrointestinal Stromal Tumors (GIST).

The Orphan Drug Designation program provides orphan status to medicines for rare diseases that are intended for the treatment, prevention or diagnosis of a rare disease or condition that affects less than 200,000 people in the U.S. Orphan Drug Designation may allow Immunicum to be eligible for a seven-year period of U.S. Marketing exclusivity upon approval of ilixadencel and a waiver of the Prescription Drug User Fee Act ("PDUFA") filing fees, subject to certain conditions.

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 26 January 2021 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) are a common type of soft tissue sarcoma (STS) and are 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:

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ABOUT IMMUNICUM AB (PUBL)

Immunicum is leveraging its unparalleled expertise in dendritic cell biology to develop novel, off-the-shelf, cell-based therapies for solid and blood-borne tumors. With complementary therapeutic approaches in Phase II clinical development that are based on intratumoral priming and cancer relapse vaccination, the company aims to improve survival outcomes and quality of life for a broad population of cancer patients. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm. www.immunicum.com