Press Release

19 February 2021

Immunicum AB (publ) Receives Orphan Drug Designation from EMA for Ilixadencel as Treatment for Gastrointestinal Stromal Tumors (GIST)

Immunicum AB (publ; IMMU.ST) announced today that the European Medicines Agency Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on the Company's application for orphan designation status for its Phase II clinical candidate, ilixadencel, a cell-based, off-the-shelf immune primer, for the treatment of Gastrointestinal Stromal Tumors (GIST). The COMP opinion was 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).

"The Orphan Drug Designations awarded by both the EMA and the FDA for ilixadencel in the GIST indication represent an important step forward for Immunicum," stated Sven Rohmann, M.D., Ph.D., CEO of Immunicum. "They open up an important regulatory pathway and provide us with the potential to rapidly and independently advance ilixadencel toward commercialization in a small patient population. We look forward to executing on our goal of providing new treatment options to GIST patients."

To qualify for Orphan Designation in the EU, an investigational medicine must be intended to treat a seriously debilitating or life-threatening condition that affects fewer than five in 10,000 people in the EU and there must be sufficient data to suggest the investigational medicine may produce clinically relevant outcomes. Applications for orphan designation are examined by the EMA's COMP, which adopts an opinion that is forwarded to the European Commission. The European Commission's decision follows a few weeks after the COMP opinion is issued. Orphan drug designation provides companies with certain benefits and incentives, including ten years of market exclusivity upon marketing authorization, clinical protocol assistance, access to a centralized marketing authorization procedure and reduced regulatory fees.

In May 2020, Immunicum received Regenerative Medicine Advanced Therapy designation from the FDA for ilixadencel for the treatment of patients with metastatic Renal Cell Carcinoma. In December 2020, Immunicum announced that it received Fast Track Designation from the FDA for ilixadencel in Gastrointestinal Stromal Tumors (GIST) and Orphan Drug Designation by the FDA for ilixadencel in hepatocellular carcinomas. In January of this year, the Company announced FDA Orphan Drug Designation for ilixadencel in STS.

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 19 February 2021 at 08:00 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.

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 GIST are limited when the disease progresses.

FOR MORE INFORMATION, PLEASE CONTACT:

Sven Rohmann, M.D., 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 76 190 90 51
E-mail: ir@immunicum.com

MEDIA RELATIONS

Eva Mulder and Sophia Hergenhan, Ph.D.
Trophic Communications
Telephone: +49 175 222 57 56
E-mail: immu@trophic.eu

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