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## Press Release

Stockholm, Sweden, 09 June 2022

### **Immunicum Received FDA Orphan Drug Designation for Ilixadencel as Treatment of Gastrointestinal Stromal Tumors (GIST)**

Immunicum AB (“Immunicum” publ; IMMU.ST), a biopharmaceutical company focused on tumor recurrence and hard-to-treat established tumors, announced today that it has been granted an Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for ilixadencel in the treatment of Gastrointestinal Stromal Tumors (GIST). This designation confirms the need and potential for ilixadencel as a new treatments for patients with GIST, which is a rare and difficult to treat subgroup of cancers referred to as Soft Tissue Sarcoma (STS).

“We continue to interact with Agencies on development of treatments for hard-to-treat tumors,” commented Jeroen Rovers, M.D., Ph.D., Chief Medical Officer at Immunicum. “This ODD will support further development of ilixadencel, including a Phase II trial which Immunicum is currently preparing with ilixadencel in combination with tyrosine kinase inhibitors in GIST.”

In January 2021, Immunicum received ODD from the FDA for ilixadencel for treatment of STS. In December 2020, Immunicum announced that it received Fast Track Designation from the U.S. FDA for ilixadencel in 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.

#### **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.

#### **ABOUT ILIXADENCEL**

Ilixadencel is an off-the-shelf cell-based cancer immunotherapy developed for the treatment of solid tumors. 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 demonstrated signs of efficacy and maintained a positive safety and tolerability profile. Immunicum’s development plans for ilixadencel focus on evaluating ilixadencel in combination with tyrosine kinase inhibitors in GIST.

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**ABOUT IMMUNICUM AB (PUBL)**

Immunicum is a biopharmaceutical company focused on therapies addressing tumor recurrence and hard-to-treat established tumors, two key challenges in oncology. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based therapies for solid and blood-borne tumors. Based in Sweden and the Netherlands, Immunicum is publicly traded on the Nasdaq Stockholm.  
[www.immunicum.com](http://www.immunicum.com)