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## Press Release

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### **Immunicum AB (publ) Announces ATMP Certificate Granted by EMA to ilixadencel for Manufacturing Quality and Non-clinical Data**

Immunicum AB (publ; IMMU.ST) a biopharmaceutical company advancing a novel, immune-priming cancer treatment against a variety of solid tumors, announced today that its lead product candidate, ilixadencel, has been granted an Advanced Therapy Medicinal Product (ATMP) certificate following a review of manufacturing quality and non-clinical data by the European Medicines Agency (EMA).

"The EMA ATMP certificate is an important development milestone for ilixadencel because it validates our manufacturing quality and preclinical data and gives us a firm foundation for the later stages of clinical development. Cell-based therapies must meet very high requirements and we are pleased to have this recognition from the EMA of our work to date," said Carlos de Sousa, CEO of Immunicum.

"Immunicum is one of very few companies that have successfully used this opportunity to submit documentation during the development phase for review and evaluation by the EMA and CAT," said Margareth Jorvid, Head of Regulatory Affairs and Quality Assurance at Immunicum. "This regulatory process is unique to small companies that develop ATMPs and to receive this certificate confirms that we are on the right path for ilixadencel."

The purpose of the ATMP certification is to provide a structured assessment and guidance to small and medium-sized enterprises (SMEs) developing advanced therapies, which include cell and gene therapies and tissue-engineered products. At the conclusion of the evaluation, a certificate may be issued by the EMA upon the recommendation of the Committee for Advanced Therapies (CAT), confirming the quality of the manufacturing process and preclinical data submitted for ATMP review. Although this certification is not a requirement for a future application for marketing authorization, it affirms that manufacturing quality and non-clinical development has been performed in accordance with regulatory guidelines, taking into consideration the stage of product development.

#### **About ilixadencel**

Ilixadencel, a cell therapy product, is an off-the-shelf cancer immune primer, developed for the treatment of solid tumors. Its active ingredient is activated allogeneic dendritic cells, derived from healthy blood donors. Intratumoral injection of these cells generates an inflammatory response which in turn leads to tumor-specific activation of the patient's cytotoxic T-cells.

#### **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. Founded and based in Sweden, Immunicum is publicly traded on the Nasdaq Stockholm. [www.immunicum.com](http://www.immunicum.com)