

# Almirall initiates first phase I clinical study of ALM223, an interleukin 2 mutant fusion protein for autoimmune diseases

- The phase I study will evaluate the safety, pharmacokinetics, immunogenicity, and pharmacodynamics of ALM223
- ALM223 has the potential to rebalance the immune system in several autoimmune diseases<sup>1,2</sup>

BARCELONA, Spain. 21<sup>st</sup> December, 2023 – Almirall S.A. (BME: ALM), a global pharmaceutical company focused on medical dermatology, today announced the initiation of the phase I study evaluating the safety, pharmacokinetics, immunogenicity, and pharmacodynamics of ALM223, an interleukin 2 mutant fusion protein (IL-2 mu-Fc) for the potential treatment of a broad spectrum of immunological diseases.

ALM223 is a modified version of the protein IL-2 designed to selectively activate **Regulatory T cells** (Tregs). Tregs are important regulators of the immune system activity. Increasing their activity enables them to normalize the function of other immune cells, which could provide a therapeutic option in diseases characterized by an overactive immune system. In preclinical studies, ALM223 selectively activates Tregs without directly interfering on other types of immune cells, such as Effector T cells or Natural Killer (NK) cells. It may therefore have potential to restore immune balance and prevent the immune cells from attacking the body's own cells.

*"We are very pleased about the initiation of the development in humans of this innovative IL-2 mutein, an important molecule that has the potential to treat a broad spectrum of immunological diseases. We look forward to further progress in clinical studies of this biologic that could improve the lives of people with immune-mediated skin diseases",* said **Karl Ziegelbauer, Ph.D., Almirall's Chief Scientific Officer.**

ALM223, previously referred to as SIM0278, had been developed by Simcere by utilizing their protein engineering platform. Almirall and Simcere Pharmaceutical signed an exclusive license agreement for the IL2-mu-Fc in September 2022, granting Almirall rights to develop and commercialize ALM223 for all indications outside of the Greater China region, while Simcere Pharmaceutical retained the rights within Greater China. Simcere also initiated the phase I development for the Chinese market in August 2023.

## About Almirall

Almirall is a global pharmaceutical company focused on medical dermatology. We collaborate with scientists and healthcare professionals to address patients' needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life". We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has focused intensely on patients' needs. Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenue in 2022 was €878.5 MM.

For more information, please visit [almirall.com](https://almirall.com)

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<sup>1</sup> Hernandez R, Pöder J, LaPorte KM, Malek TR. Engineering IL-2 for immunotherapy of autoimmunity and cancer. *Nat Rev Immunol*. 2022 Oct;22(10):614-628. doi: 10.1038/s41577-022-00680-w. Epub 2022 Feb 25. PMID: 35217787.

<sup>2</sup> Raeber ME, Sahin D, Karakus U, Boyman O. A systematic review of interleukin-2-based immunotherapies in clinical trials for cancer and autoimmune diseases. *EBioMedicine*. 2023 Apr;90:104539. doi: 10.1016/j.ebiom.2023.104539. Epub 2023 Mar 31. PMID: 37004361; PMCID: PMC10111960.