Press Release

Simcere and Almirall announce IL-2mu-Fc SIM0278 meets the primary endpoint at Week 16 in Phase II atopic dermatitis study

- **The study, conducted by Simcere, showed that SIM0278, an interleukin 2 mutant fusion protein (IL-2mu-Fc) met the primary endpoint, delivering statistically significant improvements in disease severity at Week 16[1].**
- **One of the two key secondary endpoints was met, while the other showed numerical improvement.**
- **The study is ongoing and will continue through Week 52 with detailed results expected to be presented at a future scientific congress.**
- **Almirall and Simcere's licensing partnership combines Simcere's IL-2mu-Fc programme with Almirall's deep expertise in medical dermatology.**

BARCELONA, Spain. November 26th, 2026 – Simcere Pharmaceutical Group (2096.HK), an innovation and R&D-driven pharmaceutical company, and **Almirall, S.A. (ALM),** a global pharmaceutical company dedicated to medical dermatology, today announced that the Phase II dose-ranging study evaluating IL-2mu-Fc (SIM0278 / LAD603) in adults with moderate-to-severe atopic dermatitis met its primary endpoint at Week 16. One of the two key secondary endpoints was also met, while the other showed numerical improvement.

The study, conducted by Simcere, is a randomized, double-blind, placebo-controlled, multi-center Phase II study that aims to evaluate the efficacy, safety, and pharmacokinetics of three subcutaneous doses of SIM0278 versus placebo in 184 adult patients with moderate-to-severe atopic dermatitis.

The primary endpoint of the study is mean percent change from baseline in the Eczema Area and Severity Index (EASI), with the key secondary endpoints being percentage of patients achieving clear or almost clear skin (Investigator's Global Assessment (IGA 0/1)) and percentage of patients achieving EASI-75 at Week 16.

Two doses of SIM0278 provided statistically significant improvements from baseline in EASI compared to placebo at Week 16. Additionally, statistically significant improvements in IGA 0/1 were observed, while EASI-75 showed numerical improvement. Further, one of the doses resulted in a statistically significantly greater proportion of patients achieving EASI-90 versus placebo at Week 16.

Overall, SIM0278 showed an acceptable safety and tolerability profile during the study with most TEAEs of mild/moderate intensity.

"These Week 16 results are an encouraging step in our focus on finding new treatment options for people living with atopic dermatitis, and a milestone in our collaboration with Simcere. We look forward to evaluating the 52 Weeks data investigating maintenance from this study, while also advancing our ongoing study of IL-2mu-Fc in alopecia areata," said ***Dr Karl Ziegelbauer, Chief Scientific Officer at Almirall.***

"We are pleased to see SIM0278 achieve proof of concept in patients with atopic dermatitis. Through receptor-affinity engineering, the molecule selectively directs IL-2 signaling toward regulatory T cells—a first-in-class approach to immune rebalancing. Together with our partner, we will accelerate its global clinical development to bring this potential treatment option to patients as soon as possible," said ***Dr Aik Goh, Chief Medical Officer of Simcere.***

The study is ongoing and will continue through Week 52, with Almirall and Simcere expected to present detailed results from the study at a future scientific congress.

The two companies entered into a licensing agreement in September 2022 for IL-2mu-Fc SIM0278, developed by Simcere, with Almirall holding exclusive development and commercialisation rights for all indications outside Greater China and Simcere retaining these rights within Greater China.

About SIM0278

SIM0278 is an IL-2 mu-Fc that activates regulatory T cells developed in-house by utilizing Simcere's protein engineering platform. SIM0278 exhibits improved PK profile and selective activation of Treg cells with no activation of effector T cells or NK cells to restore immune balance which has been demonstrated in multiple preclinical disease models.

About Simcere

Simcere Pharmaceutical Group Limited（2096.HK）is a pharmaceutical company driven by innovation and focusing on four therapeutic areas including Neuroscience, Oncology, Autoimmune Diseases and Infectious Disease. We proactively explore areas with significant unmet needs, and our mission is 'For patients, for life'. Driven by our in-house R&D efforts and synergistic innovation, Simcere has established strategic cooperation partnerships with many innovative companies and research institutes. Learn more at www.simcere.com.

About Almirall

Almirall is a global biopharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We advance the scientific understanding of skin diseases to develop innovative and differentiated treatments and solutions that address patients' needs. Our clinical development portfolio includes four ongoing proof-of-concept (PoC)/Phase II studies and two further PoC studies planned across key areas of medical dermatology.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2025: €1114.5 MM, over 2.100 employees globally). Almirall products help to improve the lives of patients every day and are available in over 100 countries.

For more information, please visit almirall.com

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[1] Study Details | NCT07175233 | A Phase 2 Study to Evaluate the Efficacy, Safety of SIM0278 in Subjects With Moderate to Severe Atopic Dermatitis | ClinicalTrials.gov