

Almirall, the first to assess wellbeing in a dermatology clinical study

- The protocol of the **POSITIVE** study, published in the **British Medical Journal (BMJ)**¹, applies the 5-item World Health Organization Wellbeing Index, **WHO-5**, to capture wellbeing in moderate to severe psoriasis patients under tildrakizumab treatment in a real world setting
- Although almost 8 out of 10 people with psoriasis feel that the disease negatively affects their daily activities and wellbeing², a robust prospective study had never measured before the overall wellbeing of these patients
- Adding this approach to the available psoriasis evaluation tools could provide a better understanding and enhance patients' wellbeing, as well as patient-clinician relationships

BARCELONA, Spain. April 12, 2023 – Almirall, S.A. (ALM), a global biopharmaceutical company focused on skin health, today announced the **publication in the British Medical Journal (BMJ)** of the POSITIVE study protocol, the first clinical study in dermatology to assess patients' wellbeing as a primary endpoint. The objective of the study is to capture patients' overall wellbeing in a real-world setting when in treatment with tildrakizumab, an anti-IL-23p19 biologic indicated for moderate-to-severe plaque psoriasis.

Psoriasis affects an estimated 60 million people worldwide³, and the severity of psoriasis is profound, involving both a physical and psychological burden⁴. Almost 77% of patients believe that psoriasis negatively affects their normal daily activities (personal, social, and work life⁵) and wellbeing⁶. In addition, psoriasis can significantly affect the general wellbeing of their families⁷ and physicians' satisfaction⁸.

Despite the need for a holistic, people-centric approach in the wellbeing assessment in addition to evaluating the severity of psoriasis⁹, **overall patient wellbeing and the holistic, person-centred approach to healthcare had never been measured in a robust prospective psoriasis study until now.**

The results of this study could potentially be added to the available psoriasis evaluation methods and **provide dermatologists with new tools to improve their own and their patients' wellbeing enhancing patient-clinician relationships.**

The **POSITIVE study** uses the 5-item World Health Organization Wellbeing Index, WHO-5, a widely used questionnaire that assesses health-related subjective psychological wellbeing in a variety of chronic diseases, but that had never been used in dermatology. Following the holistic approach, The POSITIVE study will also use **innovative secondary endpoints**, such as evaluating the impact on the family environment, with the FamilyPso questionnaire and on Physician wellbeing, using the Physician's Satisfaction Score.

This ongoing non-interventional, prospective, observational, real-world evidence study has enrolled approximately **780 adults with moderate-to-severe psoriasis at multiple sites in Europe**, including Austria, Belgium, France, Germany, Italy, Spain, Switzerland, The Netherlands, and the United Kingdom. The study will follow these patients for 24 months in their treatment with tildrakizumab. The first 28-week data pull will be presented in scientific meetings at the end of 2023.

Prof. Dr. Matthias Augustin, Director, Institute of Health Care Research in Dermatology and Nursing University of Hamburg and principal investigator of the POSITIVE study, mentioned: *"We need to go beyond the clinical endpoints and the current use of the DLQI (Dermatology Life Quality Index) questionnaire, extending our understanding of how the patient is really feeling. We need to switch from just looking at the disease burden and*

setting up positive treatment goals that promote good health and wellbeing. Therefore, our true goal as dermatologists is to reach the maximum wellbeing of our patients. We are really pioneers opening a large terrain of new options in research with the POSITIVE study.”

“It is crucial to consider the serious effects that a chronic disease such as psoriasis has on the physical, psychological, and social wellbeing of people living with psoriasis, their family members and partners. We are pleased that, for the first time, a study will significantly promote patient involvement and awareness, as recommended in the WHO Report on Psoriasis, while simultaneously strengthening patient-clinician relationship”, said **Frida Dunger Johnsson, Executive Director of the IFPA.**

“Our Noble Purpose guides us every day to make a physical and emotional impact on patients' lives. The publication of the POSITIVE study reinforces Almirall's dedication to assessing the impact of skin diseases on wellbeing and demonstrates our commitment to the WHO's claim for people-centred healthcare and patient engagement.” stated **Volker Koscielny, Almirall's Chief Medical Officer** “With the publication of the design of this study, we are taking a step further towards understanding the needs of our patients and will help us to continue working to provide them with real solutions that improve their health and wellbeing and that of their families”.

About tildrakizumab¹⁰

Tildrakizumab is a humanized monoclonal antibody that targets the p19 subunit of interleukin-23 (IL-23) and inhibits the release of proinflammatory cytokines and chemokines with limited impact on the rest of the immune system. It is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's 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' needs.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2022 were 878.5 million euros.

For more information, please visit almirall.com

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¹ Augustin M, Sommer R, Daudén E, et al Patient-reported well-being in value-based care using tildrakizumab in a real-world setting: protocol of a multinational, phase IV, 1-cohort prospective observational study (the POSITIVE study) *BMJ Open* 2023;13:e060536. doi: 10.1136/bmjopen-2021-060536

² Dubertret L, Mrowietz U, Ranki A, et al. European patient perspectives on the impact of psoriasis: the EUROPSO patient membership survey. *Br J Dermatol* 2006;155:729–36. doi:10.1111/j.1365-2133.2006.07405.

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- ³ Parisi R, Iskandar I Y K, Kontopantelis E, Augustin M, Griffiths C E M, Ashcroft D M et al. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study *BMJ* 2020; 369 :m1590 doi:10.1136/bmj.m1590
- ⁴ Bhosle MJ, Kulkarni A, Feldman SR, et al. Quality of life in patients with psoriasis. *Health Qual Life Outcomes* 2006;4:35. doi:10.1186/1477-7525-4-35
- ⁵ Villacorta R, Teeple A, Lee S, et al. A multinational assessment of work-related productivity loss and indirect costs from a survey of patients with psoriasis. *Br J Dermatol* 2020;183:548–58. doi:10.1111/bjd.18798
- ⁶ Dubertret L, Mrowietz U, Ranki A, et al. European patient perspectives on the impact of psoriasis: the EUROPSO patient membership survey. *Br J Dermatol* 2006;155:729–36. doi:10.1111/j.1365-2133.2006.07405.
- ⁷ Eghlileb AM, Davies EEG, Finlay AY. Psoriasis has a major secondary impact on the lives of family members and partners. *Br J Dermatol* 2007;156:1245–50. doi:10.1111/j.1365-2133.2007.07881.
- ⁸ Palota T, Szepietowski JC, Pec J, et al. A survey of disease severity, quality of life, and treatment patterns of biologically naive patients with psoriasis in central and eastern Europe. *Acta Dermatovenerol Croat* 2010;18:151–61.
- ⁹ Naldi L. Scoring and monitoring the severity of psoriasis. What is the preferred method? What is the ideal method? Is PASI passé? facts and controversies. *Clin Dermatol* 2010;28:67–72. doi:10.1016/j.clindermatol.2009.03.001
- ¹⁰ Ilumetrix® (tildrakizumab) Summary of Product Characteristics. Date of prep: October 2021 UK-IL-2100111

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