

At the 25th World Congress of Dermatology

Almirall: Ilumetri[®] (tildrakizumab) significantly improved the wellbeing of patients with moderate-to-severe plaque psoriasis

- Tildrakizumab also significantly improved skin symptoms and quality of life in patients with moderate to severe plaque psoriasis after 28 weeks in a real-world setting and with a safety profile consistent with randomized phase III clinical trials^{1,2}
- Almirall has shown for the first time that the wellbeing of patients with moderate to severe plaque psoriasis at baseline was comparable to the level of wellbeing found in other diseases³ such as breast cancer⁴
- Preliminary results of the POSITIVE study demonstrate the company's commitment to addressing unmet needs in the treatment of patients with psoriasis

BARCELONA, Spain. July 7, 2023 – Almirall, S.A. (ALM), a global biopharmaceutical company focused on medical dermatology, today announced that **Ilumetri[®] (tildrakizumab) significantly improved wellbeing in patients with moderate-to-severe plaque psoriasis** achieving a wellbeing status similar to the general population¹ after 16 weeks, which was maintained up to week 28¹. These first results of the POSITIVE study were presented in a poster at the 25th World Congress of Dermatology, held in Singapore from 3-7 July.

The preliminary analysis also showed that **tildrakizumab significantly improved skin symptoms and patients' health-related quality of life (HRQoL)**, with high rates of treatment satisfaction in patients with moderate-to-severe plaque psoriasis after 28 weeks in a real-world setting⁴, with no new safety signals and a reassuring safety profile consistent with randomized clinical trials (RCT).^{1,2} The results also demonstrated for the first time that **the wellbeing level at baseline of patients with moderate-to-severe plaque psoriasis was comparable to the wellbeing level found in other diseases³ such as breast cancer⁴.**

The POSITIVE study is the first clinical study in dermatology to assess patients' wellbeing as a primary endpoint using the WHO-5. The 5-item World Health Organization Wellbeing Index is a widely used questionnaire that assesses health-related subjective psychological wellbeing in a variety of chronic diseases. In addition to evaluating the severity of psoriasis⁵, there is a need for a **holistic, person-centred approach to the assessment of wellbeing that has never before been measured in a robust prospective study**. The results of this study could potentially be added to the available psoriasis evaluation methods and provide dermatologists with new tools to improve their patients' wellbeing by enhancing patient-clinician relationships.

Psoriasis affects an estimated 60 million people worldwide⁶, and the severity of psoriasis is profound, involving both a physical and psychological burden⁷. Almost 77% of patients believe that psoriasis negatively affects their normal daily activities (personal, social, and work life⁸) and wellbeing⁹. In addition, psoriasis can significantly affect the general wellbeing of their families¹⁰ and physicians' satisfaction¹¹.

"We are thrilled with the promising results of the POSITIVE study, as they underline the importance of incorporating wellbeing into clinical trials. Having a holistic and patient-centered approach allows for more data

on the impact of treatments on people living with psoriatic disease and therefore improves health and quality of life", said **Frida Dunger Johnsson**, IFPA Executive Director.

"At Almirall, we have long strived to improve patient quality of life by taking a holistic approach to skin diseases that captures the full impact of these conditions. The POSITIVE study marks a ground-breaking milestone in dermatology research and its preliminary findings reveal a notable enhancement in the wellbeing of individuals with psoriasis who were treated with tildrakizumab. These initial results reinforce our conviction that we are on the right track in fulfilling our commitment to offer healthcare professionals and patients innovative solutions that effectively address their unmet needs", stated **Volker Koscielny**, Chief Medical Officer at Almirall.

About the POSITIVE Study

The POSITIVE study uses the 5item World Health Organization Wellbeing Index, WHO-5, a widely used questionnaire that assesses health-related subjective psychological wellbeing in a variety of chronic diseases. Following the holistic approach, the POSITIVE study will also use **innovative secondary endpoints**, the FamilyPso questionnaire to evaluate the impact of the disease on the family environment, 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.

About tildrakizumab¹²

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 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 1943 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 €878.5MM.

For more information, please visit almirall.com

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- ¹² Ilumetri[®] (tildrakizumab) Summary of Product Characteristics. Date of prep: October 2021 UK-IL-2100111