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## Almirall's Ilumetri® (tildrakizumab) demonstrates high rates of skin clearance and sustained wellbeing restoration in Adults with Moderate-to-Severe Plaque Psoriasis to general population levels for up to one year<sup>1</sup>

- Almirall presented the interim Week 52 results of the POSITIVE clinical study at the IFPA Conference 2024, showing the benefits of the effective treatment with Ilumetri (tildrakizumab) in patients with moderate to severe psoriasis achieving improvement of physical symptoms and overall wellbeing
- This first-of-its-kind study underscores the psychosocial burden of psoriasis and its deep impact on people's wellbeing. It also demonstrates how treatment with tildrakizumab can improve high-burden symptoms and sensitive areas, benefit patients' lives beyond the disease, like enhance daily activities
- Psoriasis is a highly prevalent skin disease that affects around 60 million people worldwide<sup>2</sup>. Nearly 77% of patients state that psoriasis negatively impacts their normal daily activities (personal, social, and work life)<sup>3</sup> and overall wellbeing<sup>4</sup>

**BARCELONA, Spain. June 28, 2024.** Almirall, a global pharmaceutical company dedicated to medical dermatology, announced today new data from the real-world evidence clinical study called "POSITIVE" demonstrating that **Ilumetri® (tildrakizumab) effectively restores the level of wellbeing of patients** with moderate-to-severe plaque psoriasis to those of the general population as early as Week 16 after initiating the treatment. In the study, this fundamental benefit was shown to be maintained for up to 1 year of treatment. These interim results evaluating the impact of tildrakizumab on patient-reported outcomes and skin clearance in people with moderate-to-severe psoriasis were presented for the first time at the **International Federation of Psoriasis Associations (IFPA) Conference 2024**, held from June 27-29 in Stockholm, Sweden.

The POSITIVE study showed that **treatment with tildrakizumab led to improvements in skin clearance**, particularly in **sensitive areas** (scalp, nail and palms/soles), as well as **in high-burden symptoms** (itch, pain, joint pain and fatigue). These physical symptoms have a significant impact on patients' daily lives and wellbeing. The data from this study show that following 52 weeks of treatment, almost **6 out of 10 patients achieved a PASI\* ≤1 response**, with no new safety signals observed, consistent with previous studies. The POSITIVE study is the first clinical study in dermatology to assess patients' wellbeing as a primary endpoint using the WHO-5 approach. 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. The outcomes of the POSITIVE study highlight – from the patient perspective - the importance of understanding the psychosocial burden of

psoriasis beyond the physical symptoms of the skin perspective, considering how high-burden symptoms affect patients' overall wellbeing.

Psoriasis is a highly prevalent disease, affecting around **60 million people worldwide**<sup>2</sup> and 3% of the population in Europe.<sup>5</sup> Nearly **77% of patients believe that psoriasis negatively affects their normal daily activities (personal, social, and work life)**<sup>3</sup> and wellbeing.<sup>4</sup>

*“The impact of psoriasis on patients’ wellbeing cannot be overstated. It affects their overall health, psychological state, and social life. The interim results from the POSITIVE study are promising, they demonstrate that treatment with tildrakizumab restores patients’ well-being within 16 weeks and maintains it for at least one year. Additionally, significant improvements are observed in skin condition, high-burden symptoms, and sensitive areas. This underscores tildrakizumab’s potential to alleviate the profound burden of psoriasis on daily life,”* stated **Prof. Dr. Ulrich Mrowietz, from the Psoriasis Center at the University Medical Center Schleswig-Holstein, Campus Kiel.**

*“These findings represent a significant milestone in our ongoing efforts to address the needs of patients and dermatologists to treat chronic dermatological conditions and help improve the patients’ health and wellbeing. The POSITIVE study demonstrates not only the efficacy of Ilumetri® in clearing skin but also its impact on enhancing patients’ overall wellbeing, which ultimately can contribute to the successful treatment enabling patients to get their lives back,”* stated **Dr. Volker Koscielny, Chief Medical Officer at Almirall.**

**Almirall and IFPA have been actively collaborating** for years to improve the wellbeing of people with psoriasis and to raise awareness of the impact of this disease on their lives. Last year, [Almirall supported IFPA's "Access for All" campaign](#) on World Psoriasis Day, aiming to ensure that people with psoriasis have affordable access to the right treatment at the right time. In addition, the company highlighted the impact of the disease on the wellbeing of individuals, their families, and friends through the launch of a disease awareness campaign featuring the series called [Nina](#).

\*PASI: Psoriasis Area and Severity Index.

#### About the POSITIVE Study

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. 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 **782 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 Ilumetri (tildrakizumab)<sup>6</sup>

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 psoriasis

Psoriasis is a common, non-contagious, chronic skin disease, with no clear cause or cure. The negative impact of psoriasis on people's lives can be immense as it affects the appearance of the skin with red, scaly plaques. Psoriasis

affects people of all ages, and in all countries. The reported prevalence of psoriasis in Europe varies from 0.6% to 6.5% with an average of approximately 3% of the population,<sup>7</sup> making psoriasis a serious global problem with about 60 million individuals affected worldwide<sup>2</sup>. The flares of psoriasis can be unpredictable and significant comorbidities are common, including arthritis, cardiovascular diseases, metabolic syndrome, inflammatory bowel disease and depression.

## About Almirall

Almirall is a global pharmaceutical 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 are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients' needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2023: €898.8 MM, 1900 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 <https://www.almirall.com/>

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<sup>1</sup> Rachel Sommer, Patient-reported well-being using tildrakizumab in a real-world setting: 52-week interim data of the phase IV POSITIVE study

<sup>2</sup> Parisi R, Iskandar IYK, Kontopantelis E, et al. BMJ. 2020; 369 :m1590 doi:10.1136/bmj.m1590.

<sup>3</sup> Villacorta R, Teeple A, Lee S, et al. Br J Dermatol. 2020;183:548–58. doi:10.1111/bjd.18798.

<sup>4</sup> Dubertret L, Mrowietz U, Ranki A, et al. Br J Dermatol. 2006;155:729–36. doi:10.1111/j.1365-2133.2006.07405.

<sup>5</sup> Chandran V and Raychaudhuri SP. J. Autoimmune. 2010; 34: J314-J21.

<sup>6</sup> Ilumetri® (tildrakizumab) Summary of Product Characteristics. Date of prep: October 2021 UK-IL-2100111.

<sup>7</sup> Chandran V and Raychaudhuri SP. Geoepidemiology and environmental factors of psoriasis and psoriatic arthritis. J. Autoimmune. 2010 May; 34(3):J314-J21. doi: 10.1016/j.jaut.2009.12.001. Epub 2009 Dec 24. PMID: 20034760.