Press Release

EADV Congress 2023

Almirall's Ilumetri® (tildrakizumab) significantly improves wellbeing for patients[1] and their relatives[2] in moderate-to-severe plaque psoriasis

- **Interim data from the POSITIVE study, presented at the EADV, revealed that tildrakizumab not only significantly improved patients' wellbeing after 16 weeks, which was maintained up to week 28[1] but also had a positive impact on the wellbeing of their relatives after 28 weeks[2]**
- **Tildrakizumab also demonstrated improvements in patients' skin symptoms and health-related quality of life after 28 weeks in a real-world setting[3] and showed sustained efficacy and safety over 2 years in patients with moderate-to-severe plaque psoriasis in routine clinical practice including sensitive areas and improvements of itch[4] with no new safety signals and a reassuring safety profile[4,5]**
- **New evidence from the TRIBUTE study showed that tildrakizumab improved other important patient-reported outcomes (PROs) such as sleep quality, which is highly correlated with itch, pain, quality of life and work productivity, and not with PASI[6,7]**
- **Almirall presented 12 posters at the EADV Congress on new data regarding this biologic in patients with moderate-to-severe plaque psoriasis, along with a symposium titled "New Landmark on Psoriasis treatment: the POSITIVE study" chaired by Prof. Dr. Matthias Augustin and Prof. Dr. Ulrich Mrowietz**

BARCELONA, Spain. October 11th, 2023 – Almirall S.A. (BME:ALM), a global biopharmaceutical company focused on medical dermatology, unveiled **new data at the European Association of Dermatology and Venereology Congress 2023** that underscores its commitment to advancing the wellbeing of psoriasis patients and their families through treatments and cutting-edge research. The data presented in posters showed that **Ilumetri® (tildrakizumab) significantly improved the wellbeing of psoriasis patients,[1] as well as the wellbeing of their relatives.[2]**

New evidence presented in the POSITIVE study, the first clinical study in dermatology to assess improvements in patients' wellbeing as a primary endpoint, reveals that around **40% of the patients with moderate-to-severe plaque psoriasis showed depressive symptoms at baseline.[1]** In this regard, tildrakizumab for the first time demonstrated improvement in patients' wellbeing, achieving similar levels to the general population after 16 weeks, which was maintained up to week 28.[1] Additionally**, tildrakizumab reassures its effectiveness, improving also 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 setting,[3] with no new safety signals and a reassuring safety profile[5] consistent with previous randomized clinical trials (RCT) and real-world studies.[8,9] This study **demonstrates for the first time the impact of patient's psoriasis on the social and emotional wellbeing of their relatives, underscoring the existing unmet needs not only in the management of psoriatic patients but also their families. Tildrakizumab significantly improved relatives' wellbeing after 28 weeks.[2]**

During the congress held in Berlin from October 11th to 14th, Almirall presented 12 posters highlighting **new data on tildrakizumab in patients with moderate-to-severe plaque psoriasis. Additionally, the symposium titled "New Landmark on Psoriasis treatment: the POSITIVE study"**, chaired by Prof. Dr. Matthias Augustin and Prof. Dr. Ulrich Mrowietz, will explore the impact of tildrakizumab on physical, social and mental wellbeing in psoriasis.

The new evidences on the TRIBUTE study demonstrated that tildrakizumab **improved other important patient-reported outcomes (PROs)** such as sleep quality, which is highly correlated with itch, pain, quality of life, and work productivity and not with PASI.[6,7] The results also revealed that **tildrakizumab demonstrated similar efficacy and safety regardless of the baseline characteristics of the patients.**[10,11] These **new data highlight the importance of evaluating other endpoints beyond skin symptoms to ensure a holistic approach to psoriasis management.**

Almirall also reported results from the TILOT study that demonstrated **sustained efficacy and safety of tildrakizumab over 2 years** in patients with moderate-to-severe plaque psoriasis in routine clinical practice including **sensitive areas and improvements of itch.** [4] This was reflected in significant improvements **in all measured parameters, including treatment satisfaction and quality of life.**[12]

"*Psoriasis is a challenging disease that affects not only the skin but also the overall wellbeing of patients. Understanding the broader implications of psoriasis is a significant advance in our field and underlines the importance of a holistic approach to its treatment. The POSITIVE study represents an important step forward in our understanding of psoriasis by assessing the effect on the wellbeing of patients, their families and healthcare professionals*", said **Prof. Dr. Ulrich Mrowietz, Founder of the Psoriasis Center at the University Medical Center Schleswig-Holstein.**

"The new data presented at the EADV highlight the unmet needs not only in the treatment of psoriatic patients, but also the impact on their families. These data demonstrate the consolidated effectiveness and safety of tildrakizumab in treating plaque psoriasis and patients' overall wellbeing. At Almirall we aim to improve patients' lives and restore a state of general wellbeing, which often requires impacting dermatological diseases beyond the visible skin symptoms", stated **Dr. Volker Koscielny, Chief Medical Officer at Almirall**.

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 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 the TRIBUTE Study

TRIBUTE (NCT04229836) is an international, multicentre, open-label, interventional phase IV clinical study in patients with moderate-to-severe chronic plaque psoriasis. A total of 177 patients were included in both the safety and efficacy analyses. The objective was to **assess the efficacy, safety, and impact on HRQoL** (using the DLQI and the new proposed score, DLQI-R*) in a phase IV study in close to similar conditions to clinical practice.

About the TILOT Study

TILOT is a prospective, non-interventional, multicenter study from Germany to assess the **effectiveness and safety profile of tildrakizumab in long-term treatment** of moderate-to-severe plaque psoriasis in routine practice.

The observational period of this study will be approximately 3 years, including a large population (around 900 patients), providing the longest and largest Real-World data of the treatment.

About tildrakizumab[13]

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,[14,15] making psoriasis a serious global problem with about 60 million individuals affected worldwide.[16] 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 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 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 €878.5MM.

For more information, please visit www.almirall.com

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[3] Augustin M, et al. Real-world effectiveness, quality of life, and treatment satisfaction with tildrakizumab in patients with moderate-to-severe psoriasis: 28-week interim data of the phase IV POSITIVE study. Presented at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, 11 – 14 October 2023, Berlin, Germany. Abstract 3492.
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[12] Tsianakas A, et al. Tildrakizumab improves signs and symptoms in patients with moderate to severe plaque psoriasis in a real-world setting: a holistic approach. Presented at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, 11 – 14 October 2023, Berlin, Germany. Abstract 3106.
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