## Almirall, S.A.

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## Almirall S.A.: Experts highlight the need to focus on psoriasis patients' wellbeing in clinical practice

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- Psoriasis affects the overall emotional wellbeing of 88% of patients[1], and at least 20% of psoriasis patients have considered suicide[2]
- Currently used endpoints in psoriasis do not capture the full impact of this skin condition on patients' lives, and almost 50% of them feel that their healthcare professionals do not understand the mental health impact of the disease[3]
- In addition to clinical manifestations, experts believe that an overall assessment of the wellbeing of the patient is crucial and that such evaluation should be implemented in clinical practice
- Almirall is initiating the innovative POSITIVE study, which, for the first time, assesses the improvement in the overall wellbeing of psoriasis patients treated with tildrakizumab[4] in a real-world setting

Almirall S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, has hosted a scientific session during the 30th EADV (European Association of Dermatology and Venereology) Congress which addressed the need and importance to focus on patient wellbeing in real-life clinical practice. The symposium was part of Almirall's participation in the congress, which consisted of 21 posters and four scientific sessions.

Psoriasis is one of the most prevalent skin conditions in the world and it affects the overall emotional wellbeing of 88% of patients1, and at least 20% of them have considered suicide2. In this regard, according to the World Psoriasis Happiness Report 2018, only 27% report that their doctor talked to them about mental health. Additionally, almost 50% of psoriasis patients feel that their healthcare professionals don't understand the impact that the disease has on their mental health.3

In the symposium titled "Are you wasting your time getting to PASI100?", Prof. Piaserico (Italy) together with Prof. Mrowietz (Germany) and the happiness scientist Prof. Quoidbach (Spain), addressed questions on psoriasis patients' true needs and wellbeing. The experts pointed out that, in addition to manage the disease's clinical manifestations, the clinical practice should implement an overall and holistic assessment of the wellbeing of each patient. "The endpoints that are currently being used, such as PASI and DLQI, do not capture correctly the full impact of psoriasis on patients' life", stated Prof. Stefano Piaserico, Associate Professor at the University of Padua, Italy and Head of the Regional Centre for Psoriasis.

As a first step to measure the value of a treatment on the overall wellbeing of the patient, Prof. Quoidbach brought up some practical tips that dermatologists could implement in their clinical practice, for instance asking questions like "How do you feel? Do you feel okay? Do you feel happy?". The speakers also outlined that it is crucial to take into account the long-term control of psoriasis given the chronicity of the disease. In this context, **Prof. Ulrich Mrowietz**, Head of the Psoriasis-Center at the University Medical Center Schleswig-Holstein, presented the design of the innovative POSITIVE study, which assesses the improvement in the overall wellbeing of psoriasis patients treated with tildrakizumab3.

The overall wellbeing of a patient and the holistic approach of people-centred healthcare has never been measured in a robust prospective psoriasis study. To assess patient wellbeing, this study will apply the 5-item WHO Well-being Index (WHO-5), a widely used questionnaire assessing the subjective psychological health-related wellbeing in a variety of chronic diseases such as diabetes, cardiovascular disease, cancer, and depression. For the first time, WHO-5 will be tested as a primary endpoint in patients with psoriasis to capture the effect that tildrakizumab can have on patients' wellbeing in a real-world setting. Moreover, the long-term response on physicians' satisfaction and psoriasis patients' partners' lives will also be evaluated.

Tildrakizumab was chosen for this study as a representative of the anti-IL-23 class biologics, that block the key master cytokine in the pathogenesis of plaque psoriasis.

"Providing patients with real solutions that improve their health and wellbeing is at the core of everything we do at Almirall. The symposium has explored outcomes that truly matter to patients and their wellbeing in the context of commonly used regulatory endpoints. With advanced modern therapies now widely available to HCPs, Almirall believes that it is important to also advance our understanding of truly meaningful and ambitious outcomes for our patients," states Volker Koscielny, Chief Medical Officer at Almirall.

## About tildrakizumab[5]

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. Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

[1] Armstrong AW, Schupp C, Wu J, et al. PLoS One. 2012;7(12):e52935; 2. National Psoriasis Foundation 2008 Survey Snapshot. Available from: <a href="http://www.psoriasis.org/document.doc?id=193.">http://www.psoriasis.org/document.doc?id=193.</a>; 3. Krueger G, Koo J, Lebwohl M, et al. Arch Dermatol. 2001;137(3):280-284.

- [2] Krueger G, Koo J, Lebwohi M, et al. Arch Dermatol. 2001;137(3):280-284
- [3] The Health & Happiness Research Foundation (2018) World Psoriasis Happiness Report 2018. Available at: https://psoriasishappiness.report/
- [4] Augustin M, Sommer R, Massana E, et al. on behalf of the POSITIVE investigators. Patient-reported wellbeing in value-based care using tildrakizumab in a real world setting: The POSITIVE Study. Poster number P1493. Presented at 30th EADV Congress; 29 Sept 2 Oct: 2021.
- [5] Ilumetril® (tildrakizumab) Summary of Product Characteristics.

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