Press Release

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Almirall announces a new publication in the British Journal of Dermatology of ILUMETRI®▼ (tildrakizumab) as the first anti-IL23p19 treatment for which 5-year efficacy and safety data are reported from two phase 3 studies

- **The British Journal of Dermatology has published evidence of sustained efficacy in tildrakizumab responders and a favourable long-term safety profile with total tildrakizumab exposure of over 5400 patient-years through 5 years (256 weeks)[1]**
- **The full complete pooled dataset demonstrates long-term psoriasis control with tildrakizumab with a consistent long-term safety profile through 5 years (256 weeks)[1]**
- **This is the first and longest complete pooled dataset published in a medical journal on an anti-IL23p19 inhibitor**

Almirall, S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, announced today that the British Journal of Dermatology (BJD) has published a full 5-year pooled data analysis from two phase III clinical studies, reSURFACE 1 and reSURFACE 2 of Ilumetri® (tildrakizumab), an IL-23p19 inhibitor for the treatment of moderate-to-severe plaque psoriasis, and can be found in the BJD online library. These data provide evidence of sustained efficacy in tildrakizumab responders and in patients switched from etanercept to tildrakizumab at week 28, and a favourable long-term safety profile with total tildrakizumab exposure of over 5400 patient-years. During this period, PASI and PGA response rates were maintained in a large proportion of patients.[1] This is the first and longest complete dataset published in a medical journal on an anti-IL23p19 inhibitor.

Long-term efficacy and safety: up to 5-year results from reSURFACE 1 and reSURFACE 2[1]

Results of the 5-year pooled data from reSURFACE 1 and reSURFACE 2 demonstrated long-term control of psoriasis, with a large proportion of patients who responded at week 28 maintaining efficacy by both relative and absolute PASI. Absolute PASI <3 at week 244 for tildrakizumab 100mg and 200mg were 78.8% and 82.6% respectively. PGA 0/1 at week 244 for tildrakizumab 100mg and 200mg were 68.5% and 74.2%, respectively (multiple imputation for missing data). Results show a favourable long-term safety profile with a total tildrakizumab exposure of over 5400 patient-years. Both 100mg and 200mg doses were generally well tolerated with low rates of serious adverse events and adverse events of special interest through 5 years.

"In our study, patients who responded to tildrakizumab maintained a clinically significant response over 5 years. Control of psoriasis was sustained with a reassuring safety profile. This tildrakizumab study confirms the role that

the IL23p19 class can play in achieving long term control for our psoriasis patients." stated **Prof Diamant Thaçi**, Director of the Comprehensive Centre for Inflammation Medicine at Lübeck University in Germany, the first author of the study.

Safety was further explored in different analyses examining incidence rates of severe infections, malignancies, and major adverse cardiovascular events, as well as overall safety in patients over 65 years of age. No new reported signals were found in any of the sub-groups.

About tildrakizumab[2]

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. Tildrakizumab demonstrated superiority vs placebo and etanercept in the phase 3 reSURFACE programme. Significantly more tildrakizumab patients achieved PASI 75 at Week 12 vs. placebo in both studies [re-SURFACE-1/2: 64%/61% (100 mg), 62%/66% (200 mg) vs 6%/6% (PBO), p<0.0001] and vs. etanercept [reSURFACE-2: 61% (100 mg, p=0.001), 66% (200 mg, p<0.0001) vs 48%]. Significantly more tildrakizumab patients achieved a PGA score of 'clear' or 'minimal', with ≥ 2-grade reduction from baseline at Week 12 in both studies vs. placebo [re-SURFACE-1/2: 58%/55% (100 mg), 59%/59% (200 mg) vs 7%/4% (PBO), p<0.0001], TIL 200 mg (59%, p=0.0031) and TIL 100 mg (55%, p=0.0663) vs. ETA (48%). The incidence of severe infections, malignancies, and major adverse cardiovascular events seen in the clinical trials were low and similar across treatment groups, with the most common AE being nasopharyngitis. Tildrakizumab was administered as 100 or 200 mg injection(s) at week 0 and 4 in the induction phase and then every 12 weeks thereafter for maintenance. DLQI 0/1 at week 12 was achieved by 42% of patients (n=309); by week 28 it was achieved by 52% of the patients (n=299) with patients reporting that psoriasis no longer affected their lives. By week 52, 64% of the responders at week 28 achieved DLQI 0/1 (n=113).

Almirall in-licensed Tildrakizumab from Sun Pharmaceutical Industries Ltd. (Sun Pharma) in July 2016. The agreement is for development and commercialization of tildrakizumab in Europe. So far, tildrakizumab has been launched in Germany, United Kingdom, Switzerland, Austria, Denmark, Spain, Italy and France.

References

1. Thaçi D, Piaserico S, Warren RB, et al. Five-year efficacy and safety of tildrakizumab in patients with moderate to severe psoriasis who respond at week 28: pooled analyses of two randomised phase 3 clinical trials (reSURFACE 1 and reSURFACE 2). Br J Dermatol. 2021 Feb 5. doi: 10.1111/bjd.19866.
2. Ilumetri® (tildrakizumab) Summary of Product Characteristics.

About the British Association of Dermatologists

"The British Association of Dermatologists is the central association of practising UK dermatologists. Our aim is to continually improve the treatment and understanding of skin disease. For further information about the charity, visit www.bad.org.uk Wiley is the international scientific, technical, medical, and scholarly publishing business of John Wiley & Sons, with strengths in every major academic and professional field and partnerships with many of the world's leading societies. For more information, please visit www.wiley.com.

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 groundbreaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publically traded on the Spanish Stock Exchange and is a member of the IBEX 35 (BME: ALM). Throughout its 77-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, through 13 subsidiaries, with about 1,800 employees. Total revenues in 2019 were 908.4 million euros.

For more information, please visit almirall.com

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