Press release

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NEW DATA PRESENTED AT THE EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY (EADV) 29th CONGRESS

First complete dataset in the IL-23p19 class demonstrates ILUMETRI® ▼ (tildrakizumab) long term efficacy and safety through 5 years in Patients with Moderate to Severe Psoriasis

- **Tildrakizumab is the first anti-IL-23p19 to deliver a full complete dataset analysis demonstrating long-term psoriasis control with a consistent long-term safety profile through 5 years (256 weeks)[1]**
- **The data was presented in a late-breaking session at the EADV 29th Congress. In addition, 6 abstracts were accepted, presenting the long-term efficacy and safety of ILUMETRI® in moderate-to-severe plaque psoriasis. PASI and PGA response rates were high and durable in the studies[1]**
- **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.**

Almirall, S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, announced today that the full 5 year data analysis from two phase III clinical studies, reSURFACE 1 and reSURFACE2 of ILUMETRI® (tildrakizumab), an IL-23p19 inhibitor for the treatment of moderate-to-severe plaque psoriasis, has been presented this Saturday in a late-breaking session at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.

The late-breaking session and the 6 abstracts presented pooled long term data from reSURFACE 1 and reSURFACE 2, phase III clinical trials showing that, following up to 5 years of treatment with tildrakizumab, PASI and PGA response rates remain high and durable.[1] This is the longest complete dataset available on an anti-IL23p19 inhibitor, the most innovative class of drugs for the treatment of moderate-to-severe psoriasis.

"We are delighted and very proud that we are able to be the first anti-IL-23 to disclose a complete dataset of 5-year data on tildrakizumab. This new data demonstrate maintained response rates with a consistent safety profile. We are confident this evidence will help doctors in their clinical decision-making, further adding to our understanding of the role that the IL-23p19 class can play in achieving long-term control." said Dr **Volker Koscielny**, Chief Medical Officer of Almirall, S.A.

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

The results of the 5-year pooled data from reSURFACE 1 and reSURFACE 2 demonstrated long-term control of psoriasis, with maintained efficacy by both relative and absolute PASI, in a large cohort of patients with a total of over 5,400 patient-years exposure to ILUMETRI®. Absolute PASI <3 at week 244 for the tildrakizumab 100mg and 200mg doses were 78.8% and 82.6% respectively. Both the 100mg and 200mg doses were 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 maintained 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.

Low rates of malignancies, severe infections and MACE

Safety was further explored in the sub-group analyses examining adverse events of special interests. Low rates of severe infections, malignancies and Major Adverse Cardiovascular Events (MACEs) were reported. No dose dependent increase in events of special interests were observed. There were no new reported signals found in any of the sub-group analysis over 5 years. [2,3,4]

Safety in patients 65 years of age or older[5]

Additionally, long-term data in patients 65 years of age or older was presented. In a pooled analysis after 5 years (256 weeks) of treatment tildrakizumab was well tolerated with low serious adverse events and adverse effects of special interest. No dose related increase in the rate of adverse events were observed.

The 7 abstracts related to the 5 year data are available on the EADV event webpage: https://eadvvirtualcongress.org . Almirall also hosted a Satellite Symposium on the 5-year safety and efficacy of tildrakizumab, and a HUB Session about unmet clinical needs in other dermatology conditions and upcoming treatments.

About tildrakizumab[6]

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 R., Gupta A.K., Long-term efficacy and safety of tildrakizumab for moderate to severe psoriasis: pooled analyses of two randomised phase 3 clinical trials (reSURFACE 1 and reSURFACE 2) through 5 years. Presented at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.
2. Lambert J, Gerdes S, Schoenenberger A, Ryzhkova A. Long-term safety profile of tildrakizumab: Incidence of malignancies over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.

3. Pinter A, Lacour J-P, Schoenenberger A, Ryzhkova A. Long-term safety profile of tildrakizumab: Incidence of severe infections over 5 years of treatment in patients with moderate-to-severe psoriasis pooled analyses from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.
4. Reich K, Ghislain P-D, Schoenenberger A, Ryzhkova A. Long-term safety profile of tildrakizumab: Incidence of confirmed extended major adverse cardiovascular events over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.
5. Van de Kerkhof P, Daudén E, Schoenenberger A, Ryzhkova A. Long-term safety of tildrakizumab in patients over 65 years of age with moderate-to-severe plaque psoriasis: pooled analysis through 5 years (256 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at the 29th EADV (European Association of Dermatology and Venereology) Virtual Congress 2020.
6. ILUMETRI® (tildrakizumab) Summary of Product Characteristics.

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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