Press Release

Spain
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NICE publishes final recommendation for Almirall's ILUMETRI®▼ (Tildrakizumab), as a cost-effective option for adults with moderate-to-severe plaque psoriasis

- **Dermatologists in the UK now have an additional biologic treatment option and suitable patients can be considered for treatment with ILUMETRI® (Tildrakizumab)**
- **Tildrakizumab is a high-affinity humanized monoclonal antibody that inhibits the p19 subunit of IL-23[1], that has demonstrated lasting efficacy and safety through 3 years according to the positive results of a pooled analysis[2] of two phase III clinical trials**
- **Tildrakizumab was approved by the European Commission in September 2018, is already available in Germany and is due to be marketed in all EU Member states**
- **ILUMETRI® received a provisional approval from NICE on March 8th 2019**

Almirall, S.A. (ALM) announced today that the **NICE** (National Institute for Health and Care Excellence, in the UK) **has published its final guidance approving ILUMETRI®** (Tildrakizumab), a humanized, high-affinity IL-23p19 monoclonal antibody, **for treating adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy**.[1] Following a single health technology assessment submission to NICE in August 2018 and the subsequent questions for clarification and appraisal committee meetings, NICE completed their assessment of Tildrakizumab and has recommended **Tildrakizumab as a cost effective treatment option for the NHS for the patients specified in the Final Appraisal Determination (FAD)**.

Tildrakizumab is a high affinity, humanised, IgG1 K antibody targeting interleukin IL 23 p19 that represents an evolving treatment strategy in chronic plaque psoriasis.[3] Tildrakizumab constitutes an important step forward in the treatment of moderate-to-severe chronic plaque psoriasis.[3]

Tildrakizumab is administered by subcutaneous injection. Its convenient dosing regimen, every 3 months during maintenance, could offer convenience and quality of life for patients, potentially achieving an improved treatment satisfaction.[4] The low frequency of injections, only 4 doses per year during maintenance, may also encourage adherence.[1]

Almirall in-licensed Tildrakizumab from Sun Pharma Global FZE (Sun Pharma) in May 2016. The agreement is for commercialization of ILUMETRI® (Tildrakizumab) in Europe. It was approved by the

European Commission in September 2018, is already available in Germany and is due to be marketed in all EU Member states.

Approval based on reSURFACE 1 and reSURFACE 2 phase III trials positive results

Its approval in Europe is based on reSURFACE 1 and 2[3] positive results, with the dose of 100mg. Both pivotal phase III clinical trials, which included over 1,800 patients from more than 200 clinical sites worldwide, showed that Tildrakizumab offers clinically meaningful benefits over time, which is promising news for patients and physicians.[3]

According to both studies' data, an average of 62% of patients achieved 75% of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) by week 12 and an average of 77% at week 28 after only three doses. Moreover, an average of 54% of patients treated with Tildrakizumab 100mg achieved PASI 90 and an average of 23% reached PASI 100 at week 28; while an average of 58% of patients treated with Tildrakizumab 200mg achieved PASI 90 and an average of 29% reached PASI 200 at week 28.[5]

The results of a pooled analysis through 3 years[2] from reSURFACE 1 and reSURFACE 2 phase III trials[3] show the consistent maintenance of efficacy and safety over 3 years of Tildrakizumab in patients with moderate-to-severe plaque psoriasis who were responders at week 28. According to the data, PASI 75 responses were maintained with continued treatment with Tildrakizumab in 9 out of 10 patients up to week 148.[3,4] More than 50% of patients reported that psoriasis no longer affected their lives after only 3 doses.[1,3,4] Tildrakizumab was well-tolerated with very low drug-related serious adverse events and discontinuation rates.[1,2]

About Psoriasis

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.8 million adults in Europe and approximately 125 million people worldwide.[6] It is a non-contagious disorder that accelerates the growth cycle of skin cells and results in thick scaly areas of skin. The most common form of psoriasis, called plaque psoriasis, appears as red, raised areas of skin covered with flaky white scales, which may be itchy and painful and can crack and bleed. Despite different treatment options existing, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients and future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals by continuous improvement, bringing our innovative solutions where they are needed.

The company, founded more than 75 years ago with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has been key in value creation to society according to its commitment to major shareholders and through its decision to help others, to understand their challenges and to use Science to provide solutions for real life. Total revenues in 2018 were 811 million euros. More than 1,800 employees are devoted to Science.
For more information, please visit almirall.com

References

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6. Greb JE, Goldminz AM, Elder JT, et al. Psoriasis. Nat Rev Dis Primers. 2016;2:16082.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall at: https://www.almirall.com/en/patients/report-a-side-effect#344414

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