Press Release

Spain
August 12th 2019

Scottish Medicines Consortium (SMC) provisionally approves Almirall's Ilumetri®▼ (tildrakizumab), as a cost effective option for adults with moderate-to-severe plaque psoriasis

- **Final SMC approval is expected in October 2019**
- **From this date, dermatologists in Scotland will have an additional biologic treatment option and suitable patients can be considered for treatment**
- **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**

Almirall, S.A. (ALM) announced today that the **SMC** (Scottish Medicines Consortium) **has provisionally recommended approval of Ilumetri®** (tildrakizumab), a humanized, high-affinity IL-23p19 monoclonal antibody, **for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy**.[1]

Jacob Anker Rasmussen, Almirall's General Manager UK, IE and Northern Europe, has stated that "*patients in Scotland and physicians will be able to benefit from tildrakizumab. Dermatologists will have an additional biologic treatment option for patients suffering from moderate-to-severe plaque psoriasis".*

Tildrakizumab is a high affinity, humanised, IgG1 K antibody targeting interleukin IL 23 p19 that represents an evolving treatment strategy in chronic plaque psoriasis.[2,3] Tildrakizumab constitutes an important step forward in the treatment of moderate-to-severe chronic plaque psoriasis.

Tildrakizumab is administered by subcutaneous injection. Its dosing regimen (every 3 months during maintenance), could offer a positive improvement in patients' treatment satisfaction.

Almirall in-licensed tildrakizumab from Sun Pharmaceutical Industries Ltd. (Sun Pharma) in July 2016. The agreement is for the development and commercialization in Europe. Tildrakizumab was approved by the European Commission in September 2018, is already available in several member states and is due to be marketed in all EU.

Tildrakizumab: Positive phase III trial results

Tildrakizumab approval in Europe is based on two three-part, parallel-group, double blinded, randomized, placebo-controlled phase III trials (reSURFACE 1 and 2) in which two dose regimen where used (100mg and 200 mg). 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, vs placebo and etanercept, which is promising news for patients and clinicians.[2]

In a pooled efficacy and safety analysis (148-week data)[2] in patients from the two phase III trials (reSURFACE 1 and 2), tildrakizumab was generally well tolerated and efficacy results indicate that most patients who initially respond to tildrakizumab (achieving PASI 75 at week 28) and continue treatment with tildrakizumab maintain this efficacy over time. PASI 75 responses were well maintained with continued tildrakizumab 100 mg or 200 mg in 8 out of every 10 patients through 148 weeks of treatment (non-responder imputation, NRI). PASI 90 and PASI 100 (secondary endpoint) responses were also stable throughout the analysis period, and approximately 60% of patients had PASI 90 responses at week 148.

Safety information

In the 148-week period[2] (base study plus 2-year extension period; total exposure to tildrakizumab 100 mg and 200 mg of 4061.2 PYs), Exposure-Adjusted Incidence Rates (EAIRs) for treatment-emergent AEs for tildrakizumab 100 mg, tildrakizumab 200 mg, placebo and etanercept were 35.2, 37.2, 148.6 and 148.6 events per 100 PY respectively. The most common treatment emergent AE in all treatment group was nasopharyngitis. Other frequent AEs, (occurring at a frequency ≥5% in one or more treatment groups) were infections such as upper respiratory tract infection, influenza, bronchitis and sinusitis. Candida infections were infrequent. Few patients discontinued due to AEs, and the rates of drug-related serious AEs per 100 PYs of exposure to either tildrakizumab 100 mg or 200 mg were 0.79 and 0.54 events per 100 PYs, respectively. Incidences of severe infections, malignancies, confirmed extended MACEs and hypersensitivity reactions were low and comparable across treatment groups, although rates of severe infections tended to be higher for etanercept 50 mg.

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.[4] 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 almost 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 with 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 Global website almirall.com

References

1. Ilumetri® Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9819 Accessed: July 2019
2. Reich et al., Long term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomized phase III clinical trials (reSURFACE 1 and reSURFACE 2) through 148 weeks Brit J of Dermatology 2019
3. Reich K, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): Results from two randomized controlled, phase 3 trials. Lancet 2017; 390: 276-88
4. 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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