Press Release

Barcelona, Spain

October 13th, 2020

Almirall announces approval of the reimbursed price for Ilumetri® (tildrakizumab) in France for the treatment of adult patients with severe chronic plaque psoriasis

- **French authorities have officially published the agreement on 10th October. ILUMETRI® will be available in the following weeks to all eligible French patients with severe psoriasis who are candidates for biological systemic therapy**
- **Tildrakizumab is a high-affinity humanised monoclonal antibody that inhibits the p19 subunit of IL-23. It was approved for patients with moderate to severe chronic plaque psoriasis by the European Commission in September 2018**
- **Tildrakizumab provides high sustained efficacy overtime[1] and has the longest efficacy data among the IL23p19´s[2,3]**
- **The commercialization of Ilumetri® in France represents a key milestone of Almirall's strategy to strengthen its leadership in medical dermatology**

Almirall, S.A. (ALM) announced today that it **has signed an agreement with the French Authorities to make the biologic treatment ILUMETRI® (tildrakizumab**), a high-affinity IL-23p19 monoclonal antibody, available in France **for the treatment of adult patients with severe plaque psoriasis who are candidates for biological systemic therapy** .[1,4]

The agreement has been signed after the Commission of Transparency of the Haute Autorité de Santé (HAS), the French National Health Authority, **provided a favourable opinion for the reimbursement in France of ILUMETRI® (tildrakizumab) on June 3rd** and considered the actual benefit (Service Médical Rendu or SMR) as "important". The prevalence of chronic plaque psoriasis among the French population is around 5,6%[5].

Following the publication of the agreement in the French Official Journal, Ilumetri® (tildrakizumab) will be included in the list of reimbursable medicines by the social insurance for the treatment of adults with severe chronic plaque psoriasis. Its use is reserved, like the rest of systemic biological treatments approved in France, for those patients who have failed (defined by insufficient response, contraindication or intolerance) at least two treatments among non-biological systemic treatments and phototherapy, as well as having a significant impact in the skin and/or a significant psychosocial impact.

"Today's announcement represents great news for those patients with severe psoriasis across France who can count on a safe and convenient biological treatment for their condition. Ilumetri® provides sustained high efficacy and safety, and improves patients' quality of life" said **Alfredo Barón, Chief Commercial Officer of Almirall**. *"We*

are glad we could collaborate with French authorities to find an agreement to provide sustainable access to an additional biologic treatment option for patients suffering from this skin disease through a national reimbursement agreement," he added.

The commercialization of Ilumetri® in France represents a key milestone of Almirall's strategy to strengthen its leadership in medical dermatology through strong investments in R&D to bring ground-breaking solutions to patients suffering from dermatological conditions.

Ilumetri® (tildrakizumab) is the first biologic marketed by Almirall and constitutes an important step forward in the treatment of moderate-to-severe chronic plaque psoriasis. Since its approval by the European Commission in November of 2018, the product has been, offering a decisive benefit to patients as it has the longest efficacy and safety data among the IL23p19´s[6,3] Ilumetri is reimbursed in 10 countries around Europe, including recent agreements in Belgium and Italy.

Tildrakizumab is administered by subcutaneous injection. Its convenient dosing regimen, with lower frequency of injections,only 4 injections per year during maintenance[7], offers convenience and quality of life for patients, potentially achieving an improved treatment satisfaction and improving adherence to treatment. The favourable opinion of the Commission was based on the analysis of clinical trials reSURFACE 1 and 2[5].

About reSURFACE 1/2[8]

ReSURFACE 1 and reSURFACE 2 included over 1,800 patients from more than 200 clinical sites worldwide. According to the results of 148-week pooled analysis[1] from reSURFACE 1 and reSURFACE 2 phase III trials have shown sustained efficacy and safety over three years of tildrakizumab use in patients with moderate-to-severe chronic plaque psoriasis who were responders (≥75% improvement in PASI) or partial responders (≥50 to 75% improvement in PASI) to tildrakizumab 100 mg at week 28.

For responders to tildrakizumab 100 mg, proportions of patients (OC) achieving PASIs of <5, <3 and <1 at week 28 were 96.3%, 85.4% and 50.9%, respectively; at week 52 were 89.9%, 82.0% and 56.5%, respectively; and finally, at week 148 were 91.6%, 79.8% and 51.9%. For partial responders to tildrakizumab 100 mg, proportions of patients (OC) achieving PASIs of <5, <3 and <1 at week 52 were 58.3%, 41.7% and 19.4%, respectively; and at week 148 were 72.7%, 45.5% and 27.3%, respectively. These data confirm the robustness of the tildrakizumab data among the IL23p19 class.

The safety profile of tildrakizumab was favourable over the three years evaluated, with low rates of severe infections, malignancies, and extended MACEs (major adverse cardiovascular events) for tildrakizumab 100 and 200 mg treatment over a 148-weeks period. Exposure-adjusted incidence rates of severe infections, malignancies, NMSC (non-melanoma skin cancer), melanoma skin cancer, and extended MACEs with tildrakizumab were low and comparable to placebo, indicating in this study no increased risk of these events with tildrakizumab treatment.[6]

About tildrakizumab[¡Error! Marcador no definido.]

Tildrakizumab is a humanized monoclonal antibody that targets the p19 subunit of interleukin-23 (IL-23), the key regulatory cytokine in psoriasis, 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, in phase 3 studies tildrakizumab has shown to provide long-term efficacy, safety, and convenient dosing regimen.

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, Italy, Belgium, Netherlands and Spain.

About Psoriasis

Psoriasis is a chronic immune disease. It affects an estimated 7.8 million adults in Europe and approximately 125 million people worldwide.[6] It is a non-contagious condition 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 the different treatment options available, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

A French epidemiological study carried out in 2002 on a representative sample of the French population has estimated the prevalence of chronic psoriasis at 5.6% of the general French population[5]. The most common form of this condition is chronic plaques psoriasis, which accounts for 75% of psoriasis cases.

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 (ticker: 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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be accompanied by a copy of an official document that identifies you (ID, driver's license or passport). Finally, we inform you that you can contact the Spanish Data Protection Agency and any other competent public bodies for any claim arising from the processing of your personal data.

References

[1] Reich K, Warren RB, Iversen L, 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. Br JDermatol. Jun 2019. https://doi.org/10.1111/bjd.18232
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[5] https://www.inserm.fr/information-en-sante/dossiers-information/psoriasis
[6] Crowley J, Korman N, Spelman L, et al. Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 1. Presented at 28th European Academy of Dermatology and Venerology (EADV) Congress; October 9–13; Madrid, Spain. 2019.
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