Press Release

Barcelona,
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Almirall receives positive CHMP opinion for new anti-IL23 tildrakizumab for the treatment of patients with moderate-to-severe chronic plaque psoriasis

- **The positive opinion is based on the results from two pivotal phase III clinical trials (reSURFACE 1 and 2)[1] that showed a high level of efficacy and safety**
- **With the CHMP's positive opinion, tildrakizumab edges closer to European Commission approval, expected in approximately 60 days**
- **Tildrakizumab is a high-affinity humanized monoclonal antibody that inhibits the p19 subunit of IL-23. It marks Almirall's entry into the biological drugs market**
- **Tildrakizumab's launch is expected in late 2018, under the brand name ILUMETRI®**

Almirall, S.A. (ALM) today announced that the **Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for the regulatory approval of tildrakizumab,** under the brand name ILUMETRI®, an investigational humanized, high-affinity IL-23p19 monoclonal antibody for adults with moderate-to-severe chronic plaque psoriasis.

Tildrakizumab is a **cutting-edge biological drug** due to its **specific mechanism of action**. It has been designed to selectively **block the p19 subunit of interleukin-23 (IL-23)**, an upstream inflammatory mediator with regulatory properties and it acts by modifying the pathogenesis of the disease with limited impact on the rest of the immune system.

"We are proud of the positive recommendation announced by the CHMP for tildrakizumab as this marks our entry into the biological drugs market", commented **Peter Guenter, Almirall's CEO.** "*It is a new milestone to consolidate our leading position in medical dermatology and our focus on improving lives by reducing the burden of disease in patients with psoriasis."*

Tildrakizumab is the result of the licensing agreement reached between Almirall and Sun Pharma for the development and commercialization of this therapy for psoriasis in Europe. Last March, Sun Pharma received the Food and Drug Administration (FDA) approval for tildrakizumab in the United States for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

The CHMP positive opinion is based on reSURFACE 1 and 2[1] positive results, presented for the first time in October 2016 at the 25th European Academy of Dermatology and Venerology (EADV) Congress. Those pivotal

phase III clinical trials, which included over 1,800 patients from more than 200 clinical sites worldwide, showed that tildrakizumab has a high level of safety and efficacy.

According to both studies, after only three doses eight out of ten patients treated with tildrakizumab 100 mg or 200 mg achieved 75% of skin clearance (Psoriasis Area Severity Index or PASI 75) at week 28. Over a year, more than 90% of patients who responded to tildrakizumab within 28 weeks maintained a PASI 75 response[2].

Tildrakizumab is administered by subcutaneous injection. Its convenient dosing regimen, every 3 months during maintenance, results in greater convenience and quality of life for patients, achieving a better control and improved treatment satisfaction[1].

The European Commission (EC) generally follows the recommendations of the CHMP (EMA) and delivers its final decision thereafter. The approval of ILUMETRI® (tildrakizumab) is expected in approximately 60 days and its forthcoming launch in Europe by Almirall will be in late 2018.

About tildrakizumab

Tildrakizumab is an investigational humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this precise targeting, tildrakizumab has the potential to help control the pathogenic cells responsible for the inflammatory process of psoriasis with limited impact on the rest of the immune system.

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[3]. 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 & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed.

The company, founded 75 years ago and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenues in 2017 were 755.8 million euros. It has more than 1,830 employees.

For more information, please visit almirall.com linkedin.com/company/almirall

References

1. Reich K, et al. Tildrakizumab, selective IL-23p19 antibody, in the treatment of chronic plaque psoriasis: results from two randomized, controlled, Phase 3 trials (resurface 1 and reSURFACE 2) [abstract]. Presented as a late breaking abstract at the European Academy of Dermatology and Venereology 2016. October 1, 2016.
2. 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;390:276-288.
3. Greb JE, Goldminz AM, Elder JT, et al. Psoriasis. Nat Rev Dis Primers. 2016;2:16082.

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