

## **Press Release**

Barcelona, 15<sup>th</sup> November 2018

# Almirall launches ILUMETRI<sup>®</sup> in Germany for moderate-to-severe chronic plaque psoriasis in adults

- ILUMETRI<sup>®</sup> (tildrakizumab) is a high-affinity humanized monoclonal antibody that inhibits the p19 subunit of IL-23<sup>1</sup>
- ILUMETRI<sup>®</sup> demonstrates lasting efficacy and safety according to two pivotal phase III clinical trials data (reSURFACE 1 and 2)<sup>4</sup> that is maintained through 3 years according to the positive results of a pooled analysis<sup>2</sup> of the two-phase III clinical trials
- Administered by subcutaneous injection, ILUMETRI<sup>®</sup> offers an easy and convenient dosing regimen<sup>2</sup>. After two initial doses, the frequency is 4 injections per year
- Germany is the first country to market ILUMETRI<sup>®</sup>. In the upcoming months, the product is due to be marketed in the rest of Europe
- Last September, ILUMETRI<sup>®</sup> received European Commission's approval, constituting Almirall's entry into the biological drugs market

ILUMETRI<sup>®</sup> (tildrakizumab) is a humanized, high-affinity IL-23p19 monoclonal antibody, for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy.<sup>1</sup> Almirall S.A. starts to market ILUMETRI<sup>®</sup> in Germany on 15<sup>th</sup> November, being the first country where the company commercializes this biological therapy. In the upcoming months, ILUMETRI<sup>®</sup> is due to be marketed also in the rest of Europe.

"ILUMETRI<sup>®</sup> launch in Germany marks our entry into the biological drug market and it is aligned with our aim to provide innovative therapies to patients and healthcare professionals", commented **Peter Guenter**, Chief Executive Officer, Almirall. He added that "ILUMETRI<sup>®</sup> provides a lasting efficacy and safety based on 3 year data with an easy and convenient dosing regimen. It completes our psoriasis portfolio together with Skilarence<sup>®</sup>, launched one year ago as the first and only fumaric acid ester (FAE) containing dimethyl fumarate (DMF) alone<sup>3</sup>. Skilarence<sup>®</sup> has become the leading product in DMF market in Germany with many patients being treated".

### ILUMETRI<sup>®</sup> has demonstrated its efficacy and safety profile within 3 years long term data

ILUMETRI<sup>®</sup> is a humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this potential to help control the pathogenic cells responsible for the inflammatory process of psoriasis with limited impact on the rest of the immune system. ILUMETRI<sup>®</sup> constitutes a step forward in the treatment of moderate-to-severe chronic plaque psoriasis.<sup>4</sup>

ILUMETRI<sup>®</sup> is administered by subcutaneous injection every 3 months, after two initial doses, 4 weeks apart during maintenance<sup>4</sup>, offering a convenient dosing regimen that results in greater quality of life for patients.<sup>4</sup>

ILUMETRI<sup>®</sup> received European Commission's approval in September 2018 based on reSURFACE 1 and 2<sup>4</sup> positive results, presented at the 25<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress in Vienna (Austria). Both pivotal phase III clinical trials, which included over 1,800 patients from more than 200 clinical sites worldwide, showed ILUMETRI<sup>®</sup> has a high level of safety and efficacy.

According to both studies' data, an average of 63% of patients achieved 75% of skin clearance (Psoriasis Area Sensitivity Index por PASI 75) by week 12 and an average of 78% at week 28, after only three doses.<sup>4</sup> The data further showed that a higher number of patients on tildrakizumab achieved PASI 90 and 100 compared to placebo and etanercept: an average of 59% of patients achieved PASI 90 and an average of 30% reached PASI 100 at week 28.<sup>4</sup> Over a year, more than 92% of patients who responded to ILUMETRI<sup>®</sup> within 28 weeks maintained a PASI 75 response (262 from 329 patients responders at week 28).<sup>4</sup>

Moreover, the results of a pooled analysis through 3 years<sup>2</sup> from reSURFACE 1 and 2 phase III trials<sup>3</sup> show the consistent maintenance of efficacy and safety over three years of ILUMETRI<sup>®</sup> in patients with moderateto-severe chronic plaque psoriasis who were responders at week 28. According to the data, PASI 75 responses were maintained with continued treatment with ILUMETRI<sup>®</sup> in 9 out of 10 patients up to week 148.<sup>4</sup> More than 50% of patients reported that psoriasis no longer affected their quality of live - DQLI score of 0 or 1- after only 3 doses.<sup>4</sup> ILUMETRI<sup>®</sup> was well-tolerated with very low drug-related serious adverse events -only a 4.2% of patients- and discontinuation rates -0.8% of patients.<sup>4</sup>

Almirall in-licensed ILUMETRI<sup>®</sup> from Sun Pharmaceutical Industries Ltd. (Sun Pharma) in July 2016. The agreement is for development and commercialization of ILUMETRI<sup>®</sup> in Europe.

#### **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.<sup>5</sup> 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 to 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. More than 1,830 employees are devoted to Science.

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

#### References

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