Barcelona, September 18th, 2018

SIGNIFICANT EVENT

European Commission (EC) approves Almirall´s ILUMETRI® (tildrakizumab) for moderate-to-severe chronic plaque psoriasis

Almirall, S.A. ("Almirall"), pursuant to article 17 of Regulation (EU) No. 596/2014 on market abuse and article 228 of the restated text of the Securities Market Act approved by the Royal Legislative Decree 4/2015, of 23 October and related provisions, hereby announces that:

The European Commission (EC) has approved ILUMETRI® (tildrakizumab), a high-affinity humanized monoclonal antibody that inhibits the p19 subunit of 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.

ILUMETRI® (tildrakizumab) is due to be marketed in all EU Member states. Germany will be the first country to launch it in Q4 2018.

Its approval in Europe is based on reSURFACE 1 and 2 positive results, presented for the first time in October 2016 at the 25th European Academy of Dermatology and Venerology (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 that ILUMETRI® (tildrakizumab) has a high level of safety and efficacy.

Almirall in-licensed tildrakizumab from Sun Pharmaceutical Industries Ltd. (Sun Pharma) in July 2016. The agreement is for development and commercialization in Europe.

Sun Pharma got approval for tildrakizumab from the US FDA in March this year for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In July 2018, tildrakizumab received the CHMP positive opinion for its marketing in Europe.

Please find attached the Press Release.

Yours sincerely,

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Press Release

Barcelona,
18th September 2018

The European Commission approves Almirall's ILUMETRI® (tildrakizumab) for moderate-to-severe chronic plaque psoriasis

- **The approval of ILUMETRI® (tildrakizumab) marks Almirall's entry into the biological drugs market**
- **ILUMETRI® is a high-affinity humanized monoclonal antibody that inhibits the p19 subunit of IL-23 [1]**
- **ILUMETRI® (tildrakizumab) demonstrates lasting efficacy and safety through 3 years according to the positive results of a pooled analysis[2] of two phase III clinical trials**
- **With only 4 doses per year during maintenance, ILUMETRI® (tildrakizumab) offers an easy and convenient dosing regimen[2]**
- **ILUMETRI® (tildrakizumab) is due to be marketed in all EU Member states. Germany will be the first country to launch it in Q4 2018**

Almirall, S.A. announced today that the **European Commission (EC) has approved ILUMETRI®** (tildrakizumab), 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[1]**. Roll out of ILUMETRI® (tildrakizumab) in Europe will start in the next few weeks. Germany will be the first country to launch the product.

According to **Peter Guenter, Almirall's CEO**, *"we are proud of the EC's approval for ILUMETRI®, as it constitutes a new therapeutic option for European healthcare professionals and patients with moderate-to-severe chronic plaque psoriasis. ILUMETRI® is a safe, easy to administer, targeted IL-23p19 inhibitor that provides durable efficacy and long-term safety, this marks a very important milestone for Almirall in the medical dermatology area, specifically in the biological drugs market".*

Tildrakizumab is a humanized high-affinity anti-IL-23p19 monoclonal antibody.[1] Due to its specific mechanism of action, it selectively blocks interleukin-23 (IL-23), an upstream inflammatory mediator cytokine, and acts by modifying the pathogenesis of the disease with limited impact on the rest of the immune system. Tildrakizumab constitutes a very significant step forward in the treatment of moderate-to-severe chronic plaque psoriasis, it is a drug with a high level of safety and efficacy that achieves a long-term control of the disease.[3]

ILUMETRI® (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]. With only 4 doses per year during maintenance, ILUMETRI® offers a convenient dosing regimen.[3] This low frequency of injections may also encourage adherence.[3]

Its approval in Europe is based on reSURFACE 1 and 2[3] positive results, presented for the first time in October 2016 at the 25th European Academy of Dermatology and Venerology (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® 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 or PASI 75) by week 12 and an average of 78% at week 28 after only three doses. Moreover, an average of 59% of patients achieved PASI 90 and an average of 30% reached PASI 100 at week 28. Over a year, more than 92% of patients who responded to ILUMETRI® within 28 weeks maintained a PASI 75 response.

Moreover, 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 three years of ILUMETRI® in patients with moderate-to-severe chronic plaque psoriasis who were responders at week 28. According to the data, PASI 75 responses were maintained with continued treatment with ILUMETRI® in 9 out of 10 patients up to week 148.[3] More than 50% of patients reported that psoriasis no longer affected their lives after only 3 doses.[1,3] ILUMETRI® was well-tolerated with very low drug-related serious adverse events and discontinuation rates.

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

Sun Pharma got approval for Tildrakizumab from the US FDA in March this year for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In July 2018, tildrakizumab received the CHMP positive opinion for its marketing in Europe.

About ILUMETRI®

ILUMETRI® is a humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this precise targeting, ILUMETRI® 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.[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 & 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. More than 1,830 employees are devoted to Science.

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

References

1. ILUMETRI® Summary of Product Characteristics
2. Thaçi D, Iversen L, Pau-Charles I, Rozzo S, Blauvelt A, Reich K. Long-term efficacy and safety of tildrakizumab in patients with moderate-to-severe psoriasis who were responders at week 28: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. EADV 2018
3. 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.
4. Greb JE, Goldminz AM, Elder JT, et al. Psoriasis. Nat Rev Dis Primers. 2016;2:16082.

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