



## SIGNIFICANT EVENT

Almirall and Sun Pharma announce the Validation of Regulatory Filing for tildrakizumab for the treatment of moderate-to-severe plaque Psoriasis in Europe

Almirall, S.A. (ALM.MC), as per section 228 of the Royal Legislative Decree 4/2015, of 23 October 2015, approving the Restated Text of the Securities Market Act, hereby announces:

The validation of Regulatory Filing for tildrakizumab, an investigational IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23 for the treatment of moderate-to-severe plaque Psoriasis, by the European Medicines Agency (EMA).

In July 2016, Almirall closed a licensing agreement with Sun Pharma on the development and commercialization of tildrakizumab for Psoriasis in Europe.

Attached is the Press Release published today with further details.

Yours sincerely,

Pablo Divasson del Fraile Corporate Communications & Investors Department investors@almirall.com





# Almirall and Sun Pharma Announce Regulatory Filing of Tildrakizumab in Europe

Pivotal Phase 3 Data Demonstrated Potential of Tildrakizumab to
Offer Patients Treatment for Moderate-to-Severe Plaque Psoriasis without Burden of
Frequent Injections

Barcelona, SPAIN and Mumbai, INDIA, March 24, 2017: Almirall S.L, (Spanish Stock Exchange ticker: ALM, "Almirall") and Sun Pharmaceutical Industries Ltd (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries or associate companies) announced today the validation of the Regulatory Filing of tildrakizumab with the European Medicines Agency (EMA) by Almirall. Tildrakizumab is an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate-to-severe plaque psoriasis.

The filing includes efficacy and safety data from the pivotal Phase III clinical trials (reSURFACE 1 and 2) that included over 1,800 patients across more than 200 clinical sites.

"The filing of tildrakizumab in Europe is a significant step forward for healthcare providers as many patients are still suffering from the disease. Tildrakizumab adds a novel biologic treatment option to our extensive and innovative portfolio, strengthening our position as a leading Dermatology player," said Eduardo Sanchiz, Almirali's CEO.

According to Mr Jesper Jensen, Executive Vice President - Biologics & Dermatology, Sun Pharma, "Not all people living with psoriasis achieve long-term systemic control with currently available treatments, there are those who continue to struggle every day with the chronic nature of psoriasis. The European filing of tilidrakizumab is the next step in our effort to bring a new treatment option to people suffering from psoriasis."

In July 2016, Almirall entered into a licensing agreement with Sun Pharma for the development and commercialization of tildrakizumab for psoriasis in Europe. Under the terms of the signed agreement, Sun Pharma will continue to lead other indications, for which Almirall will have the right to primary negotiation. In addition, Almirall will be able to lead European studies, and participate in larger Global clinical studies for psoriasis.

#### **About Psoriasis**

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.5 million people in the U.S. and approximately 125 million people worldwide. It is a non-contagious disorder that speeds the growth cycle of skin cells and results in thick scaly areas of skin. The most common form of psoriasis, called plague 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 existing treatment options, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

#### **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. Phase III tildrakizumab data provides further evidence for the role of the IL-23 pathway in helping to control the inflammatory process of psoriasis.

### **About Sun Dermatology**

Sun Pharma is committed to expanding our dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions with high unmet medical needs like psoriasis. Sun Pharma, along with its subsidiaries, is ranked fourth in dermatology prescription volume within the U.S. per IMS and is fifth largest specialty generic pharmaceutical company globally. In addition to the investigational candidate Tildrakizumab, an investigational anti-IL- 23p19 monoclonal antibody, Sun Dermatology is comprised of several branded products indicated for the treatment of Acne and Actinic Keratosis with a focus on other dermatologic conditions with unmet needs such as psoriasis and atopic dermatitis. For more information, visit <a href="https://www.SunPharmaDerm.com">www.SunPharmaDerm.com</a>.

#### About Sun Pharma, Almirall S.A, Europe, Agreement

Sun Pharma and its wholly owned subsidiary and Almirall (Spanish Stock Exchange ticker: ALM) entered into a licensing agreement in July 2016 for the development and commercialization of tildrakizumab for psoriasis in Europe. Under terms of the license agreement, Almirall is able to lead European studies, and participate in larger Global clinical studies for psoriasis indication subject to the terms of the Sun Pharma – Merck agreements, as well as certain cost sharing agreements. Sun Pharma will be eligible to receive development and regulatory milestone payments and, additionally, sales milestone payments and royalties on net sales. Sun Pharma will continue to lead development of tildrakizumab for other indications, where Almirall will have right of first negotiation for certain indications in Europe. The agreement between Sun Pharma and Almirall remains subject to the exclusive license agreement between Sun Pharma and Merck.

#### Disclaimer:

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

## About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 49 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multicultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes US\$ 2.1 billion. In India, the company enjoys leadership across 12 different classes of doctors with 31 brands

featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 8% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma Live

#### **About Almirall**

Almirall is a global pharmaceutical company with a strong focus in Dermatology and Aesthetics with the mission of providing valuable medicines and medical devices to present and future generations. Our R&D is focused on Dermatology, with a wide range of programs including key indications. Through our innovative products, agreements and alliances, our work covers the entire drug value chain. Almirall is continually growing as a specialist company in a wide range of skin diseases, in order to cover our customers unmet needs.

Founded in 1943, headquartered in Barcelona, Spain, Almirall is listed on the Spanish Stock Exchange (ticker: ALM) and it has become a source of value creation for society due to its vision and the commitment of its long-standing major shareholders. In 2016, its revenues totaled 859.3 million euros and, with more than 2.000 employees, it has gradually built up a trusted presence across Europe, as well as in the US.

For more information, please visit www.almirall.com.

#### **Contacts: Sun Pharma**

<u>Media</u> Frederick Castro

Tel +91 22 4324 4324, Xtn 2777

Tel Direct +91 22 4324 2777 Mobile +91 99206 65176

E mail <u>frederick.castro@sunpharma.com</u>

<u>Investors</u> Nimish Desai

Tel +91 22 4324 4324, Xtn 2778

Tel Direct +91 22 4324 2778 Mobile +91-98203 30182

E mail <u>nimish.desai@sunpharma.com</u>

#### **Contacts: Almirall**

Media contact Cohn & Wolfe Rebeca Rocha

rebeca.rocha@cohnwolfe.com

Tel.: (+34) 91 531 42 67

**Investors contact** 

Almirall

Pablo Divasson del Fraile pablo.divasson@almirall.com

Tel.: (+34) 93 291 30 87