

## **SIGNIFICANT EVENT**

Almirall to Announce Late-Breaking Results for Investigational IL-23p19 inhibitor, Tildrakizumab, Achieves Primary End Point in Both Phase-3 Studies in Patients with Moderate-to-Severe Plaque Psoriasis

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 that:

Almirall, S.A. (Spanish Stock Exchange ticker: ALM) and Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies, through its wholly owned subsidiary), have announced late breaking data from two pivotal phase-3 clinical trials (reSURFACE 1 and 2) achieving de primary endpoint of Tildrakizumab, an investigational IL-23p19 inhibitor, in patients with moderate-to-severe plaque psoriasis. Results have been presented at the 25th EADV Congress in Vienna, Austria.

The Phase-3 data results through week 28 have been presented for the first time as part of the "Late Breaking News" Session at the premier European dermatology conference where the latest in research and developments in the field are presented each year. Tildrakizumab clinical trials included over 1,800 patients from more than 200 clinical trial sites worldwide.

In the trials, an average of 63 percent of patients achieved 75 percent of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) by week 12 after only two injections, and 77 percent achieved 75 percent skin clearance after 28 weeks and three injections of the 100 mg dose of Tildrakizumab (64 percent and 80 percent in reSURFACE1, 61 percent and 74 percent in reSURFACE2). Similarly, an average of 57 percent and 66 percent of patients had a Physician's Global Assessment (PGA) score of "clear" or "minimal" with the 100 mg dose at weeks 12 and 28 respectively.

Those receiving the 200 mg dose also saw an average of 64 percent and 78 percent of patients achieving PASI 75 at weeks 12 and 28 respectively. Also, 59 percent and 69 percent of the patients had PGA score of "clear" or "minimal" at weeks 12 and 28 respectively.

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 37 percent and 36 percent of patients on Tildrakizumab achieved PASI 90 at week 12 with the 100 mg dose and 200 mg dose respectively which increased to 54 percent and 59 percent at week 28. Correspondingly, an average of 13 percent on Tildrakizumab achieved PASI 100 at week 12 regardless of dose with an increase to 24 percent for the 100 mg dose and 30 percent for the 200 mg dose at week 28.



The overall safety profile of Tildrakizumab in both Phase-3 clinical trials was consistent with the safety data observed in previously reported studies. The incidences of severe infections, malignancies, and extended major cardiovascular events (MACE) were low and similar across treatment groups (1-3 percent).

Additional findings from the phase-3 clinical trials will be presented at upcoming scientific meetings and the preparations for regulatory submissions in both the U.S. and Europe are proceeding. In July 2016, Almirall had announced a strategic licensing agreement with Sun Pharma on the development and commercialization of Tildrakizumab for psoriasis in Europe.

Yours sincerely,

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