

Barcelona, September 28th 2016

SIGNIFICANT EVENT

Almirall announces positive phase III results showing efficacy of LAS41008 (dimethyl fumarate), a new systemic oral drug for patients with chronic 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. (ALM), the global pharmaceutical company based in Barcelona, will present positive results from the randomised, double-blind, placebo-controlled phase III trial (BRIDGE), assessing the efficacy and safety of a new oral formulation of dimethyl fumarate (LAS41008) compared to Fumaderm®, in adults with moderate-to-severe chronic plaque psoriasis.

Results from the BRIDGE trial, accepted for publication in the British Journal of Dermatology, including co-primary and secondary endpoints, will be presented tomorrow, September 29th, during the satellite symposium organized by Almirall at the 25th EADV Congress, in Vienna, Austria.

The symposium, entitled 'Treating psoriasis: a matter of renewed experience', will provide an update on oral systemic treatments for patients with moderate-to-severe psoriasis, with a special focus on fumaric acid esters (FAEs) and on the existing clinical experience with their use in the long-term management of the disease.

During the session, the results from the BRIDGE trial will also be presented, which show that LAS41008 (DMF) is effective for the treatment of psoriasis and can provide an efficacy and safety profile comparable with the equivalent dose of DMF contained in the FAEs combination product approved and widely commercialized in Germany.

"The most important results are that oral LAS41008 (DMF) is efficacious in treating patients with moderate-to-severe plaque psoriasis and that there is no inferiority to Fumaderm®, currently approved in Germany, which is a mixture of different fumaric acid esters with DMF as the main active ingredient", says Prof. Ulrich Mrowietz, Head of the Psoriasis-Center at the University Medical Center Schleswig-Holstein, and one of the main investigators and co-author of the BRIDGE study manuscript.

Clinical experience with the use of fumaric acid esters (FAEs)

FAEs are a well-established treatment option with a long record of a favorable efficacy and safety profile for adults with moderate-to-severe chronic plaque psoriasis⁵. "In Germany, where Fumaderm® has been used for more than 20 years, DMF-containing oral drugs are first-line and first choice options for systemic therapy of moderate-to-severe plaque psoriasis", affirms Prof. Ulrich Mrowietz.

Furthermore, "in the countries where FAEs are available, these are used for long-term therapy in particular. When FAEs are efficacious, well-tolerated and safety monitored they do not show

evidence of adverse effects, therefore, treatment can be continued as long as the condition requires disease control”, concludes Prof. Ulrich Mrowietz.

The use of FAEs is recommended in European psoriasis guidelines for the induction and long-term treatment of adults with moderate-to-severe chronic plaque psoriasis. However, despite being recommended, FAEs are still not available in most European countries.

“These results represent an important milestone for Almirall as LAS41008 (DMF) will allow us to bring a new therapeutic alternative that covers unmet needs in the systemic treatment of psoriasis to many patients in Europe,” says Thomas Eichholtz, Executive Vice-president, Research & Development at Almirall. “Thanks to its efficacy and safety profile, LAS41008 (DMF) will provide a great addition to the existing therapeutic arsenal in the treatment of moderate-to-severe psoriasis”.

BRIDGE trial results

The co-primary efficacy endpoints were the percentage of patients achieving PASI 75 (Psoriasis Area and Severity Index) and the percentage of patients achieving a score of 0 or 1 (‘clear’ or ‘almost clear’) in the PGA (Physician’s Global Assessment) at week 165.

Significantly more patients achieved PASI 75 at week 16 following treatment with LAS41008 compared with placebo (37.5% vs 15.3%; $p < 0.0001$). Furthermore, LAS41008 was non-inferior to Fumaderm® in PASI 75 at week 16 (37.5% vs 40.3%; $p = 0.0003$). At week 16, 33% of patients treated with LAS41008 achieved a score of ‘clear’ or ‘almost clear’ in the PGA, a significantly greater percentage compared to those receiving placebo (13.0%).

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