

SIGNIFICANT EVENT

European Commission (EC) approves Almirall's Skilarence[®] for moderate-to-severe 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:

The European Commission (EC) has approved Skilarence[®], a new oral formulation of dimethyl fumarate (DMF) developed by Almirall, for the treatment for patients with moderate-to-severe chronic plaque Psoriasis. Skilarence[®] is to be indicated as a first-line induction and long-term maintenance treatment.

Almirall is due to start marketing Skilarence[®] in the third quarter of 2017 in all EU Member states, as well as in Iceland and Norway.

Skilarence[®] is the first fumaric acid ester (FAE) for the treatment of Psoriasis approved by the EC. Its approval in Europe is based on the positive results from the randomised, double-blind, placebo-controlled Phase III trial (BRIDGE), evaluating the efficacy and safety of this new oral formulation of dimethyl fumarate compared to Fumaderm[®], presented in September 2016 at the prestigious 25th EADV Congress in Vienna (Austria). Published in the British Journal of Dermatology, the BRIDGE trial showed the non-inferiority of DMF compared to Fumaderm[®] and a good efficacy and safety profile.

To date, a fixed combination of fumaric acid esters was only available in Germany in a different composition as well as locally compounded formulations in some countries like the Netherlands, Austria and some Nordic countries. The EC's decision will place this new oral formulation within the reach of all patients residing in all of the European countries.

Fumaric acid esters are a well-established oral systemic treatment for Psoriasis and are recommended in the European guidelines for both induction and long-term maintenance of the treatment of the disease. Long-term evidence coming from retrospective studies and registries highlights the clinical usefulness of the drug as well as its balanced safety profile.

Yours sincerely,

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