Results to be presented at the 25th European Academy of Dermatology and Venereology (EADV) Congress, Vienna 2016

The BRIDGE study accepted for publication in the British Journal of Dermatology

Almirall announces positive phase III results showing efficacy of LAS41008 (dimethyl fumarate), a new systemic oral drug for patients with chronic plaque psoriasis

- Results from a randomised, double-blind, placebo-controlled Phase III trial (BRIDGE), which used Fumaderm® as a comparator and assessed the efficacy and safety of dimethyl fumarate (DMF) for patients with moderate-to-severe chronic plaque psoriasis, will be presented at the 25th EADV Congress

- Dimethyl fumarate (DMF) is a fumaric acid ester. Fumaric acid esters (FAEs) are recommended in the European S3 psoriasis guidelines for both induction and long-term treatment of adults with moderate-to-severe chronic plaque psoriasis.  

- A combination of FAEs, including dimethyl fumarate (DMF), is currently approved for the treatment of moderate-to-severe psoriasis in Germany, with a positive risk-benefit profile for long-term use. DMF is considered the main active component in the combination.

- The BRIDGE study demonstrated non-inferiority of DMF to Fumaderm® and a good efficacy and safety profile

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 psoriasis. “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 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 16.

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%)5.

About psoriasis
Psoriasis is a chronic immune disease that appears on the skin. Psoriasis can have a significant negative physical and psychosocial impact on quality of life. It affects
approximately 125 million people worldwide\(^7\). It is a non-contagious disorder that speeds up the growth cycle of skin cells\(^7\) and results in thick scaly areas of skin\(^8\).

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\(^8\). Despite existing treatment options, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease that often has a debilitating impact not only on their bodies but also on their everyday lives.

**About Almirall**

Almirall is a global company based in Barcelona dedicated to providing valuable medicines and medical devices through its R&D, agreements and alliances. Our work covers the whole of the drug value chain. A consolidated growth allows us to devote our talent and efforts towards specialty areas and particularly to further grow as a leading Dermatology player. We are a specialist company, enabling us to accomplish the purpose of providing our innovative products wherever they are needed.

Founded in 1943, 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 2015, Almirall revenues totalled 769 million euros and, with 1,800 employees, it has become a trusted presence across Europe, as well as in the US.

For more information, please visit [www.almirall.com](http://www.almirall.com).

**References**


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