

Geneva,
14th September 2017

This fumaric acid ester has been presented at the European Academy of Dermatology and Venereology (EADV) Congress

Almirall launches new oral formulation of dimethyl fumarate (DMF) in Europe for moderate-to-severe chronic plaque psoriasis

- **Dimethyl fumarate (DMF) is to be indicated as a treatment for adults with moderate-to-severe chronic plaque psoriasis**
- **United Kingdom is the first country to market this product, followed by Germany, Denmark, Sweden, Austria, Norway**
- **In June 2017, this new formulation received European Commission's approval to be marketed in all EU Member states**
- **Almirall will hold two satellite symposiums at the 26th EADV Congress to bring the newest data about psoriasis therapies**

Almirall S.A. is starting to market **a new oral formulation of dimethyl fumarate (DMF) developed by the pharmaceutical company R&D team for the treatment of patients with moderate-to-severe chronic plaque psoriasis**. The United Kingdom is the first country where it will be available, starting tomorrow 15th September, followed by Germany, Denmark, Sweden and Norway. In the upcoming months, it is due to be marketed in all the EU Member states, as well as in Iceland. This new product is the first and only fumaric acid ester (FAE) approved by the European Commission for the treatment of psoriasis, constituting an interesting option for a longer number of patients with the disease.

According to **Bhushan Hardas**, Almirall's Executive Vice President R&D and Chief Scientific Officer, *"the launch of this new formulation of DMF responds to Almirall's aim to find innovative solutions to fight psoriasis, a disease that affects 7.8 million people in Europe"*.

Alfredo Barón, Almirall's Executive Vice President, Global Commercial Operations, said that *"Almirall's fumaric acid ester is to be indicated as a first-line oral systemic therapy for induction and long-term maintenance treatment. It is the first launch of our psoriasis franchise since we decided to focus on dermatology and it becomes a very important step in reinforcing Almirall's position as a significant player in this field"*.

*“This product will provide a new cost-effective option to patients with psoriasis welcomed by healthcare providers and payers in all EU countries, Iceland and Norway”, explained today **Rajesh Gupta**, Global Marketing Dermatology Director at Almirall.*

DMF is the only active ingredient of the treatment. To date, a fixed combination of FAEs was only available in Germany in a different composition, as locally compounded formulations in Netherlands, Austria and some Nordic countries. **Prof. W.H. Boehncke**, Department of Dermatology at the University Hospital of Geneva (Switzerland), affirmed today that *“with the approval of a new DMF treatment, fumarate therapy becomes widely available on a registered basis in Europe. FAEs are effective and safe in the long-run, and a major advantage of DMF treatments is the possibility for individual dose adjustment that allows efficacious therapy with limited treatment exposure”.*

In June 2017, this new oral formulation was approved by the European Commission (EC) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis in all EU State members. Its approval by the EC was based on the positive results from the randomized double-blind, placebo-controlled Phase III trial (BRIDGE), evaluating the efficacy and safety of this new oral formulation of DMF. The BRIDGE trial showed the non-inferiority of DMF compared to the fixed combination of FAEs available in Germany, in efficacy and safety, and an improvement in patients' quality of life.

The launch of the product takes place within the framework of the 26th EADV Congress, in Geneva, Switzerland, where Almirall has organized two satellite symposiums to bring new data on the changing landscape in psoriasis, specifically in oral and biological therapies.

About psoriasis

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.8 million adults in Europe and approximately 125 million people worldwide. It is a non-contagious disorder that accelerates the growth cycle of skin cells and results in thick scaly areas of skin. 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. Despite different treatment options existing, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

Psoriasis is also associated with comorbidities of the metabolic syndrome (cholesterol, hypertension, diabetes and obesity), cardiovascular diseases (stroke, ischemic heart disease), depression, anxiety and an increase in autoimmune diseases such as diabetes, rheumatoid arthritis, Crohn's Disease, inflammatory bowel disease and multiple sclerosis-The 20% of patients with psoriasis have psoriatic arthritis.

Almirall's commitment to psoriasis

At Almirall, we want to help dermatologists treating every aspect of psoriasis with a pipeline from our own R&D, as well as from acquisitions and licensing agreements. We fight psoriasis with topical and systemic oral and biological therapies, helping a large percentage of the psoriasis patients. Nonetheless, there are still many patients with untreated needs, comorbidities or suffering side effects. For these reasons, at Almirall we work every day to develop new solutions and to offer new treatments options more effective.

Currently, we are developing other cutting-edge treatments in the process of being approved. We develop and lead the introduction of an IL-23 inhibitor in Europe with a licensing agreement with Sun Pharma. Also, we have strategic collaborations in dermatology with Nuevolution to develop RORyt inhibitors for the treatment of inflammatory dermatological diseases and psoriatic arthritis; and with Mercachem, to identify and develop oral cytokine blockers, novel small molecule therapeutics for inflammatory skin diseases.

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed.

The company, founded in 1943 and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenue in 2016 was 859.3 million euros and more than 2,000 employees are devoted to Science.

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

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References

1. SmPC Fumaderm®.
2. Thaci D, Weisenseel P, Philipp S, et al. Efficacy and safety of fumaric acid esters in patients with psoriasis on medication for comorbid conditions - a retrospective evaluation (FACTS). J Dtsch Dermatol Ges. 2013;11(5):429-35.
3. Balak DMW. Fumaric acid esters in the management of psoriasis. Psoriasis: Targets and Therapy. 2015; 5:9-23.
4. Mrowietz U, Szepletowski JC, Loewe R, et al. Efficacy and safety of LAS41008 (dimethyl fumarate) in adults with moderate-to-severe chronic plaque psoriasis: a randomized, double-blind, Fumaderm® - and placebo-controlled trial (BRIDGE). Br J Dermatol. 2017;176(3):645-23.
5. Van de Kerkhof P, Szepletowski J, Loewe R, et al. Treatment with LAS41008 (dimethyl fumarate) improves health-related quality of life and has a positive impact on the patient benefit index in adults with moderate-to-severe chronic plaque psoriasis: results of the BRIDGE study. E-poster: P1998. Presented at the European Academy of Dermatology and Venereology, Vienna, 28th September –2nd October 2016. 2016.
6. SmPC Skilarence.
7. Rostami Yazdi M, Clement B, Schmidt TJ, et al. Detection of metabolites of fumaric acid esters in human urine: implications for their mode of action. J Invest Dermatol. 2009;129(1):231-4.

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