

Geneva,  
14<sup>th</sup> September 2017

A new oral systemic treatment for psoriasis has been presented at the European Academy of Dermatology and Venereology (EADV) Congress

# Almirall launches Skilarence<sup>®</sup> in Europe for moderate-to-severe chronic plaque psoriasis

- **Skilarence<sup>®</sup> is a new oral formulation of dimethyl fumarate (DMF), to be indicated as a treatment for adults with moderate-to-severe chronic plaque psoriasis**
- **The United Kingdom is the first country to market Skilarence<sup>®</sup>, where NICE has issued Technology Appraisal Guidance recommending it as a cost-effective option for NHS England when the disease has not responded to other systemic therapies**
- **In June 2017, Skilarence<sup>®</sup> received European Commission's approval. It is expected to be available in EU Member states, Iceland and Norway**
- **Almirall will hold two satellite symposiums at the 26<sup>th</sup> EADV Congress to bring the newest data about psoriasis therapies**

Almirall S.A. is starting to market **Skilarence<sup>®</sup>**, a new oral formulation of dimethyl fumarate (DMF) developed by the R&D team indicated as a first-line induction and long-term maintenance therapy for patients with moderate-to-severe chronic plaque psoriasis. Skilarence<sup>®</sup> is the first and only fumaric acid ester (FAE) approved by the European Commission (EC) for the treatment of adults with psoriasis in need of systemic medicinal therapy, constituting a new option for a larger number of patients with the disease.

According to **Bhushan Hardas**, Almirall's Executive Vice President R&D and Chief Scientific Officer, "*the launch of Skilarence<sup>®</sup> responds to Almirall's aim to find innovative solutions to fight psoriasis, a disease that affects 125 million people worldwide<sup>1</sup>*". From his part, **Rajesh Gupta**, Global Marketing Dermatology Director at Almirall, explained that "*this product will provide a new cost-effective option to patients with psoriasis welcomed by healthcare providers and payers in EU countries, Iceland and Norway*".

The **United Kingdom**, where it is estimated that around 2% of people is affected by psoriasis<sup>2</sup>, is the first country where **Skilarence<sup>®</sup>** will be available, starting tomorrow 15<sup>th</sup> September, followed by Germany, Denmark, Sweden and Norway. In addition, the **National Institute for Health and Care Excellence (NICE)** has issued a **Technology Appraisal Guidance (TAG)** recommending dimethyl fumarate (marketed as **Skilarence<sup>®</sup>**) for adult patients with severe chronic plaque psoriasis. Thus, according to NICE guidance, Skilarence<sup>®</sup> is recommended as a cost-effective treatment option for NHS

England where the disease has not responded to other systemic therapies or these options are contraindicated or not tolerated in England and Northern Ireland. Skilarence<sup>®</sup> is Almirall's first product to go through the HTA process with NICE and with this recommendation, suitable patient candidates will be able to receive Skilarence<sup>®</sup>.

### **Skilarence<sup>®</sup>, the first FAE only containing DMF as active ingredient**

Skilarence<sup>®</sup> is the first FAE containing only DMF as its active ingredient. 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**, from the Department of Dermatology at the University Hospital of Geneva (Switzerland), affirmed that *“with the approval of a new DMF treatment, Skilarence<sup>®</sup>, 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, including Skilarence<sup>®</sup>, is the possibility for individual dose adjustment that allows efficacious therapy with limited treatment exposure”*.

The approval of Skilarence<sup>®</sup> by the EC and NICE's decision are based on the positive results from the randomized double-blind, placebo-controlled Phase III trial (BRIDGE)<sup>3</sup>, evaluating the efficacy and safety of this new oral formulation of DMF. The BRIDGE trial showed the non-inferiority of DMF compared to Fumaderm<sup>®</sup> in efficacy and safety, and an improvement in patients' quality of life. Furthermore, Skilarence<sup>®</sup> was superior to placebo and non-inferior to Fumaderm<sup>®</sup> in PASI 75 at week 16<sup>3</sup>.

The launch of the product takes place within the framework of the 26<sup>th</sup> 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 approximately 125 million people worldwide<sup>1</sup>. 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<sup>1</sup>. Over a third of people living with psoriasis of the skin also develop psoriatic arthritis<sup>4</sup>.

## 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](http://almirall.com) [linkedin.com/company/almirall](https://www.linkedin.com/company/almirall)

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### Disclaimer

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