

Almirall Receives Positive CHMP Opinion for Dimethyl Fumarate for the Treatment of Patients with Moderate-to-Severe Chronic Plaque Psoriasis

- **Dimethyl fumarate (DMF) is a fumaric acid ester indicated as an oral first-line treatment for adults with moderate-to-severe chronic plaque psoriasis**
- **Results from the randomised, double-blind, placebo-controlled Phase III trial (BRIDGE) showed the efficacy and safety of dimethyl fumarate (DMF)**
- **Dimethyl fumarate is due to be marketed in Europe from Q3 2017**

Barcelona, 21st April 2017

Almirall, S.A., the global pharmaceutical company based in Barcelona, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for the regulatory approval of a new oral formulation of dimethyl fumarate (DMF), under the trade name Skilarence[®], in all EU member states as a first-line induction and long-term treatment for adults with moderate-to-severe chronic plaque psoriasis.

*"We are proud of the positive recommendation announced by the CHMP for dimethyl fumarate as this will provide European patients and healthcare professionals with a new therapeutic alternative in the systemic treatment of this chronic dermatological disease", commented **Eduardo Sanchiz, Almirall's CEO**. "This is a new milestone in order to consolidate our leading position in Dermatology and maintains our focus on improving lives of psoriasis patients", he added.*

In September 2016, Almirall presented positive results from the randomised, double-blind, placebo-controlled Phase III trial (BRIDGE) showing the efficacy and safety of dimethyl fumarate compared to Fumaderm[®], at a satellite symposium at the 25th EADV Congress, in Vienna, Austria. The BRIDGE study demonstrated non-inferiority of DMF to Fumaderm[®] and a good efficacy and safety profile¹. These results, including co-primary and secondary endpoints, were accepted for publication in the British Journal of Dermatology.

*"Thanks to its efficacy and safety profile, this new oral formulation will allow us to bring a new therapeutic alternative that covers unmet needs in the systemic treatment of moderate-to-severe psoriasis to many patients in Europe", explained **Alfredo Barón de Juan, Almirall's Executive Vice President, Global Commercial Operations**. "We are convinced that DMF will provide an important addition to the available therapeutic arsenal in the treatment of this disease".*

Furthermore the regulatory approval of Skilarence[®] will enable Almirall to give access to a new systemic therapy for the patients with moderate and severe psoriasis. *"From now on patients in Germany and in the rest of the European Union will have a new alternative for treating their psoriasis. We are proud to extend the access of this fumaric acid derivative (only available in Germany in a different composition), to the rest of the European Union and clearly give a new opportunity to improve psoriatic patients life", said **Xavier Llaurado, Almirall's Regulatory Affairs Director**.*

The European Commission generally follows the recommendations of the CHMP (EMA) and delivers its final decision thereafter. Dimethyl fumarate is due to be marketed in Europe by Almirall from Q3 2017, under the trade name Skilarence® in all EU Member states plus Iceland, Norway and Switzerland.

About Dimethyl fumarate (DMF)

Dimethyl fumarate (DMF) is a type of fumaric acid ester (FAEs), which are recommended in the European S3 psoriasis guidelines for both induction and long-term treatment of adults with moderate-to-severe chronic plaque psoriasis². A combination of FAEs is currently approved for the treatment of moderate-to-severe psoriasis in Germany, with a positive risk-benefit profile for long-term use³. DMF is considered the main active component in this combination.^{4,5}

About Psoriasis

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.5 million people in the U.S. and approximately 125 million people worldwide. It is a non-contagious disorder that speeds 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 existing treatment options, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

About Almirall

Almirall is a global pharmaceutical company with a strong focus in Dermatology and Aesthetics with the mission of providing valuable medicines and medical devices to you and future generations. Our R&D is focused on Dermatology, with a wide range of programs including key indications. Through our innovative products, agreements and alliances, our work covers the entire drug value chain. Almirall is continually growing as a specialist company in a wide range of skin diseases, in order to cover our customers unmet needs.

Founded in 1943, headquartered in Barcelona, Spain, 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 2016, its revenues totaled 859.3 million euros and, with more than 2.000 employees, it has gradually built up a trusted presence across Europe, as well as in the US.

For more information, please visit www.almirall.com

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