

Almirall launches the innovative Wyzora[®] cream in Denmark for the treatment of mild to moderate plaque psoriasis including scalp in adults¹

- Based on PAD Technology formulation and drug delivery system, Wyzora[®] is the first and only once-daily aqueous cream^{2,3} with a fixed combination of calcipotriol and betamethasone dipropionate (CAL/BDP)¹. It is designed to provide high efficacy combined with favourable safety and superior treatment convenience in a single product³
- The cream provides a fast onset of action within 1 week^{3,4}. Results from Phase III clinical trials demonstrated that, after 8 weeks of once-daily use, Wyzora cream provided greater efficacy and patient quality of life (QoL) compared to the currently available topical CAL/BDP gel⁴
- The product is already available in Spain, Germany, and the United Kingdom, with roll-out in other EU countries in 2022 remaining on schedule
- Psoriasis is one of the world's most prevalent skin diseases, affecting approximately 100 million individuals worldwide⁵ and about 2.2% of adults in Denmark (102,000 estimated people)⁶

BARCELONA, Spain, May 25, 2022 – Almirall S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, announced today the commercial launch in Denmark of Wyzora[®] cream (50 µg/g calcipotriol and 0.5 mg/g betamethasone as dipropionate), developed for the topical treatment of mild to moderate plaque psoriasis in adults including scalp. Denmark joins Spain, Germany and the United Kingdom, which were the first European countries to make the cream available on prescription. Following the launch of this innovative topical, Almirall became the only biopharmaceutical company in Europe to offer psoriasis patients multiple options covering the entire spectrum of the disease, from topicals to oral systemics and biologics.

Powered by PAD Technology, a new method of mixing oil and water, Wyzora[®] Cream is the only calcipotriol and betamethasone dipropionate topical that allows the combination of active ingredients in an aqueous cream^{2,3}. Wyzora[®] offers high efficacy and fast onset of action within 1 week.^{3,4} The results from a pooled analysis of two randomized Phase III trials demonstrated that this CAL/BDP PAD-cream offered superior efficacy and patient quality of life in the topical treatment of psoriasis in comparison to the calcipotriol and betamethasone dipropionate gel formulation for all efficacy endpoints including PGA treatment success, mPASI, and PASI75 after 8 weeks of once-daily use⁴.

After eight weeks of treatment, the clinical investigation also showed that a significantly greater proportion of subjects treated with CAL/BDP PAD-cream reported that psoriasis had no effect at all on their life (DLQI 0 or 1) compared to CAL/BDP gel⁴. Superior patient treatment convenience (PTCS) at Week 8 was also achieved with CAL/BDP PAD-cream compared to the CAL/BDP gel.⁴

The results of pooled data from Phase III clinical trials were published in the Journal of the European Academy of Dermatology and Venereology (JEADV)⁴. Psoriasis is one of the world's most prevalent skin diseases, affecting approximately at least 100 million individuals worldwide⁵ and about 2.2% of adults in Denmark (102,000 estimated people)⁶. The disease negatively affects quality of life and represents a significant burden in the daily life of 71% of patients⁷, affecting the overall emotional wellbeing of 88% of people who suffer from the condition⁸.

"I find it highly commendable that new innovation and improvement in topical treatment of psoriasis is brought to light. Based on the phase III trials, the PAD formulation may provide additional benefit to patients with mild to moderate plaque psoriasis in terms of efficacy, quality of life and favourable safety profile of the CAL/BDP PAD-cream" stated **Lars Iversen, Professor, Aarhus University Hospital**.

"The Danish Psoriasis Association is pleased to learn that this novel innovative treatment is made available to Danish psoriasis patients. The possibility to improve the quality of life and adherence to treatment are obviously very important features in topical treatment of psoriasis," said **Lars Werner, Managing Director, Danish Psoriasis Association**.

The deployment of Wynzora[®] Cream in the rest of Europe is on track for 2022. Almirall started marketing the cream in the UK, Spain and Germany in February and expects to roll out in other European countries in the coming months once national marketing authorisations are granted. The product has received regulatory approval in 14 countries in Europe with the name Wynzora[®], and in Austria with the name Winxory[®].

"The launch of Wynzora[®] Cream in Europe is on schedule and we are very pleased that Danish patients can now have this novel treatment option available to them. Initial feedback on the product in the UK, Germany and Spain is very positive and we are convinced that this innovative formulation will represent a substantial improvement for patients thanks to its galenic characteristics," said **Gianfranco Nazzi, CEO of Almirall**.

"The Wynzora journey started more than a decade ago fuelled by our desire to meet the demand of patients through our innovative PAD Technology. It is a special feeling to see this new drug being made available also to patients in our home country, Denmark, while we continue the global roll-out.", stated **Jesper J. Lange, CEO of MC2 Therapeutics**, developer of the PAD Technology and Wynzora[®] Cream.

In February 2021, Almirall and MC2 Therapeutics entered into a strategic agreement under which MC2 Therapeutics granted Almirall exclusive European rights to commercialise Wynzora[®] Cream for treatment of plaque psoriasis. Both companies announced the successful completion of a decentralised procedure in July 2021. The cream is also commercialized in the US by MC2 Therapeutics in collaboration with another company.

About pooled analysis of two randomized Phase III trials

WYNZORA[®] (CAL/BDP PAD-cream) demonstrated superiority for all efficacy end points after 8 weeks of treatment. PGA treatment success for CAL/BDP PAD-cream (43.2%) was greater than CAL/BDP gel (31.9%; $P < 0.0001$), the mean percent reduction in mPASI for CAL/BDP PAD-cream was 64.6% compared to 56.4% for CAL/BDP gel ($P < 0.0001$), DLQI 0/1 was obtained by 43.8% in CAL/BDP PAD-cream versus 34.2% CAL/BDP gel ($P = 0.0005$) and superior patient treatment convenience (PTCS) at Week 8 (40.4) was achieved with CAL/BDP PAD-cream compared to CAL/BDP gel (37.0; $P < 0.0001$). There was no adverse drug reaction reported with a frequency of $> 1\%$, associated with CAL/BDP PAD-cream.⁴

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life". We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange and is a member of the IBEX35 (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2021 were 836.5 million euros.

For more information, please visit almirall.com

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¹ WYNZORA® Cream Summary of Product Characteristics.

² Præstegaard M, et al. Phase 3 trial demonstrates superior patient treatment convenience of MC2-01 calcipotriene plus betamethasone dipropionate cream compared to current topical suspension. *J of Skin.* 2020;4(5):s62

³ Stein Gold L, et al. A phase 3, randomized trial demonstrating the improved efficacy and patient acceptability of fixed dose calcipotriene and betamethasone dipropionate cream. *J Drugs Dermatol.* 2021;20(4): 420-425 doi:10.36849/JDD.5653.

⁴ Pinter A, et al. A pooled analysis of randomized, controlled, phase 3 trials investigating the efficacy and safety of a novel, fixed dose calcipotriene and betamethasone dipropionate cream for the topical treatment of plaque psoriasis. *JEADV* 2022; 36, 228–236.

⁵ World Health Organization. (2016). Global report on psoriasis. World Health Organization. <https://apps.who.int/iris/handle/10665/204417>

⁶ Parisi R, Iskandar I Y K, Kontopantelis E, Augustin M, Griffiths C E M, Ashcroft D M et al. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study *BMJ* 2020; 369 :m1590 doi:10.1136/bmj.m1590

⁷ National Psoriasis Foundation 2008 Survey Snapshot. Available from: PTT-24087-quality-of-life-issues-and-measurement-in-patients-with-psor (researchgate.net)

⁸ Armstrong AW, Schupp C, Wu J, et al. *PLoS One.* 2012;7(12):e52935;