

Almirall initiates decentralised procedure in Europe for the treatment of mild to moderate fungal nail infection with efinaconazole

- The company filed for the regulatory submission in Germany, that is acting as Reference Member State, and Italy
- The successful completion of a decentralised procedure is the prior step before national marketing authorizations can be granted by the European countries and the outcome of the regulatory filing is expected to be known around Q3 2023
- Global prevalence of onychomycosis is estimated to be around 5.5%¹ and the condition is responsible for 50% of all consultations for nail disorders²

BARCELONA, SPAIN, May 26, 2022 – Almirall S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, announced today the filing for the regulatory submission for efinaconazole, a triazole antifungal compound indicated for the treatment of mild-to-moderate fungal infection of the nail in adults and children (aged 6 years and older) in Germany and Italy under the European decentralised procedure. The German regulatory authority is acting as Reference Member State.

The successful completion of a decentralised procedure is the prior step before national marketing authorizations can be granted by the European countries and the outcome of the regulatory filing is expected to be known around the third quarter of 2023.

This submission follows the agreement with Kaken Pharmaceutical Co. Ltd. on 1 July 2021 to proceed with the marketing authorization of efinaconazole in European countries. The product has been marketed in Japan since 2014 under the trade name of Clenafin®. It has also been launched in the United States, Canada, Korea, Taiwan, Hong Kong and Macau by Kaken Pharmaceutical's partner companies under the trade name of Jublia®.

Global prevalence of onychomycosis is estimated to be around 5.5%¹ and the condition is responsible for 50% of all consultations for nail disorders². The active principle of efinaconazole, a triazole antifungal compound discovered by Kaken Pharmaceutical, is indicated for the treatment of onychomycosis, a fungal infection of the nail. Since it has low binding affinity with keratin, the main component of nails, it has superior nail-penetrating properties.

"We are pleased to have submitted the application for efinaconazole on schedule. Existing data suggest that the addition of this product to the European market will enhance the treatment options for onychomycosis and thus improve the quality of life of patients," stated Karl Ziegelbauer, Ph.D., Almirall S.A.'s Chief Scientific Officer. "This milestone demonstrates Almirall's dedication to offering innovative treatments to patients for a range of dermatological diseases and the good progress of our pipeline. We look forward to continuing this positive momentum in the rest of the year and to further unlocking its great potential."

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

Media contact:

Tinkle
Laura Blázquez
lblazquez@tinkle.es
Phone: (+34) 600 430 581

Investors' Relations contact

Almirall
Pablo Divasson del Fraile
pablo.divasson@almirall.com
Phone: (+34) 93 291 3087

Corporate Communications contact:

Almirall
Mar Ramírez
mar.ramirez@almirall.com
659 614 173

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1. Gupta AK, Mays RR, Versteeg SG, et al. Global perspectives for the management of onychomycosis. Int J Dermatol. 2018.
 2. Piraccini, B.M, Alessandrini, A. Onychomycosis: A Review. J Fungi [Internet]. 2015 Jun;1(1): 30-43. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5770011/>. doi: 10.3390/jof1010030.