

For media and investors only  
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## Almirall announces completion of decentralized regulatory approval procedure for efinaconazole in Europe

- **Efinaconazole is a triazole antifungal compound indicated for the treatment of onychomycosis, a persistent and difficult to treat fungal infection of the nail**
- **The completion of the decentralized regulatory procedure marks the final phase before European countries can grant national marketing authorizations**
- **Efinaconazole is already available in Japan, the US, Canada, Korea, Hong Kong, and Macau and in 2021 Almirall obtained exclusive rights for the development and commercialization of efinaconazole in Europe from KAKEN PHARMACEUTICAL**

**BARCELONA, Spain. October 15, 2024 – Almirall, S.A. (ALM)**, a global pharmaceutical company dedicated to medical dermatology announced today the successful completion of the decentralized regulatory procedure in Europe for efinaconazole, a triazole antifungal compound indicated for the treatment of fungal infection of the nail, known as onychomycosis, under the trade name of Jublia®.

Onychomycosis affects approximately 5.5%<sup>1</sup> of the global population and accounts for 50% of all nail disorder consultations<sup>2</sup>. It is an often persistent and difficult to treat condition with low rates of treatment success due to challenging long term adherence. The low binding affinity of efinaconazole topical to keratin, the main component of nails, allows high nail-penetrating properties supporting strong efficacy.

With the addition of this treatment, Almirall enhances its European medical dermatology portfolio and reaffirms its commitment to people living with skin infections and dermatologists by providing innovative therapeutic options that make a significant impact on their lives.

*“At Almirall, we are dedicated to medical dermatology, and to addressing unmet needs of people living with skin conditions such as persistent and difficult to treat nail infections. The completion of the decentralized regulatory procedure for efinaconazole in Europe enables European countries to approve this advanced treatment option to support people with onychomycosis. Efinaconazole as a topical treatment is a valuable addition to our expanding onychomycosis portfolio and we are looking forward to being able to offer it to European dermatologists and their patients in the near future,”* said **Almirall Executive VP of R&D and CSO Dr. Karl Ziegelbauer**.

In July 2021, Kaken and Almirall entered into a **license and distribution agreement**, granting Almirall the exclusive rights for the development and commercialization of this topical formulation in Europe.

The product has been marketed in Japan since 2014 under the trade name Clenafin®. It has also been launched in the United States, Canada, Korea, Hong Kong, and Macau by Kaken Pharmaceutical's partner companies under the trade name Jublia®.

The successful completion of the decentralized procedure is the final step before national marketing authorizations can be granted by European countries. Work with the national regulatory authorities is now underway, and marketing authorizations are expected within H1 2025.

### About Almirall

Almirall is a global pharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We are at the forefront of science to deliver ground-breaking,

differentiated medical dermatology innovations that address patients' needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2023: €898.8 MM, 1900 employees globally). Almirall products help to improve the lives of patients every day and are available in over 100 countries.

For more information, please visit <https://www.almirall.com/>

**Corporate Communications:**  
[corporate.communication@almirall.com](mailto:corporate.communication@almirall.com)  
Phone: (+34) 659 614 173

**Investor Relations**  
[investors@almirall.com](mailto:investors@almirall.com)  
Phone: (+34) 93 291 30 87

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  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.