



PRESS RELEASE

## National approval for MOB-015 in all 13 countries

**STOCKHOLM, May 6<sup>th</sup>, 2024, Moberg Pharma AB (OMX:MOB) hereby announces that MOB-015 has received national approvals for all countries included in the decentralized procedure. MOB-015 is thus approved for the treatment of mild to moderate fungal infections of the nails in adults in 13 European countries.**

National approvals follow the completion of the decentralized procedure with a positive result where MOB-015 is recommended for approval in 13 European countries, see press release from June 28<sup>th</sup>, 2023. The following EU countries are included: Austria, Belgium, Czech Republic, Denmark, Finland, France, Hungary, Ireland, Italy, Netherlands, Norway, Spain and Sweden.

MOB-015 can be obtained with a prescription (Rx) in the Czech Republic, Denmark, Finland, France, Ireland and Spain, while it's approved as a non-prescription medicinal product, i.e. over-the-counter (OTC) in Austria, Belgium, Hungary, Italy, the Netherlands, Norway and Sweden.

*"It is gratifying to see that as many as seven countries have issued approvals for OTC sales right from the start, as the largest sales volumes in Europe are expected to come from non-prescription sales. I'm delighted to conclude the series of national approvals with OTC approval for Italy, one of the largest nail fungus markets in Europe", says Anna Ljung, CEO of Moberg Pharma AB.*

**For additional information, please contact:**

Anna Ljung, CEO, telephone: +46 707 66 60 30, E-mail: [anna.ljung@mobergpharma.se](mailto:anna.ljung@mobergpharma.se)

**About this information**

The information was submitted for publication, through the agency of the contact person set out above, on May 6<sup>th</sup>, 2024, at 3.30 pm CEST.

**About MOB-015 and Onychomycosis**

Approximately 10% of the general population suffer from onychomycosis and a majority of those afflicted go untreated. The global market opportunity is significant with more than hundred million patients worldwide and a clear demand for better products. Moberg Pharma estimates the annual worldwide peak sales potential for MOB-015 to be in the range of USD 250-500 million.

MOB-015 is an in-house developed topical formulation of terbinafine, enabling effective concentrations of terbinafine to the nail and nail bed while avoiding the risk of systemic exposure seen with oral terbinafine use. Oral terbinafine is currently the gold standard for treating onychomycosis but associated with safety issues, including drug interactions and liver damage. MOB-015 has been granted marketing authorization in 13 countries and is launched during spring 2024 in Sweden under the brand name Terclara®. The approval is supported by two Phase 3 trials where MOB-015 demonstrated superior levels of mycological cure (76% vs up to 42% for comparators), and a significantly better complete cure rate compared to vehicle, without any serious adverse reactions.

**About Moberg Pharma, [www.mobergpharma.com](http://www.mobergpharma.com)**

Moberg Pharma AB (publ) is a Swedish pharmaceutical company focused on commercializing proprietary innovations based on drug delivery of proven compounds. The Company's asset, MOB-015, is a novel topical treatment for onychomycosis with market approval in 13 EU countries. MOB-015 is available in Sweden under the brand name Terclara®. Data from phase 3 clinical trials in more than 800 patients for MOB-015 indicate that the product has the potential to become the future market leader in onychomycosis. Moberg Pharma has agreements with commercial partners in place in various regions including Europe and Canada. Moberg Pharma is headquartered in Stockholm and the Company's shares are listed on the Small Cap list of the Nasdaq Stockholm (OMX: MOB).