



PRESS RELEASE

## Moberg Pharma has completed enrollment to the Phase 3 study for MOB-015 in North America

STOCKHOLM, October 6<sup>th</sup>, 2023, Moberg Pharma AB (OMX: MOB) has completed the recruitment of 384 patients with onychomycosis (nail fungus) for the ongoing MOB-015 phase 3 study in North America. The aim is to provide a pivotal part of the clinical data set for registration and commercialization of MOB-015 in the U.S. Topline results are expected in January 2025.

The enrollment to the North American study has now been completed with 384 patients randomized at 33 sites in the U.S. and Canada. Topline results are expected in January 2025. The patients are evaluated over 52 weeks and the primary endpoint is the proportion of subjects achieving complete cure of their target nail. The study design builds on the experience gained from the previous Phase 3 studies. Moberg Pharma cooperate with the same CRO, lead investigator and successful sites from the previous North American study. The purpose of the study is to facilitate market approval in the US as well as strengthen the product's clinical evidence and marketing claims globally.

*"Completing the enrollment in North America well ahead of year-end is an important milestone and the result of excellent teamwork and committed investigators. I am very pleased with the progress and the rigorous screening process and positive collaborative atmosphere which increases the probability of strong phase 3 results",* says Anna Ljung, CEO of Moberg Pharma AB.

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### **About this information**

This information is information that Moberg Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, on October 6<sup>th</sup>, 2023, at 8.00 am CEST.

### **About MOB-015 and Onychomycosis**

Approximately 5-10% 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 recently been granted its first marketing authorization, and 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, for which the first market approval has recently been obtained. 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).