



## PRESS RELEASE

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

**STOCKHOLM, September 11<sup>th</sup>, 2018, Moberg Pharma AB (OMX: MOB) has completed the recruitment of 365 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. Topline results are expected in the fourth quarter of 2019.**

Phase 3 studies for MOB-015 are progressing in the EU and North America evaluating the efficacy and safety of MOB-015, Moberg Pharma's proprietary topical formulation of terbinafine. The primary endpoint for both trials is the proportion of subjects achieving complete cure of their target nail at 52 weeks.

The enrollment to the North American study has now been completed with 365 patients randomized at 32 sites in the U.S. and Canada. Topline results from the North American Phase 3 study are expected in the fourth quarter of 2019.

*“Completing the enrollment in North America is an important milestone and the result of excellent work from the team. I am very pleased with the progress and the rigorous screening process which increases the probability of strong phase 3 results”, says Peter Wolpert, Moberg Pharma's CEO.*

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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 person set out above, at 8.30 a.m. CET on September 11<sup>th</sup>, 2018.

#### **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 peak sales potential for MOB-015 to be in the range of \$250 - 500 million.

MOB-015 is an internally developed topical formulation of terbinafine based on Moberg Pharma's experience from its leading OTC product Kerasal Nail®/Emtrix®. Oral terbinafine is currently the gold standard for treating onychomycosis but associated with safety issues, including drug interactions and liver damage. For many years, developing a topical terbinafine treatment without the safety issues of oral terbinafine has been highly desirable, but unsuccessful due to insufficient delivery of the active substance through the nail.

In a previous phase 2 study, MOB-015 demonstrated delivery of high microgram levels of terbinafine into the nail and through the nail plate into the nail bed. Mycological cure of 54% and significant clear nail growth was observed in patients who completed the phase 2 study. The results are remarkable, particularly when taking into account the severity of the nails included in the study – on average approximately 60% of the nail plate was affected by the infection. Plasma levels of terbinafine with MOB-015 were substantially lower than after oral administration, reducing the risk of liver toxicities observed with oral terbinafine.

MOB-015 is currently being evaluated over 52 weeks in two randomized, multicenter, controlled Phase 3 studies. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. In total, approximately 750-800 patients are expected to be enrolled in the two studies in North America and Europe.



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

Moberg Pharma AB (publ) is a rapidly growing Swedish pharmaceutical company with OTC sales operations in the U.S. and a distributor network in more than 40 countries. The company's portfolio includes the OTC brands Kerasal®, Kerasal Nail®, New Skin®, Dermoplast® and Domeboro®. Kerasal Nail® (Emtrix®, Zanmira® or Nalox™ in certain markets) is a leading OTC treatment of nail disorders in the U.S., Canada as well as in several markets in EU and Southeast Asia. The company is growing organically as well as through acquisitions. Internal development programs focus on innovative drug delivery of proven compounds and include two assets in late-stage clinical development, MOB-015 (onychomycosis) and BUPI (pain management in oral mucositis). Moberg Pharma has offices in Stockholm and New Jersey and the company's shares are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm (OMX: MOB).