

PRESS RELEASE

# Moberg Pharma announces approvals to start Phase 3 study for MOB-015 in U.S. and Canada

STOCKHOLM, August 10, 2016. Moberg Pharma AB (OMX: MOB) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Investigational New Drug (IND) application and that a No Objection Letter has been received from Health Canada to begin its Phase 3 trial for MOB-015 in the treatment of onychomycosis.

This allows Moberg Pharma to start enrolling patients in the U.S. and Canada pending approval from the Institutional Review Board (IRB/independent ethics committee). The approvals concern a randomized, multicenter, vehicle-controlled Phase 3 study. The patients will be evaluated over 52 weeks and the primary endpoint will be the proportion of patients achieving complete cure of their target nail. The company expects to start enrollment in the third quarter of this year.

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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 CET on August 10, 2016.

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

Approximately 10% of the general population suffer from onychomycosis and a majority of those afflicted go untreated. The prescription market is growing rapidly after the recent introduction of new topical treatments in North America and Japan. Moberg Pharma expects the U.S. market alone to exceed \$2 billion by 2020 and 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 building on Moberg Pharma's experience from its leading OTC product Kerasal Nail<sup>®</sup>. Oral terbinafine is 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.

## About Moberg Pharma, 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<sup>®</sup>, Kerasal Nail<sup>®</sup>, Balmex<sup>®</sup>, NewSkin<sup>®</sup>, Domeboro<sup>®</sup>, Fiber Choice<sup>®</sup> and PediaCare<sup>®</sup>. Kerasal Nail<sup>®</sup> (Emtrix<sup>®</sup> or Nalox<sup>™</sup> in certain markets) is a leading OTC treatment of nail disorders in the U.S., Canada and several EU markets and is currently being launched in Southeast Asia. The company is growing organically as well as through acquisitions. Internal development programs focuses on innovative drug delivery of proven compounds and include two clinical stage assets, 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).