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## **Moberg Pharma announces successful results for MOB-015 in a Phase II study for the treatment of onychomycosis**

**Moberg Pharma AB (OMX: MOB) announces successful top-line results from a phase II study for MOB-015 in onychomycosis (nail fungus). The primary endpoint, mycological cure after 15 months, was achieved in 54% of the patients.**

The purpose of the study was to demonstrate proof-of-concept for MOB-015 in onychomycosis. The open-label clinical study including 25 patients was conducted at Sahlgrenska University Hospital, Sweden with Professor Jan Faergemann as the coordinating investigator. Patients with onychomycosis affecting 25-75% of at least one great toe nail received treatment with MOB-015 during 12 months and were followed for a total of 15 months. The study included patients with more severe onychomycosis than recently published studies of topical treatment alternatives. Of the 24 patients who completed the study, 13 (54%) met the primary endpoint, mycological cure, defined as both negative microscopy and fungal culture after 15 months from start of treatment. The secondary endpoint, mycological cure and excellent clinical improvement or cure was observed in 7 of 24 patients (29%). Biopsies confirmed high levels of terbinafine in the nail plate and nail bed (median values 1610 and 45 ug/g, respectively). MOB015 was generally well tolerated.

*"The mycological cure rate and clinical outcome in the study are remarkable for a topical treatment. Especially since the majority of these patients had more than 50% nail involvement at inclusion. These results are promising for future phase III studies. An efficacious and safe topical terbinafine product would be highly attractive for Dermatologists worldwide",* stated Dr Jan Faergemann, M.D., Ph.D., Professor, Dermatology Unit at Sahlgrenska University Hospital.

*"The excellent phase II results exceeded our expectations. MOB-015 has the potential to become a superior and leading product in the large and growing onychomycosis market. We are now proceeding with partner discussions for further development and commercialization of MOB-015",* said Peter Wolpert, CEO of Moberg Pharma AB.

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

MOB-015 is a proprietary topical formulation of terbinafine developed by Moberg Pharma. Terbinafine is currently the most widely used oral prescription treatment for onychomycosis and was a blockbuster before patent expiry. Topical administration of terbinafine eliminates concerns of oral treatment, such as drug interactions or liver injury, but has previously not been successful due to insufficient delivery of the active substance through the nail. Preclinical and clinical data confirm that MOB-015 delivers effective levels of terbinafine through the nail and into the nail bed.

Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi that typically occurs under the toenail, though fingernails may also be affected. Approximately 10% of the general population suffers from onychomycosis. The estimated market potential exceeds USD 1 billion in the U.S. only. The untapped potential is significant since the majority of patients are untreated.

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### **About this information**

Moberg Pharma discloses this information pursuant to the Swedish Securities Markets Act and/or the Financial Instruments Trading Act. The information was submitted for publication at 08.00 am (CET) on September 17th, 2014.



#### **About Moberg Pharma**

Moberg Pharma AB (publ) is a rapidly growing Swedish pharmaceutical company with a direct sales and marketing organization in the U.S. and an extensive distributor network in more than 40 countries. The company's OTC portfolio includes the brands Kerasal<sup>®</sup>, Jointflex<sup>®</sup>, Kerasal Nail<sup>®</sup>, Domeboro<sup>®</sup>, Vanquish<sup>®</sup>, and Fergon<sup>®</sup>. Kerasal Nail<sup>®</sup> (Nalox<sup>™</sup> in certain ex-U.S. markets) is the leading product for the treatment of nail disorders in the U.S. and Nordic market. The current portfolio will be supplemented by the acquisition and in-licensing of additional products as well as product development with a focus on innovative drug delivery of proven compounds. Moberg Pharma has offices in Stockholm and New Jersey and the company's shares (OMX: MOB) are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm. For further information, please visit: [www.mobergpharma.com](http://www.mobergpharma.com).