



PRESS RELEASE

## Moberg Pharma and Bayer sign exclusive license agreement for MOB-015 in Europe

**STOCKHOLM, February 11th, 2019, Moberg Pharma AB (OMX: MOB) has signed an exclusive license agreement with Bayer for commercialization of MOB-015 in Europe. Under the agreement, Moberg Pharma is eligible to receive up to EUR 50 million contingent on development and commercial success, as well as supply fees including royalties.**

Moberg Pharma has entered into a license agreement granting the Consumer Health division of Bayer exclusive European rights to MOB-015, a new topical treatment of onychomycosis based on Moberg's patented proprietary formulation of terbinafine. Bayer will be marketing, distributing and selling MOB-015 in Europe upon completion of Phase III clinical development and registration.

*"We are thrilled to partner with Bayer for the European launch, as part of our vision of making MOB-015 the leading nail fungus treatment worldwide. This is the second major agreement for MOB-015 and a further validation of the significant market potential for our asset,"* says Peter Wolpert, Moberg Pharma's CEO.

Under the terms of the license agreement, Moberg Pharma will finalize the ongoing Phase III program, complete registration in Europe and provide supply for the product. Moberg Pharma is eligible to receive up to EUR 50 million in milestone payments, including EUR 1.5 million paid at signing. The majority of the milestone payments are contingent on sales targets, with the balance contingent on development and regulatory milestones. Moberg Pharma will also receive supply fees including royalties.

*"We are excited about the opportunity to partner with Moberg and the potential to bring this cutting-edge technology to market in order to advance one of our key categories,"* says Heiko Petersen, Head of Bayer's Global Category Business Unit Dermatology.

The European OTC market for onychomycosis drugs amounted to EUR 192 million in 2017, growing at 2.6% (Source: Nicholas Hall DB6 database, 2017 update, value in Euro @ MSP prices).

### **For additional information, please contact:**

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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, at 6.00 p.m. CET on February 11<sup>th</sup>, 2019.

### **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 internally developed topical formulation of terbinafine based on Moberg Pharma's experience from its leading OTC product Kerasal Nail<sup>®</sup>/Emtrix<sup>®</sup>. 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, including in total approximately 800 patients in North America and Europe. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. Topline results from the North American study are expected in the fourth quarter of 2019, followed by results in Europe in 2020.

**About Moberg Pharma,**

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 30 countries. The company's portfolio includes the OTC brands Kerasal<sup>®</sup>, Kerasal Nail<sup>®</sup>, New Skin<sup>®</sup>, Dermoplast<sup>®</sup> and Domeboro<sup>®</sup>. Kerasal Nail<sup>®</sup> (Emtrix<sup>®</sup>, Zanmira<sup>®</sup> or Nalox<sup>™</sup> 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). For more information, please see [www.mobergpharma.com](http://www.mobergpharma.com).