



PRESS RELEASE

## All patients in the European MOB-015 Phase 3 study have completed their last visit

**STOCKHOLM, March 23<sup>rd</sup>, 2020 - Moberg Pharma AB (publ) announces that all patients in the European MOB-015 Phase 3 study have completed their last study visit. The data collection in the study were completed without any negative impact from COVID-19. The timeline remains unchanged with topline results expected by the end of the second quarter.**

MOB-015 is a new topical treatment of onychomycosis based on Moberg's patented proprietary formulation of terbinafine. In the European study, 452 patients were initially randomized and 379 patients completed the study resulting in a drop-out rate of only 16% and avoiding any loss of data due to the current COVID-19 situation in Europe. After the last visit, nail samples are sent to a central lab for mycological testing. Data base lock and statistical analysis are on schedule and will be completed by the CRO partner.

*"We are very grateful that the data collection in the EU study was finalized without any negative impact from the COVID-19 situation in Europe. We expect to announce topline data according to plan, by the end of the second quarter"* says Anna Ljung, CEO of Moberg Pharma.

### **About the Phase 3 study in Europe**

The ongoing Phase 3 study is conducted at sites in Germany, UK and Poland and includes a total of 452 patients, 2/3 of whom received MOB-015 and 1/3 who were in the control group and received the most widely used topical treatment. The patients had at least one great toenail that was 20–60 percent affected at start of the trial. Treatment was administered once daily for 48 weeks and patients were followed up for a total of 52 weeks.

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

Approximately 10 percent 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.

MOB-015 is an internally developed topical formulation of terbinafine based on Moberg Pharma's experience from previously having developed and commercialized a leading OTC product for onychomycosis. 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. 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 more than 800 patients in North America and Europe. In December 2019, the company reported that the primary endpoint for MOB-015 was reached in the North American study. Topline results in Europe are expected by the end of the second quarter 2020.

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

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### **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 main asset, MOB-015, is a novel topical treatment for onychomycosis, with ongoing phase 3 studies covering more than 800 patients. Topline results from the North American



study are now available, followed by results from the European study expected by the end of the second quarter of 2020. The pipeline also includes the late-stage asset BUPI for pain relief in oral mucositis. Clinical data generated for both assets indicate they have the potential to become market leaders in their respective niches. Moberg Pharma is headquartered in Stockholm and the company's shares are listed on Nasdaq Stockholm (OMX: MOB).