



PRESS RELEASE

## Moberg Pharma completes enrollment for MOB-015 Phase 3 study in Europe

STOCKHOLM, March 22<sup>nd</sup>, 2019, Moberg Pharma AB (OMX: MOB) has completed the recruitment of 452 patients with onychomycosis (nail fungus) for the ongoing MOB-015 phase 3 study in Europe. Two Phase 3-studies are currently underway in North America and Europe with topline results expected in the fourth quarter of 2019 and the second quarter of 2020 respectively.

Phase 3 studies for MOB-015 are progressing in Europe 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 European study has now been completed with 452 patients randomized at 48 sites in Europe. Topline results from the European Phase 3 study are expected in the second quarter of 2020.

The North American study was fully enrolled in September 2019, with topline results expected in the fourth quarter of 2019.

*"Completing the Phase 3 enrollment for MOB-015 is truly an important milestone. I am very grateful to the team for the hard work in completing the recruitment for both studies. More than 5,000 patients have been screened to recruit 800+ patients in the rigorous screening process, ultimately increasing the probability of strong phase 3 results for MOB-015",* says Peter Wolpert, Moberg Pharma's CEO.

### For additional information, please contact:

Peter Wolpert, CEO, telephone: +1 908 432 2203, e-mail: [peter.wolpert@mobergpharma.se](mailto:peter.wolpert@mobergpharma.se)

Eleonora Stern-Nejman, Investor relations, phone: +46 701 76 22 42, e-mail: [eleonora.stern-nejman@mobergpharma.se](mailto:eleonora.stern-nejman@mobergpharma.se)

### 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 March 22<sup>nd</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 products with a better efficacy and safety profile. Moberg Pharma estimates the peak sales potential for MOB-015 to be in the range of \$250 - 500 million.

Moberg Pharma has entered two license agreements for the commercialization of MOB-015 – with Bayer AG in Europe and Cipher Pharmaceuticals in Canada. MOB-015 is currently being evaluated in more than 800 patients in two randomized, multicenter, controlled Phase 3 studies in North America and Europe. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail over 52 weeks.

MOB-015 is an internally developed topical formulation of terbinafine based on Moberg Pharma's experience from developing a leading OTC product in the category. Oral terbinafine is currently the gold standard for treating onychomycosis but associated with risk for safety issues, including drug interactions and liver damage. For many years, developing a topical terbinafine treatment without the safety risks 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, in patients with severely affected nails, MOB-015 demonstrated delivery of high microgram levels of terbinafine through the nail plate into the nail bed as well as into the nail, excellent mycological cure rates and clear nail growth. Plasma levels of terbinafine with MOB-015 were substantially lower than after oral administration, reducing the risk of liver toxicities observed with oral terbinafine.



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

Moberg Pharma AB (publ) is a Swedish pharmaceutical company that, as of April 1<sup>st</sup> 2019, focuses solely on innovative drug delivery of proven compounds, including two assets in late-stage clinical development, MOB-015 (onychomycosis) and BUPI (pain management in oral mucositis). The company's OTC business is currently under divestment, comprising direct sales of OTC-brands in the U.S. and distributor sales in more than 30 countries in EU and Southeast Asia. The divested product portfolio is dominated by the leading OTC brand Kerasal Nail<sup>®</sup> (Emtrix<sup>®</sup>, Zanmira<sup>®</sup> or Nalox<sup>™</sup>) treating nail disorders. Other brands are New Skin<sup>®</sup>, Dermoplast<sup>®</sup> and Domeboro<sup>®</sup>. Moberg Pharma's shares are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm (OMX: MOB) and the headquarters are located in Stockholm.