



PRESS RELEASE

Moberg Pharma provides update on timeline for MOB-015

STOCKHOLM, November 8th 2017, Moberg Pharma AB (OMX: MOB) today announced an updated timeline for patient recruitment to the ongoing Phase 3 studies for MOB-015, with recruitment in the North American study expected to be completed during the summer 2018 and recruitment in the European study expected to be completed in the second half of 2018.

Recruitment to the Phase 3 studies for MOB-015, a proprietary topical formulation of terbinafine for the treatment of onychomycosis, is underway simultaneously in North America and Europe. However, a significantly higher screening failure rate than expected has caused delays and increased costs. A rigorous screening process is basically positive, as it is critical to obtaining robust study results. But since the progress of the studies has been unsatisfactory we have initiated an extensive action program.

Our current assessment is, that recruitment in North America will be completed in the summer of 2018 and recruitment in Europe will be completed in the second half of 2018. Topline results are expected approximately 15 months after completion of recruitment for each study. We expect to complete both studies without additional external financing.

"MOB-015 is our most valuable pipeline asset and we see a potential to meet the significant unmet needs of patients suffering from nail fungus. The team is working hard to balance a rigorous screening process while maintaining an aggressive timeline for completing the enrollment. The rigorous screening process is instrumental for the outcome of the Phase 3 studies and to achieve strong claims", commented Peter Wolpert, Moberg Pharma's CEO.

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 need for better products. Moberg Pharma 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[®]/Emtrix[®]. 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.

MOB-015 is currently being evaluated over 52 weeks in two randomized, multicenter, controlled Phase 3 studies. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. In total, approximately 750-800 patients are expected to be enrolled in the two studies in North America and Europe.

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.

For additional information, please contact:

Peter Wolpert, CEO, telephone: +1 908 432 22 03 (us), +46 707 35 71 35 (se), e-mail: peter.wolpert@mobergpharma.se
Anna Ljung, CFO, telephone: +46 707 66 60 30, e-mail: anna.ljung@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 November 8th, 2017.

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[®], Kerasal Nail[®], Balmex[®], New Skin[®], Dermoplast[®] and Domeboro[®]. Kerasal Nail[®] (Emtrix[®], Zanmira[®] or Nalox[™] 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).