



PRESS RELEASE

Moberg Pharma replaces CRO in Phase 3 studies for MOB-015

STOCKHOLM, November 20th, 2017, Moberg Pharma AB (OMX: MOB) is replacing the CRO with primary responsibility for the two ongoing Phase 3 studies for MOB-015. This is a key step in the extensive action program now underway to finalize patient recruitment, with the goal of delivering strong topline results in 2019 without further external financing. The actions fall within the updated timeline presented on November 8, 2017, which allows for handoff to a new CRO.

Two parallel Phase 3 studies for MOB-015 have been underway in the EU and North America for the last year. The CRO (contract research organization) with primary responsibility for the studies has also coordinated the work with subcontractors on both continents. Recruitment to both studies has to date incurred significant delays, primarily in Europe. Moberg Pharma has therefore decided to replace the CRO with primary responsibility with TFS International, which has now been tasked with finalizing the European study. TFS has extensive expertise within dermatology and nail fungus, a broader presence in Europe and a concrete strategy to accelerate patient recruitment, making us confident in their capability to successfully finalizing the study. In North America, Moberg Pharma will work directly with Novella Clinical, previously serving as a subcontractor, which we expect shall streamline the process compared to the former setup.

This action is included in the previously announced timeline, according to which patient recruitment will be completed in North America in the summer of 2018 and in Europe in the second half of 2018. Topline results are expected approximately 15 months after completion of recruitment for each study. We are confident as well that both studies can be completed without additional external financing.

"Replacing the CRO is a key step in the extensive action program that was recently announced. TFS has the capability to accelerate patient recruitment and finalizing the European study. Combined with the new setup in North America, we are confident in achieving strong Phase 3 results within the timeline." commented Peter Wolpert, Moberg Pharma's CEO.

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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 person set out above, at 1.00 p.m. (CET) on November 20th, 2017.

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.

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. 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.

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).