PRESSM RELEASE
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Moberg Pharma announces regulatory submission to FDA for North American phase 3 study

Moberg Pharma AB (publ) has submitted regulatory filing for the next clinical Phase 3 study for MOB-015 (nail fungus treatment) to the U.S. Food and Drug Administration (FDA).

The randomized, multicenter, vehicle-controlled Phase 3 study will include approximately 350 patients in North America. The patients will be evaluated over 52 weeks and the primary endpoint will be the proportion of subjects achieving complete cure of their target nail. The company expects to start enrolling patients in the second quarter of this year. The study design builds on the experience gained from the previous Phase 3 studies. Moberg Pharma will cooperate with the same CRO, lead investigator and successful sites from the previous North American study. The purpose of the new study is to facilitate market approval in the US as well as strengthen the product's clinical evidence and marketing claims globally.

"*For market approval in the U.S., the FDA typically requires two studies that demonstrate statistical superiority of the active drug versus its vehicle (placebo) for the primary endpoint. The first study was successfully completed in 2019 and we are now conducting the second study. The North American study is a top priority in the near future, in addition to the registration process in Europe where our goal is to receive first market approval and launch in 2023*", says Anna Ljung, CEO of Moberg Pharma AB.

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About this information
The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 a.m. CET on March 18th, 2022.

About Moberg Pharma, www.mobergpharma.se
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. Data from phase 3 clinical trials in more than 800 patients for MOB-015 indicate that the product has the potential to become the future market leader in onychomycosis. Moberg Pharma has agreements with commercial partners in place in Europe and Japan, among others, and the company's goal is to receive its first market approval and launch MOB-015 in 2023. Moberg Pharma is headquartered in Stockholm and the company's shares are listed on the Small Cap list of the Nasdaq Stockholm (OMX: MOB).