PRESS RELEASE

Moberg Pharma comments on the results of the North American Phase 3 study with MOB-015

STOCKHOLM, December 12th, 2019, Moberg Pharma AB (OMX: MOB): On Monday the topline results were presented from the first study in the Phase 3 program for MOB-015, where the primary endpoint and the two key secondary endpoints were met. Since the results are somewhat contradictory and the company has received many questions, we want to clarify the various study parameters as well as our view of the current status and next step.

The company's comment on the results

On Monday December 9th, the topline results were presented from the first of two clinical studies in the Phase 3 program for MOB-015. The primary endpoint was met and provided that the second study also produces positive results, both studies could form a basis to register the product. However, the outcome of the first study as a whole is more difficult to interpret.

Treatment of onychomycosis involves two main parameters: curing the fungal infection (mycological cure) and restoring the nail's normal appearance (clinical cure), where the former is objectively determined through laboratory results and the latter is determined subjectively by the investigators. The fact that MOB-015 achieved mycological cure in 70 percent of the patients in this study is exceptional and exceeded our expectations. The study also showed that MOB-015 significantly outperformed the vehicle[1] for the key endpoints and confirmed the product's ability to rapidly achieve visible improvement. Already by the first follow-up visit, 83 percent of the patients reported improvement. The investigators' clinical assessment of the nails' appearance was not as positive, however.

The outcome of the study is surprising, since a high mycological cure is normally over time followed by normalization of the nail's appearance.

In collaboration with leading experts, the company is now fully engaged in reviewing the study results in detail, including all nail photos, to better understand the reasons for the outcome. We also expect further insight from the ongoing European study, where MOB-015 is being compared to the most commonly used topical treatment. Lessons learned from both studies can later be used to optimize how the product will be used.

It is too early to draw any firm conclusions from the first study in the Phase 3 program. The company plans to provide an update once additional information is available.

Definitions of endpoints and topline results

Complete cure - Primary endpoint

The primary endpoint in the study is complete cure at week 52, which is a composite measure of *mycological cure* and *clinical cure*. The primary endpoint was met, since significantly more patients in the MOB-015 group – 4.5 percent – reached complete cure compared to none in the control group (p=0.019).

Mycological cure

Mycological cure is an objective measure composed of two laboratory results: fungal culture and KOH microscopy. The physician/nurse takes nail clippings, which are sent to a central laboratory for analysis. If fungus cannot be cultured from the sample and fungal elements subsequently cannot be seen in a microscopic examination, the nail is mycologically cured (fungus free). A 70 percent mycological cure after one year is remarkably high for a topical treatment and on par with the best oral treatment. Mycological cure is defined in the study as a key secondary endpoint.

Clinical cure

Clinical cure is a subjective measure where an experienced physician at each clinic performs a visual assessment of how

[1] Vehicle – The MOB-015 product without its active substance, terbinafine

much of the nail is affected by onychomycosis. No signs of infection should be visible on the nail to achieve complete cure. This endpoint is difficult to determine and takes different lengths of time to achieve for different nails, depending among other things on the condition of the nail at treatment start. Data for clinical cure has not yet been reported, since it was not included in the initial topline data but will be delivered in the complete data package.

Treatment success
Since the difficulty in achieving complete cure in 52 weeks is well known, Treatment success is also reported, a composite measure of mycological cure combined with a clinical assessment that the nail should be clear or almost clear (up to 10 percent affected nail area). Treatment success was reached in 15.4 percent of the patients and was significantly better than the control group (p=0.0018). Treatment success is defined in the study as a key secondary endpoint.

The patient's own assessment
The patient's own assessment is a subjective measure where the patient assesses the improvement in the nail according to a standardized scale. Of the patients who completed the study, 33 percent reported that their treated toenails were completely cured or almost cured. In addition, 83 percent of the patients reported a visible improvement after just twelve weeks of treatment.

About the Phase 3 study in North America
The recently completed Phase 3 study was conducted at 32 sites in the U.S. and Canada and included a total of 365 patients, 246 of whom received MOB-015 and 119 who were in the control group and received the vehicle. The patients had at least one great toenail that was 20–60 percent affected. Treatment was administered once daily for 48 weeks and patients were followed up for a total of 52 weeks. A second Phase 3 study is currently underway in Europe comprising 452 patients and is expected to be finalized in spring 2020.

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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 persons set out above, at 8.00 a.m. CET on December 12th, 2019.

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. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. Topline results from the North American study are now available, followed by results in Europe expected in the second quarter of 2020.

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, with ongoing phase 3 trials in more than 800 patients. Topline results from the North American study are now available, followed by results in Europe expected in 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 the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm (OMX: MOB).