PRESS RELEASE
STOCKHOLM, DECEMBER 10th 2024

Moberg Pharma reports topline data in the North American phase 3 study and will regain rights to MOB-015 in EU

Moberg Pharma AB (OMX: MOB) announces that MOB-015 (topical terbinafine) did not meet the primary endpoint in the phase 3 study using 8 weeks of daily dosing followed by weekly maintenance dosing. The company's focus going forward will be on the effective daily dosing regimen approved in 13 EU countries.

In line with previous communication on September 13th 2024, the results now confirm that the primary endpoint was not met. The North American Phase 3 study was conducted at 33 study centers in the US and Canada, including a total of 384 patients, 260 patients receiving MOB-015 and 124 patients receiving vehicle. The study differs from previous studies with MOB-015, which is the basis for drug approval in 13 EU countries, by reducing the dosage – 8 weeks daily dosing followed by weekly maintenance treatment for 40 weeks, compared to daily dosing throughout the entire treatment period.

The expectation on the North American study was to strengthen the product claims further. With a positive outcome, it would have been a competitive advantage to only need weekly treatments after the initial phase. The study results establish the fact that daily treatment for only 8 weeks is insufficient and that a longer daily treatment regimen, as approved in EU, is required for topical treatment of onychomycosis.

Bayer Consumer Health has conducted an extensive review on its pipeline and decided to stop the upcoming launch of MOB-015 due to strategic reasons and the topline data received. Therefore, Bayer and Moberg Pharma has expressed a mutual intent to terminate the license agreement whereby Moberg Pharma regains the full rights for MOB-015 in EU and retains milestone revenues already paid by Bayer.

We remain confident of the competitive profile of MOB-015, as seen in the recent successful launch in Sweden where MOB-015 under brand name Terclara® is the clear market leader and have grown the market with 44%[1]. Having 76% mycological cure with daily dosing is outstanding for a topical onychomycosis drug and the success in Sweden confirms that the marketing message and claims of the product resonates well with consumers.

Our intended strategy has been to combine direct sales in the U.S. with strategic collaborations in other major territories. Given the data, we are reassessing our plans for the US and shifting our focus to the European market, which presents the greatest opportunities for growth. Moberg Pharma aims to secure a larger share of the value chain in Europe by taking an active role in the commercialisation and establishing a stronger direct presence, including ownership of the brand. To support this strategy, Moberg Pharma is in discussions with potential partners in Europe to identify an optimal path forward.

"*While the topline results of the North American study creates new conditions, the data reinforce the superior efficacy of daily dosing, which is already approved and thriving in the Swedish market. We now have the opportunity to establish a stronger presence in EU and capturing a larger part of the value chain for this great product*", says Anna Ljung, CEO of Moberg Pharma AB.

The primary endpoint, the proportion of patients achieving complete cure of their target toenail at 52 weeks, was achieved in 1.5 percent of the patients for MOB-015 and in none of the patients receiving vehicle (p=ns). Complete cure is a composite endpoint that requires both a completely clear nail and mycological cure. Mycological cure, defined as both negative KOH and negative dermatophyte culture, was achieved in 25.0 percent of the patients on active treatment (p=0.030). Treatment success (mycological cure and almost or completely clear great toenail) assessed by the investigator was achieved in 11.2 percent of the patients in active treatment (p=0.003).

MOB-015 was generally well tolerated. No safety issues were identified in the trial and no serious adverse events related to MOB-015 were reported.

[1] Source: IQVIA MIDAS, Pharmacy Sell-Out data, April-September 2024

On December 11th, 2024, at 12:00 pm CEST, Moberg Pharma's CEO Anna Ljung, CMO Anders Bröijersén, and CSO Amir Tavakkol will answer questions during a telephone conference. The Q&A session will be held in English.

To participate in the conference, please dial in on one of the numbers below before the conference starts:
SE: +46 8 10 884 80 16. Access Code: 972764
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About this information
This information is information that Moberg Pharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication at 8.30 pm CEST on December 10th, 2024, through the contact persons above.

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 better products. MOB-015 is an in-house developed topical formulation of terbinafine, enabling effective concentrations of terbinafine to the nail and nail bed while avoiding the risk of systemic exposure seen with oral terbinafine use. Oral terbinafine is currently the gold standard for treating onychomycosis but associated with safety issues, including drug interactions and liver damage. MOB-015 has been granted marketing authorization in 13 countries. The approval is supported by two Phase 3 trials where MOB-015 demonstrated superior levels of mycological cure (76% vs up to 42% for comparators), and a significantly better complete cure rate compared to vehicle, without any serious adverse reactions.

About Moberg Pharma, www.mobergpharma.com
Moberg Pharma AB (publ) is a Swedish pharmaceutical company focused on commercializing proprietary innovations based on drug delivery of proven compounds. The company's drug MOB-015 is a novel topical treatment for onychomycosis (nail fungus) with market approval in 13 EU countries. MOB-015 is sold in Sweden under the brand name Terclara® and is available at all pharmacy chains. Phase 3 clinical trials for MOB-015 involving more than 800 patients 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 various regions including Europe and Canada. Moberg Pharma is headquartered in Stockholm and the company's shares are listed under Small Cap on Nasdaq Stockholm (OMX: MOB).