PRESS RELEASE

Expert evaluation clarifies Phase 3 results and provides strong support for MOB-015

STOCKHOLM, January 22nd, 2020. Moberg Pharma AB (OMX: MOB) has now completed the expert evaluation of the results from the North American Phase 3-study. The analysis conducted with key opinion leaders (KOLs) has confirmed the validity of the data presented in December 2019 and increased the understanding of the study outcomes. Key conclusions include: i) MOB-015 delivers a very high mycological cure rate that compares favorably to oral antifungal drugs with the added advantage of an earlier onset of action; ii) Confirmation that the proprietary vehicle technology increases the hydration and permeability of the nail plate enabling efficient terbinafine delivery, however it also confounds the assessment of clinical cure and complete cure and iii) A likely solution to the problem – a shorter dosing regimen with the potential to deliver superior complete cure rates.

In December 2019, the topline results were presented from the first of two clinical studies in the Phase 3 program for MOB-015, meeting the primary endpoint. Mycological cure (eradicating the fungal infection) was achieved in 70 percent of the patients, which is substantially higher than reported for other topical treatments (30-54 percent). Furthermore, 83 percent of the patients reported visible nail improvement by the first follow-up visit. However, despite the strong mycological cure and rapid visible improvement, a lower than expected complete cure rate of 4.5 percent (normal looking nails and negative fungal culture) was reached, which was surprising because a high mycological cure is typically followed by clinical cure and the combined endpoint complete cure.

The company has since engaged leading key opinion leaders to help Moberg Pharma verify the results and better understand the reasons for the conflicting outcome. The key question for the KOLs has been to help the company understand why the high mycological cure did not result in high complete cure. The KOLs found the mycological cure rate of MOB-015 remarkable and very exciting, as the first topical treatment with mycological cure rate at the same level as oral terbinafine, the current gold standard for treatment of onychomycosis. Furthermore, the onset of the antifungal effect is more rapid than for oral terbinafine, with MOB-015 delivering 55 percent mycological cure at 6 months (vs 40 percent for oral terbinafine) and 37 percent already at 3 months (vs 15 percent for oral terbinafine). In addition, after detailed analysis of the data and individual photos from the study, the KOLs concluded that while the vehicle technology enables high delivery of terbinafine through the nail plate, its hydrating properties also cause whitening/discoloration in nails. This phenomenon is transient but makes the assessment of clinical cure challenging and contributed to the low complete cure rate observed.

A solution to the problem was identified in collaboration with the KOLs. Analysis of the available clinical data, including data from the recent Phase 3 study, earlier Moberg Pharma studies as well as from the literature, the KOLs as well as the company experts conclude that the complete cure rate for MOB-015 likely can be increased substantially by a shorter treatment period followed by a maintenance period.

The current gold standard in onychomycosis is three months treatment with oral terbinafine. Before this phase 3 trial for MOB-015, it appeared unrealistic that a topical treatment would achieve 70 percent mycological cure rate - the same level as oral terbinafine. Treatment with MOB-015 resulted in 1000x higher amounts of terbinafine in the nail plate and 40x higher in the nail bed compared to oral terbinafine treatment. Considering also the rapid onset and high mycological cure rate, the data indicates that a shorter dosing regimen has the potential to increase complete cure rates. The KOL evaluation concludes that once-daily treatment period for not more than three months, followed by maintenance dosing once weekly until week 48 should maintain high concentrations of terbinafine in the tissue, while reducing the hydrating effects after the initial treatment phase and thus the impact on the clinical cure assessment at week 52.

"*The high mycological cure rate demonstrated is very impressive and given the rapid onset of the antifungal effect, MOB-015 offers exciting benefits. I will definitely use it for my patients. A higher complete cure rate is likely to be achieved with a shorter treatment period and this would also be much more attractive to patients*", said Dr Boni Elewski, Professor and Chair of the Department of Dermatology, University of Alabama.

"*I am a strong supporter of this concept. With an optimized dosing regimen this product has great potential and may become the preferred therapeutic option, not only for monotherapy, but also as maintenance therapy to reduce recurrence after oral treatment*", said Dr Aditya Gupta, Professor, Department of Medicine, University of Toronto.

"*Based on decades of experience with terbinafine and the excipients used in MOB-015, I believe a shorter treatment period has the potential to provide higher complete cure rates. Killing the fungus is the driver of also reaching complete cure",* said Dr Jan Faergemann, Professor in Dermatology, Sahlgrenska Academy, University of Gothenburg, Sweden.

Since the primary endpoint as well as secondary endpoints were met in the North American trial and provided that the second study also produces positive results, these studies could form a basis to register the product. The timing to optimize the dosing regimen will depend on the outcome of the EU trial.

"*From a medical and commercial perspective, a regimen with daily dosing for up to three months followed by less frequent treatment, is highly attractive and further improves the target product profile of MOB-015. This is further supported by U.S. market data indicating that real-life usage of current topicals on average is 3-4 months, despite being labeled for 48 weeks' daily treatment*", said Dr. Amir Tavakkol, CSO of Moberg Pharma AB.

"*We are very grateful for the thorough analysis of the key opinion leaders which not only shed light on the conflicting data points, but also strengthened our conviction that MOB-015 has the potential to become the future market leader in onychomycosis",* said Anna Ljung, CEO of Moberg Pharma AB.

Press conference
An investor Q&A will be held in a telephone conference today, January 22, 2020, at 3:00 p.m. CET.
Dial-in: SE: +46 8 505 583 53, US: +1 833 526 83 80

Definitions of endpoints and topline results in the North American Phase 3 study for MOB-015

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 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 time to achieve for different nails, depending among other things on the condition of the nail at treatment start. The clinical cure was identical to the complete cure.

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. The setup in the European study in similar to the North American study, the only difference is that instead of being vehicle-controlled, in EU, MOB-015 is compared head to head against the most widely used topical treatment.

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About this information
This is information that Moberg Pharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication, through the contact persons set out above at 08.00 a.m. CET on January 22nd, 2020.

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 main asset, MOB-015, is a novel topical treatment for onychomycosis, with ongoing phase 3 studies covering more than 800 patients. Topline results from the North American study are now available, followed by results from the European study 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 Nasdaq Stockholm (OMX: MOB).