PRESS RELEASE

Moberg Pharma meets primary endpoint for MOB-015 in a Phase 3 study for the treatment of onychomycosis

STOCKHOLM, December 9th, 2019, Moberg Pharma AB (OMX: MOB) announces that MOB-015 (topical terbinafine) met the primary endpoint as well as key secondary endpoints in the North American Phase 3 study including 365 patients with mild to moderate toenail onychomycosis (nail fungus). At week 52, significantly more patients reached complete cure for MOB-015 than for vehicle (p=0.019), following 48 weeks of daily treatment.

The purpose of this randomized, multicenter, controlled clinical Phase 3 study was to evaluate the efficacy and safety of MOB-015 in patients with mild to moderate distal subungual onychomycosis (DSO) affecting 20-60 percent of the great toenail. The study was conducted at 32 sites in the U.S. and Canada and included 365 patients, 246 patients receiving MOB-015 and 119 patients receiving vehicle. Patients received treatment during 48 weeks and had the last follow-up assessment at week 52.

The primary endpoint, the proportion of patients achieving complete cure of their target toenail at 52 weeks, was achieved in 4.5 percent of the patients for MOB-015 and in none of the patients receiving vehicle (p=0.019). 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 70 percent of the patients (p<0.0001). Treatment success (mycological cure and almost or completely clear great toenail) assessed by the investigator was achieved in 15.4 percent of the patients (p= 0.0018). In the patients' self-assessments, a clear majority (83 percent) of the patients completing the study reported improvement from MOB-015 as early as 12 weeks after starting treatment, and at week 52, 33 percent reported their treated toenails were cured or almost cured.

MOB-015 was generally well tolerated. The number of patients with treatment related adverse events was similar for MOB-015 and vehicle, and consistent with our past experience. No safety issues were identified in the trial and no serious adverse events related to MOB-015 were reported.

"The mycological cure rate in the study is remarkably high for a topical treatment. We believe this is due to fungicidal activity of terbinafine in MOB-015. We would normally expect more patients reaching complete cure following eradication of the infection in such a clear majority of the patients. This will be further investigated and we expect additional insights from the European study (n=452), in which MOB-015 is compared head to head against the most widely used topical treatment. A safe, efficacious topical terbinafine product eradicating the infection and progressing healthy nail growth for many patients is highly attractive for practicing physicians worldwide", stated Amir Tavakkol, Senior Advisor R&D at Moberg Pharma AB.

"To cure 70 percent of the patients from their fungal nail infection is a superior result and better than expected for a topical product. We were however expecting a higher complete cure rate, following the high mycological cure, despite the well-known challenges in demonstrating completely cleared nails at 52 weeks even after the fungal infection is cured. The study confirms the rapid visible improvement experienced by patients, where four out of five patients reported some improvement already at the first follow up visit, and at the end of the study, 33 percent of patients rated their nail to be cured or almost cured", said Anna Ljung, CEO of Moberg Pharma AB.

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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 9th, 2019.

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 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.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 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).