PRESS RELEASE

Moberg Pharma meets primary endpoint in the European Phase 3 study

STOCKHOLM, June 25th, 2020, Moberg Pharma AB (OMX: MOB) announces that MOB-015 (topical terbinafine) met the primary endpoint in the European Phase 3 study including 452 onychomycosis patients, showing non-inferiority versus topical ciclopirox. Mycological cure was achieved in 84 percent of patients, which is unprecedented for a topical treatment and even higher than reported for oral treatments. The pattern is consistent with the results from the North American Phase 3 study, with low complete cure rates despite the high mycological cure rates. Moberg Pharma will discuss next steps with partners and regulatory agencies.

This is the second Phase 3 study for MOB-015. The study was conducted at sites in Germany, the U.K. and Poland and included 452 patients with mild to moderate distal subungual onychomycosis (DSO) affecting 20-60 percent of the great toenail. Patients were randomized to daily treatment for 48 weeks, either with MOB-015 or 8 percent ciclopirox, the most widely used topical drug for onychomycosis.

The primary endpoint, the proportion of patients with complete cure of their target toenail at 52 weeks, was achieved in 1.8 percent of patients receiving MOB-015 and in 1.6 percent of patients receiving ciclopirox. Mycological cure was achieved in 84 percent of patients for MOB-015, superior to 42 percent for ciclopirox. Treatment success (mycological cure and almost or completely clear great toenail) was reached for 21.9 percent of the MOB-015 patients versus 18.9 percent in the ciclopirox group. The study confirmed early onset of action with 46 percent of patients mycologically cured already at 12 weeks.

MOB-015 was generally well tolerated. The number of patients with treatment related adverse events was consistent with previous trials and no serious adverse events related to MOB-015 were reported.

A detailed analysis of photos and data has been conducted with key opinion leaders (KOLs) providing consistent conclusions across both studies; i) MOB-015 delivers a very high mycological cure rate, comparing favorably to oral antifungal drugs with the advantage of earlier onset of action; and ii) the vehicle enables efficient terbinafine delivery but also causes transient whitening/discoloration in nails which contributes to the low complete cure rate reported.

"The superior mycological cure rate for MOB-015 has now been confirmed in two pivotal studies, showing that MOB-015 has the potential to become the future market leader in onychomycosis. We look forward to finding the best path to approval in dialogue with our partners and regulatory agencies", 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 June 25th, 2020.

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 has recently been 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 was met in both studies, the proportion of patients achieving complete cure of their target nail.

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 recently completed phase 3 trials in more than 800 patients. 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).