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ASIA EDITION

DongKoo inks agreement to market onychomycosis drug

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The Korean market for topical drugs for onychomycosis amounts to $40 million

Swedish firm Moberg Pharma AB has signed a distribution agreement with South Korea headquarteredDongKoo Bio & Pharma Co., Ltd for MOB-015 in the Republic of Korea. Under the agreement DongKoo is granted exclusive rights to market and sell MOB-015 in the Republic of Korea. Moberg Pharma assumes production and supply responsibility.

DongKoo will conduct registration activities in the Republic of Korea, and will be marketing, distributing and selling MOB-015 in the Republic of Korea upon completion of registration.

"*This is the fourth commercial agreement for MOB-015, this time with the market leader in dermatology in Korea with excellent coverage of the dermatology clinics. We look forward to work with DongKoo and making MOB-015 available in Korea, contributing to our vision of making MOB-015 the leading nail fungus treatment worldwide*", says Anna Ljung, CEO of Moberg Pharma.

According to Moberg Pharma's market intelligence, the Korean market for topical drugs for onychomycosis amounts to$40 million (rolling 12m ending June 2019).

Approximately 10% of the general population suffer from onychomycosis (fungal nail infection) 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. Moberg Pharma estimates the annual worldwide peak sales potential for MOB-015 to be in the range of $250-500 million.

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. Mycological cure of 54% and significant clear nail growth was observed in patients who completed the phase 2 study. The results are remarkable, particularly when taking into account the severity of the nails included in the study – on average approximately 60% of the nail plate was affected by the infection. 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 expected inDecember 2019, followed by results in Europe expected in the second quarter of 2020.