



PRESS RELEASE

Moberg Pharma intends to submit a registration application in Europe in 2021

STOCKHOLM, October 14th, 2020, Moberg Pharma AB (OMX: MOB) announced today its decision to request pre-submission meetings with regulatory agencies, with the goal of submitting a registration application in the second half of 2021 in Europe.

In June, Moberg Pharma presented topline results from the second of two clinical Phase 3 studies for MOB-015. In the European study – as well as in the North American study – the primary endpoint was achieved and no serious adverse events were reported. MOB-015's superior mycological cure (percentage of patients who were fungus free) has now been demonstrated in two pivotal studies, providing further support for the company's target to make MOB-015 the future market leader in onychomycosis. Moberg Pharma will now finalize the documentation for the registration application which the company expects to submit during the second half of 2021.

"After thorough analysis of the data with our scientific advisors and partners, we see strong potential for MOB-015 and are now through submission preparations pursuing the next key steps toward market approval. There is great need for better topical treatments with the ability to really cure the fungal infection. The superior mycological cure enables a unique position for MOB-015," says Anna Ljung, CEO of Moberg Pharma.

After the European meetings, Moberg Pharma intends to discuss next steps for the US market in an advice meeting with the FDA.

For additional information, please contact:

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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 October 14th, 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.

Moberg Pharma has secured commercialization partners for MOB-015 in Europe, Japan, Canada and the Republic of Korea.

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. Mycological cure (eradicating the fungal infection) was achieved in



70 percent of the patients in the North American study and 84 percent of the patients in the European study, which is substantially higher than reported for other topical treatments.

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).