PRESS RELEASE

MOB-015 is recommended for approval in EU

STOCKHOLM, June 28th, 2023, Moberg Pharma AB (OMX:MOB) hereby announces that the Decentralized Procedure has ended with a positive outcome and that MOB-015 is recommended for national approval in 13 European countries for the treatment of mild to moderate fungal infections of the nails in adults.

- **The approval in the European Union represents the first marketing authorizations for Moberg Pharma´s new onychomycosis treatment worldwide**
- **Approval is supported by two Phase 3 trials where MOB-015 demonstrated superior levels of mycological cure (76% vs up to 42% for comparators), and a significantly better complete cure rate compared to vehicle, without any serious adverse reactions**
- **MOB-015 is a topical formulation of terbinafine, enabling effective concentrations of terbinafine to the nail and nail bed while avoiding the risk of systemic exposure seen with oral terbinafine use**

The Decentralized Procedure includes the following EU countries: Austria, Belgium, Czech Republic, Denmark, Finland, France, Hungary, Ireland, Italy, Netherlands, Norway, Spain and Sweden. Next steps include national implementation in each country and granting of marketing authorizations including OTC-approvals when applicable. National approvals are expected to follow during upcoming months and timelines may vary between countries.

"*We are excited about the MOB-015 program, with its cutting-edge technology and the promising 76% mycological cure rate shown in the clinical trials. It is a good fit for our Canesten® brand, with potential to become a game changer within onychomycosis,*'' says Karen Hackney, Bayer Consumer Health Head of R&D Dermatology.

"*We are incredible proud to bring a new efficacious treatment option with a favorable safety profile to people living with onychomycosis in Europe, an important part of our vision of making MOB-015 the leading nail fungus treatment worldwide,"* says Anna Ljung, CEO of Moberg Pharma.

Our commercialization rollout will be a two-step process, planned to start in our home market Scandinavia. We will initiate launch as quickly as possible following national approval, expecting to initiate launch preparations in Sweden before the end of the year. Exact choice of countries will depend on time to national approval - which may vary.

This early Scandinavian launch enables us to gain valuable insights into consumer behaviour, collecting patient feedback and provide user data to support direct to OTC/OTC-switches in more countries. The launch in Scandinavia will take place in collaboration with our partner Allderma, managed by the commercial leaders which were responsible for the successful Nordic launch of Nalox®, Moberg Pharma's first-generation nail fungus product.

Step 2 of the launch will be a pan-European rollout together with our partner Bayer, following the results in the ongoing North American study. This as we believe it is likely that we will be able to strengthen the product claims further, including a shorter dosing regimen with the potential to deliver superior complete cure rates. The timing is also driven by our need to secure sufficient API for a pan-European launch.

Over the recent months we have had many interactions with investigators in the ongoing North American trial, confirming the enthusiasm of the physicians for the treatment and the progress in the clinical study.

Our partner Bayer is a world leader in OTC fungus treatments with the Canesten® brand, and we are excited to work together on the pan-European launch. Our shared conviction is that it is in the best interest of MOB-015's long term potential to include the new data expected from the North American trial into this launch.

Recruitment in the trial is expected to be completed before year end, followed by expected topline results in the first quarter of 2025. Already now, Bayer is closely involved in the project and will co-invest in development work such as packaging improvements ahead of the pan-European launch.

Out of the two API manufacturers initially included in our registration file, only one is approved at this timepoint, and the one approved will stop its production of terbinafine later this year. Short term we therefore have a limited supply of terbinafine and are building as much API stock as possible. We expect to be able to include the second API supplier within short post approval. We are also looking for an additional API source and have identified several possible suppliers to commence discussions to secure long-term supply of terbinafine.

For additional information, please contact:
Anna Ljung, CEO, telephone: +46 707 66 60 30, E-mail: anna.ljung@mobergpharma.se

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 person set out above, on June 28th, 2023, at 11.00 am CEST.

About MOB-015 and Onychomycosis
Approximately 5-10% 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. Moberg Pharma estimates the annual worldwide peak sales potential for MOB-015 to be in the range of USD 250-500 million.

MOB-015 is an in-house developed topical formulation of terbinafine based on Moberg Pharma's experience from the leading OTC product Kerasal Nail®/Emtrix®. 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.

A total of 953 subjects received MOB-015 in the clinical development program across seven studies. Safety and efficacy were investigated in two randomized, controlled, multicentre, international Phase 3 studies in patients with toenail onychomycosis. MOB-015 has shown to be superior to vehicle. At week 12 mycological cure was shown in 42.8% of subjects in the MOB-015 group, increasing to 75.6% at Week 52. The systemic absorption of topical terbinafine is several orders of magnitude lower than for orally administered terbinafine. The systemic exposure to terbinafine has been assessed in a Phase 1 systemic absorption study under maximal use conditions in subjects with onychomycosis. The mean plasma terbinafine concentration after 4 weeks of treatment was approximately 2000 times lower than the mean plasma level observed after oral administration of 250 mg terbinafine once daily for 28 days. Therefore, systemic bioavailability of terbinafine from topical application of MOB-015 is considered negligible.

MOB-015 is currently being evaluated over 52 weeks in a randomized, multicenter, controlled Phase 3 study, including in total approximately 350 patients in the U.S. and Canada. The primary endpoint is the proportion of patients achieving complete cure of their target nail. Recruitment is expected to be completed before year end, followed by expected topline results in the first quarter of 2025.

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. Data from phase 3 clinical trials in more than 800 patients for MOB-015 indicate that the product has the potential to become the future market leader in onychomycosis. Moberg Pharma has agreements with commercial partners in place in Europe and Canada, among others, and the Company's goal is to receive its first market approval and initiate launch preparations of MOB-015 in 2023. Moberg Pharma is headquartered in Stockholm and the Company's shares are listed on the Small Cap list of the Nasdaq Stockholm (OMX: MOB).

Forward-looking statements

This press release contains forward-looking statements related to the Company's intentions, estimates or expectations with regard to the Company's future results, financial position, liquidity, development, outlook, estimated growth, strategies and opportunities as well as the markets in which the Company is active. Forward-looking statements are statements that do not refer to historical facts and can be identified by the use of terms such as "believes," "expects," "anticipates," "intends," "estimates," "will," "may," "implies," "should," "could" and, in each case, their negative, or comparable terminology. The forward-looking statements in this press release are based on various assumptions, which in several cases are based on further assumptions. Although the Company believes that the assumptions reflected in these forward-looking statements are reasonable, there is no guarantee that they will occur or that they are correct. Since these assumptions are based on assumptions or estimates and involve risks and uncertainties, actual results or outcomes, for many different reasons, may differ materially from those what is stated in the forward-looking statements. Due to such risks, uncertainties, eventualities and other significant factors, actual events may differ materially from the expectations that expressly or implicitly are contained in this press release through the forward-looking statements. The Company does not guarantee that the assumptions which serve as a basis for the forward-looking statements in this press release are correct, and each reader of the press release should not rely on the forward-looking statements in this press release. The information, opinions and forward-looking statements that expressly or implicitly are stated herein are provided only as of the date of this press release and may change. Neither the Company nor any other party will review, update, confirm or publicly announce any revision of any forward-looking statement to reflect events that occur or circumstances that arise with respect to the contents of this press release, beyond what is required by law or Nasdaq Stockholm's rules for issuers.