



PRESS RELEASE

## Patent granted for MOB-015 in China

**STOCKHOLM, November 23<sup>rd</sup>, 2018, Moberg Pharma AB (OMX: MOB) is pleased to announce that MOB-015 has been granted patent protection in China, valid until 2032. MOB-015 is an internally developed topical formulation of terbinafine for the treatment of onychomycosis, currently under clinical development in phase 3. MOB-015's patent protection thus covers the key markets for commercialization.**

The Chinese Patent Office has issued patent no. 201280007874.9 for MOB-015, valid until 2032. The Chinese patent covers an internally developed topical formulation of terbinafine for the treatment of onychomycosis. Moberg Pharma has previously been granted patent protection for MOB-015 in EU, US and Canada among others.

*"Having been granted the Chinese patent means we now cover the main markets in which we are planning to commercialize MOB-015. It is an important milestone in our strategy to establish a broad patent protection for our proprietary products,"* says Peter Wolpert, Moberg Pharma's CEO.

MOB-015 is under clinical development in phase 3. Studies are progressing in the EU and North America with first topline-results expected in the fourth quarter of 2019. In September this year, the enrollment to the North American study was completed, including in total 365 patients, randomized at 32 sites in the U.S. and Canada. As for the European study, screening and randomization of patients is expected to be completed by the beginning of 2019, with topline-results around 15 months later.

Moberg Pharma estimates the global peak sales potential for MOB-015 to be in the range of USD 250-500 million. The recent license agreement with Cipher Pharmaceuticals in Canada confirms the market potential for MOB-015. Under the agreement, Moberg Pharma is entitled to milestones of USD 14.6 million in addition to attractive royalties on net sales.

### **For additional information, please contact:**

Peter Wolpert, CEO, phone: Sweden: +46 707 35 7135, US: +1 908 432 2203, e-mail: [peter.wolpert@mobergpharma.se](mailto:peter.wolpert@mobergpharma.se)  
Eleonora Stern-Nejman, Investor relations, phone: +46 701 76 22 42, e-mail: [eleonora.stern-nejman@mobergpharma.se](mailto:eleonora.stern-nejman@mobergpharma.se)

### **About this information**

This 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 contact persons set out above, at 8.30 a.m. CET on November 23<sup>rd</sup>, 2018.

### **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. Moberg Pharma estimates the peak sales potential for MOB-015 to be in the range of USD 250-500 million.

MOB-015 is an internally developed topical formulation of terbinafine based on Moberg Pharma's experience from its leading OTC product Kerasal Nail<sup>®</sup>/Emtrix<sup>®</sup>. 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. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. In total, approximately 750-800 patients are expected to be enrolled in the two studies in North America and Europe.

**About Moberg Pharma, [www.mobergpharma.com](http://www.mobergpharma.com)**

Moberg Pharma AB (publ) is a rapidly growing Swedish pharmaceutical company with OTC sales operations in the U.S. and a distributor network in more than 40 countries. The company's portfolio includes the OTC brands Kerasal<sup>®</sup>, Kerasal Nail<sup>®</sup>, New Skin<sup>®</sup>, Dermoplast<sup>®</sup> and Domeboro<sup>®</sup>. Kerasal Nail<sup>®</sup> (Emtrix<sup>®</sup>, Zanmira<sup>®</sup> or Nalox<sup>™</sup> in certain markets) is a leading OTC treatment of nail disorders in the U.S., Canada as well as in several markets in EU and Southeast Asia. The company is growing organically as well as through acquisitions. Internal development programs focus on innovative drug delivery of proven compounds and include two assets in late-stage clinical development, MOB-015 (onychomycosis) and BUPI (pain management in oral mucositis). Moberg Pharma has offices in Stockholm and New Jersey and the company's shares are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm (OMX: MOB).