



PRESS RELEASE

## European Patent granted for BUPI

**STOCKHOLM, October 19, 2016 -- Moberg Pharma AB (OMX: MOB) announced that the European Patent Office (EPO) has issued Patent No. 2701681 which protects BUPI, currently in development for oral mucositis.**

The new patent covers pharmaceutical compositions comprising a local anesthetic, such as bupivacaine, for local administration to the mouth or throat. The patent also protects lozenge formulations of a local anesthetic for use in the treatment of oral mucositis in cancer patients. This patent is expected to provide coverage through at least 2031. Additional patent applications are pending in the United States and Canada.

*"This patent provides Moberg with important intellectual property protection for BUPI, our lozenge formulation of bupivacaine for pain management of oral mucositis in cancer patients,"* commented Peter Wolpert, Moberg Pharma's CEO. *"This issuance of this patent is an important milestone for the BUPI development program and part of our overall strategy to establish a broad portfolio of patent claims to protect our proprietary products."*

Earlier in 2016, the Company announced positive Phase 2 results with BUPI in treating pain associated with oral mucositis in patients with head and neck cancer undergoing radiotherapy. The primary endpoint was met with high statistical significance. The Company is moving forward with one Phase 3 trial to be conducted in Europe, co-funded by a grant from Eurostars. A second Phase 3 study will be conducted in India, financed by Moberg's partner Cadila Pharmaceuticals. The agreement with Cadila in combination with the Eurostars grant means that Moberg's investment for the BUPI phase 3 program is substantially reduced.

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

Peter Wolpert, CEO, Phone: +46 707 35 71 35, E-mail: [peter.wolpert@mobergpharma.se](mailto:peter.wolpert@mobergpharma.se)

Kjell Rensfeldt, VP R&D, Phone: +46 707 12 4532, E-mail: [kjell.rensfeldt@mobergpharma.se](mailto:kjell.rensfeldt@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, at 8.30 CET on October 19, 2016.

### **About Oral Mucositis and BUPI**

Oral mucositis ("OM") is a painful inflammation and ulceration of the mucous membranes lining the mouth. OM is a common and often debilitating complication of cancer treatment which affects 80% of patients with head and neck cancer receiving radiotherapy, almost all patients undergoing bone marrow transplantation, and a wide range of patients receiving chemotherapy. OM makes the patient less likely to comply with their cancer treatment, increases mortality and morbidity and contributes to rising health care costs. In the U.S., every year approximately 400 000 patients suffer from OM during cancer therapy.

The patent protected BUPI technology encompasses novel lozenge formulations of bupivacaine, a local anesthetic with a well-established long acting effect, currently available on the market for other indications as an injectable. In Phase 2, the group treated with BUPI had 31% reduction in pain in mouth or pharynx compared to standard pain treatment ( $p=0.0032$ ). The difference measured in the mouth only was even more pronounced - BUPI provided 50% additional pain reduction compared to standard treatment ( $p=0.0002$ ).

### **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®, Kerasal Nail®, Balmex®, NewSkin®, Domeboro®, Fiber Choice® and PediaCare®. Kerasal Nail® (Emtrix® or Nalox™ 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 focuses on innovative drug delivery of proven compounds and include two clinical stage assets, 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 (MOB.ST).