



PRESS RELEASE

## Moberg Pharma announces positive phase II data for BUPI

**STOCKHOLM, January 11, 2016. Moberg Pharma AB (OMX: MOB) announces positive top-line results from a phase II-study with BUPI for the treatment of pain due to oral mucositis in patients with head and neck cancer. BUPI achieved a statistically significant reduction in pain.**

32 patients completed the phase II-study in which the efficacy of BUPI was compared to standard treatment for pain in the oral cavity. The open clinical study was conducted at two hospitals in Denmark.

The primary endpoint was a measurement of pain in the mouth or pharynx 60 minutes post administration of BUPI compared to the average pain during the day for the control group. The group treated with BUPI had 23% reduction in pain compared to the control group (VAS\* 37.47 in BUPI vs. 48.94 in control,  $p=0.0326$ ). Both groups were allowed to use standard treatment options for pain during the study. The control group was furthermore allowed to use locally acting anesthetics for the oral cavity, in the form of a lidocaine gel. The difference in the mouth (pharynx excluded) was even more pronounced. Treatment with BUPI resulted in an additional pain reduction of 46% compared to standard treatment (VAS 17.74 vs. 33.03,  $p=0.0027$ ). No serious adverse events were reported among the patients treated with BUPI.

Kjell Rensfeldt, VP Research and Development at Moberg Pharma, commented:

*"This study shows that BUPI provided additional pain reduction to levels below VAS 40 in a patient population for which it is difficult to achieve adequate pain relief. Developing a new formulation of bupivacaine, intended for self-administration at home, requires a thorough evaluation of the safety profile of the product. Moberg Pharma will now proceed with in-depth analyses of all other data collected in this study, in order to guide further clinical development of BUPI".*

\* Pain evaluation with VAS (visual analogue scale) where VAS 0 = no pain and VAS 100 = worst imaginable pain.

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### 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 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. A BUPI lozenge is currently investigated in an ongoing clinical phase II study.

### About this information

Moberg Pharma discloses this information pursuant to the Swedish Securities Markets Act and/or the Financial Instruments Trading Act. The information was submitted for publication at 8:30 am (CET) on January 11, 2016.

### About Moberg Pharma

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>, Balmex, Domeboro<sup>®</sup>, Jointflex<sup>®</sup>, Vanquish<sup>®</sup>, and Fergon<sup>®</sup>. Kerasal Nail<sup>®</sup> (Emtrix<sup>®</sup> or Nalox<sup>™</sup> in certain markets) is a leading OTC treatment of nail disorders in the U.S., Canada and several EU markets and is currently being launched in 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 phase II assets, MOB-015 (onychomycosis) and BUPI (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). For further information, please visit: [www.mobergpharma.com](http://www.mobergpharma.com).