



PRESS RELEASE

## Moberg Pharma announces plans to develop BUPI through phase III

**STOCKHOLM, March 22, 2015. Moberg Pharma AB (OMX: MOB) today announced a decision to initiate development of BUPI through phase III. The decision follows an evaluation of the complete data set from the recent phase II study for BUPI.**

BUPI is a patent pending lozenge formulation of bupivacaine for pain management in oral mucositis in cancer patients. Following positive phase II results, the board has approved a de-risked strategy to continue development through phase III, including one phase III trial to be conducted in Europe co-funded by a grant from Eurostars. A second phase III study will be conducted in India and financed by Moberg's partner Cadila Pharmaceuticals.

The evaluation of the complete data set from the Phase II study supports the efficacy and safety of BUPI. Key findings include:

- The primary endpoint was met with high statistical significance. 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 31% reduction in pain compared to the control group (VAS\* 35.14 in BUPI vs. 50.94 in control,  $p=0.0032$ ). 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.
- When the effect in the mouth, excluding the pharynx, was measured, the difference between the groups was even more pronounced. Treatment with BUPI resulted in an additional pain reduction of 50% compared to standard treatment (VAS\* 17.93 vs. 36.10,  $p=0.0002$ ).
- Compared to pain at baseline (Average VAS = 58), patients on BUPI treatment had substantially lower pain during the study period (Average VAS = 35).
- BUPI provided meaningful pain relief until the next administration of a lozenge. On average, the patients used 3-4 lozenges per day.
- No serious adverse events were reported among the patients treated with BUPI.

\* Pain evaluation with VAS (visual analogue scale) where VAS 0 = no pain and VAS 100 = worst imaginable pain. NOTE: The positive effect of BUPI is slightly higher than previously announced topline results due to correction and final evaluation of the complete data set.

*"We are thrilled by the prospect of developing BUPI through Phase III and subsequently making the product available to patients in great need of improved pain relief. The de-risked strategy significantly reduces our investment requirement, while allowing us to retain commercial rights in all major territories as well as rights to data from the two Phase III studies. This strategy will enable Moberg Pharma to build substantial value in the BUPI asset for its shareholders,"* said Peter Wolpert, CEO of Moberg Pharma AB.

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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 patent pending 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.

**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 March 22, 2016.

**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>, Balmex<sup>®</sup>, Domeboro<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 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 (OMX: MOB).