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First patient included in phase II study of BUPI, a novel topical formulation for treatment of oral pain

Moberg Pharma AB (OMX: MOB) announced that the first patient has been included in a randomized controlled phase II study with BUPI, a novel topical formulation for the treatment of oral pain. The aim is to confirm the promising results gained from several smaller pilot studies and to evaluate if bupivacaine formulated as a lozenge can be an effective, safe and patient friendly treatment of oral pain. The results are expected in the first half of 2015.

"After acquiring the BUPI assets in April, the project has progressed rapidly. It is exciting that the clinical program now has started for this very promising treatment for severe oral pain. The goal is to make the treatment available to patients within a few years", says Peter Wolpert, CEO of Moberg Pharma AB.

About the phase II study and the product
The phase II study is conducted at Rigshospitalet in Denmark in cooperation with and under the supervision of Klinisk Forskningscenter, Hvidovre Hospital and will recruit up to 40 patients with head and neck cancer suffering from pain due to oral mucositis. The primary endpoint will be average oral pain intensity measured by a Visual Analog Scale, a standard method for measuring pain. The patients will be randomized to get standard pain treatment with or without the addition of a bupivacaine lozenge.

The product is a novel lozenge formulation of bupivacaine, a local anaesthetic with a well-established long acting effect, currently available on the market for other indications as an injectable. The original innovation came out of work by clinicians at Hvidovre Hospital, Copenhagen, Denmark facilitated by XOventure GmbH and SEED Capital Denmark. Moberg Pharma acquired the rights to the product in April 2014.

About oral mucositis
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.

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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 08.30 am (CET) on October 28, 2014.

About Moberg Pharma
Moberg Pharma AB (publ) is a rapidly growing Swedish pharmaceutical company with a direct sales and marketing organization in the U.S. and an extensive distributor network in more than 40 countries. The company's OTC portfolio includes the brands Kerasal®, Jointflex®, Kerasal Nail®, Domeboro®, Vanquish®, and Fergon®. Kerasal Nail® (Nalox™ in certain ex-U.S. markets) is the leading product for the treatment of nail disorders in the U.S. and Nordic market. The current portfolio will be supplemented by the acquisition and in-licensing of additional products as well as product development with a focus on innovative drug delivery of proven compounds. Moberg Pharma has offices in Stockholm and New Jersey and the company's shares (OMX: MOB) are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm. For further information, please visit: www.mobergpharma.com.