Company Announcement
Stockholm, November 19, 2015

# PLEDPHARMA REPORTS CONSTRUCTIVE MEETING WITH THE FDA AND PRESENTS NEW FOLLOW-UP DATA

**PledPharma AB (Publ) today announced that the company has completed an end of phase II/pre phase III-meeting with the U.S. Food and Drug Administration (U.S. FDA), which provides guidance on how to perform the continued documentation of the drug candidate PledOx®. Final minutes from the meeting are expected in December 2015. During the meeting, new follow up-data from the final Phase IIb-trial (PLIANT) with PledOx® was presented. The results from two follow-ups, at 12 and 24 weeks after completed treatment, show that PledOx® reduces the risk for persistent symptoms from nerve damage that occur in connection with chemotherapy for advanced colorectal cancer in a statistically significant way**

A large proportion of patients undergoing chemotherapy suffers from symptoms (tingling, numbness and pain) caused by nerve damage that have occurred in connection with the chemotherapy. After completing the treatment, it is common that these symptoms linger and that, in many cases, they become more severe. The long term follow-up that was presented during the meeting with the FDA shows that PledOx® not only decreases the incidence of symptoms during the treatment, but also statistically and significantly decreases these symptoms after completion of the treatment. Furthermore, the study shows that the effect of PledOx® is higher at the 24-week follow-up control after completed treatment than at the corresponding 12-week control.

“The FDA’s assessment of the clinical data and constructive advice regarding the final trials are of great value to us, not least since it increases clarity on what is expected in the next step. This is particularly important in the context of discussions with potential commercial partners”, says Jacques Näsström, CEO of PledPharma.

PledPharma has, as announced previously, presented results that demonstrate that PledOx® decreases the incidence of symptoms caused by nerve damage by 43 percent compared with placebo during ongoing treatment and that PledOx® does not negatively affect the anti-cancer effect of the chemotherapy.

“The new results give us a better picture of PledOx®‘s ability to improve cancer patients’ quality of life in the long term. This is, as far as we know, the first time that a controlled trial has been able to show that a treatment can reduce the risk for persistent problems with sensory impairments after completing chemotherapy”, says Prof. Sten Nilsson.

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ABOUT THE STUDY
PLIANT is a randomized double-blinded placebo-controlled phase IIb study with three parallel groups in which patients with advanced colorectal cancer received FOLFOX6 chemotherapy for up to eight treatment cycles and either PledOx® at a dose of 2 µmol/kg, 5 µmol/kg or placebo (a small portion of the patients were treated with 10 µmol/kg). The study was conducted at about thirty centres in Europe and the US, and included a total of 173 patients. The purpose of this study was to investigate whether pre-treatment with PledOx® decreased the frequency and severity of side effects related to FOLFOX6 treatment. The primary endpoint was the incidence of neuropathy (sensory disturbances), which was evaluated every two weeks during the first 16 weeks. The incidence of neuropathy was evaluated using three testing methods - Oxaliplatin Sanofi Specific Scale, Cold Allodynia Test and Leonard Questionnaire. Secondary endpoints included changes in the number of neutrophil granulocytes (a type of white blood cells) and thrombocytes (platelets). In addition, the patients were monitored to ensure that PledOx® treatment did not decrease the effect of the chemotherapy. FOLFOX is a very commonly used combination of the drugs folinic acid, 5-fluorouracil and oxaliplatin. ‘

ABOUT PLEDOX®
PledOx® is developed to prevent nerve damage caused by chemotherapy in cancer treatment. The active ingredient calmangafodipir is a New Chemical Entity (NCE) and has been shown to protect human cells against oxidative stress; a condition caused by formation of reactive oxygen and nitrogen compounds during e.g. chemotherapy. Oxidative stress may, among other things, cause damage to the sensory nerves (neuropathy). PledOx® mimics the endogenous enzyme MnSOD, which represents the cell's intrinsic protection against oxidative stress.

ABOUT NERVE DAMAGE CAUSED BY CHEMOTHERAPY IN COLORECTAL CANCER
Treatment with the cytotoxic drug oxaliplatin, one of the components in FOLFOX combination chemotherapy, often causes neuropathy i.e. hypersensitivity to cold, problems with fine motor skills and pain. This side effect leads to reduction in chemotherapy dose in approximately 40 percent of patients and is the most common reason for premature discontinuation of this cancer chemotherapy. Neuropathy is often transient, but about 15-20 percent of patients experience persistent problems, especially severe pain in the hands and feet. There is currently no cure for neuropathy.

ABOUT PLEDPHARMA

PledPharma develops new drugs that protect the body against oxidative stress – a condition that can be caused by chemotherapy and acetaminophen (paracetamol) poisoning. The company's most advanced project PledOx® reduces nerve damage associated with chemotherapy. The drug candidate Aladote™ is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. The project PP-099 seeks to limit the damage that occurs to the heart muscle during myocardial infarction. PledPharma's drug candidates are based on the further development of a substance that, for completely different purposes, already has been used by more than 200 000 patients. This may limit the development risk and simplify the approval process. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bankaktiebolag is the company's Certified Adviser (phone: +46 8-463 80 00). For more information, see www.pledpharma.se

*PledPharma AB discloses the information provided herein pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act*