PRESS RELEASE
STOCKHOLM, March 29, 2015.

PLEDPHARMA PRESENTS TOP-LINE RESULTS FROM ITS PHASE IIb STUDY – PLEDOX® REDUCES NERVE DAMAGE IN CONJUNCTION WITH CHEMOTHERAPY BY 43 PERCENT

PledPharma AB (publ) today announces top-line results from a randomized double-blind placebo-controlled phase IIb study (PLIANT) with the drug candidate PledOx®. In the study, patients were treated with PledOx® to reduce the risk of side effects associated with chemotherapy for advanced colorectal cancer. The study showed a clinically relevant reduction in the incidence of sensory nerve damage (neuropathy) of 43 percent compared to placebo. In addition, the anti-cancer effect of the chemotherapy was not negatively affected by the PledOx® treatment. Based on these positive data, discussions with potential partners will be intensified. Additionally, registration studies will be designed in dialogue with the U.S. Food Drug Administration (U.S. FDA).

PledPharma invites shareholders, analysts and media to a conference call (held in Swedish only) on Monday, March 30, at 11.00 AM CET. Participants are asked to call in on telephone number: +46 (0) 8 519 990 31.

"An important milestone has been reached. The clear reduction in neuropathy observed in this study has the potential to improve the quality of life and outcomes for a large number of cancer patients. There is currently no preventative treatment against this type of damage. We now look forward to, based on the promising results of the study, intensifying discussions with potential partners and to continue preparations for the next step in the clinical development of PledOx®, said Jacques Näsström, CEO of PledPharma.

Neuropathy in conjunction with chemotherapy can cause debilitating problems, for example hypersensitivity to cold, disruption of fine motor skills and severe pain especially in the hands and feet. This is one of the most common serious side effects in the treatment of colorectal cancer with FOLFOX combination chemotherapy. These side effects often require reduction of the prescribed chemotherapy dose and in the most severe cases treatment must be discontinued.

“This is, to my knowledge, the first study where a treatment has been shown to reduce this kind of side effects in a clinically meaningful manner, but with no apparent negative impact on the efficacy of the chemotherapy”, said Bengt Glimelius, professor emeritus in oncology at Uppsala University and principal investigator of the PLIANT-study.

This randomized double-blind placebo-controlled phase IIb study (PLIANT) includes 173 patients with advanced colorectal cancer who, in connection with chemotherapy received treatment with PledOx® or placebo. Treatment with PledOx® in one of the two studied doses resulted in a 43 percent decrease in the incidence of neuropathy compared to placebo. The difference did not reach statistical significance, which is also not a requirement at this stage of development. However, no clinically relevant reductions of two other common side effects – thrombocytopenia and neutropenia – were observed in patients treated with PledOx®. The anti-cancer effect of the chemotherapy was not negatively affected by the PledOx® treatment. No differences in side effects between the treatment groups were noted in the study.

The study results will provide the basis for the continued development plan, which will be discussed at a so called end of phase II-meeting with the U.S. Food and Drug Administration, FDA.

FOR MORE INFORMATION, PLEASE CONTACT:

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TO THE EDITORS:

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. 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. Secondary endpoints included changes in the number of neutrophils (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 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 substance calmangafodipir is a New Chemical Entity (NCE) and has been shown in preclinical studies 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, will often cause neuropathy i.e. hypersensitivity to cold, problems with fine motor skills and pain. This side effect leads to reduction in chemotherapy dose in 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 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. 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