Company Announcement
Stockholm, June 26, 2015

PLEDPHARMA PRESENTS ADDITIONAL RESULTS FROM A PHASE IIB STUDY WITH PLEDOX® AT THE SCIENTIFIC CONFERENCE MASCC

PledPharma AB (publ) presents additional topline results from PLIANT – a Phase IIb study with the drug candidate PledOx® – at the scientific conference MASCC (Multinational Association of Supportive Care in Cancer) in Copenhagen, Denmark. The results confirm that PledOx® can reduce the risk of symptoms caused by sensory nerve damage associated with chemotherapy treatment of advanced colorectal cancer in a clinically relevant manner.

The study results presented at MASCC show that patients treated with PledOx® have a lower risk than the placebo group to suffer from nerve damage. As previously reported, the incidence of symptoms caused by sensory nerve damage (neuropathy) was 43 percent lower in the group of patients treated with PledOx® at a dose of 5 µmol/kg, compared to the placebo group. New data from three different test methods consistently show a positive effect of the treatment. The data also clearly confirms that the anti-cancer effect of chemotherapy was not negatively impacted by PledOx® treatment. It was concluded that PledOx® had a benign safety profile and was not associated with any serious adverse effects.

Moreover, the additional results revealed that symptoms occur later and disappear faster after pretreatment with PledOx®.

The findings were presented by Associate Professor Devalingam Mahalingam, M.D., Ph.D., University of Texas Health Science Center, San Antonio, Tx, USA and principal investigator for the PLIANT study in the United States.

"To our knowledge, this is the first controlled study to show a clinically significant prevention of chemotherapy-induced sensory nerve damage, with no apparent negative impact on the efficacy of the chemotherapy," said Jacques Näsström, CEO 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 the FOLFOX chemotherapy combination. These side effects often require reduction of the prescribed chemotherapy dose and in the most severe cases treatment must be discontinued.

The presentation from the MASCC meeting is available on PledPharma's website.

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PledPharma

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 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

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