PledPharma

PRESS RELEASE
PledPharma AB
Stockholm November 16, 2017

PledPharma initiates Phase III studies with PledOx® before year end 2017

PledPharma AB announced today that the company, following interactions with the European Medicines Agency EMA, has finalized the design of the global Phase III program for the drug candidate PledOx®. The Phase III studies are expected to be initiated before year end 2017. The company's current funds are expected to cover costs up to the planned read out of top line results in 2020. PledPharma's CEO Nicklas Westerholm is hosting a corporate presentation today, November 16th at 12:00 CET, where the design of the Phase III program will be covered.

PledOx® is developed to prevent chemotherapy induced peripheral neuropathy (CIPN) which affects between 40 to 60 percent of patients treated with standard of care for colorectal cancer. This type of toxicities may lead to a dose reduction of the chemotherapy or, in worst case, discontinuation of treatment. Up to half of the affected patients develops chronic nerve damages, leading to numbness, tingling and discomfort in hands and feet, and negative impact on quality of life. There is currently no approved drug to prevent or treat chemotherapy induced peripheral neuropathy.

The design of the Phase III program for PledOx®
The Phase III program has been designed based on interactions with the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and PledPharma's Scientific Advisory Board.

It consists of two double-blind, randomized, placebo-controlled studies, POLAR-M and POLAR-A:

- POLAR-M includes 300 patients undergoing chemotherapy for metastatic colorectal cancer and is planned to be conducted in Europe and the US. In the study, 2 µmol/kg and 5 µmol/kg of PledOx® are compared to placebo.

- POLAR-A includes 200 patients undergoing adjuvant chemotherapy for colorectal cancer and is planned to be conducted in Europe. In the study, 2 µmol/kg and 5 µmol/kg of PledOx® are compared to placebo.

In both studies, patients will receive PledOx® or placebo as add-on to the chemotherapy FOLFOX. The primary efficacy parameter is patient-reported symptoms of CIPN nine (9) months after initiation of chemotherapy. Evaluation of symptoms is performed using the validated FACT/GOG-NTx instrument. Secondary efficacy parameters evaluate other aspects of CIPN, functional loss, the need for dose

adjustments of chemotherapy, pain and quality of life. Patients are followed in the studies for two years after initiation of chemotherapy, focusing on progression free survival and overall survival (POLAR-M) and disease-free survival (POLAR-A). In the POLAR-M study, an additional follow-up of overall survival is performed after three years.

PledPharma intends to initiate the Phase III studies before year end 2017 and to have first patient in by early 2018. As previously announced, PledPharma's funding is expected to cover costs for the Phase III program up to the read out of top line results, which is estimated to occur in 2020.

"We are very pleased to have completed the dialogue with the European Medicines Agency in a way that enables us to initiate the global Phase III program with PledOx before year end. PledOx has the potential to address the significant unmet medical need among colorectal cancer patients to prevent the potentially debilitating chemotherapy induced neuropathy, "says PledPharma's CEO, Nicklas Westerholm.

Invitation to participate in a teleconference, November 16th at 12:00 CET.
Today, November 16th, PledPharma will host a corporate presentation at 12:00, where Nicklas Westerholm, CEO, will describe the development plan for PledOx® and cover the status of the Aladote® project. The presentation can be followed by telephone, and the presentation material will be made available on the corporate website, www.pledpharma.se.

Telephone numbers for participation in the presentation:

From Sweden: 08-503 365 91 or 020-088 3536 (toll-free)
From United Kingdom: +44 330 606 8318 or 0808-238 0274 (toll-free)
From United States: +1 631 621 5253 or +1 877 914 2018 (toll-free)

Participation Code: 669 182 8949

For more information, please contact:
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About PledOx®
PledOx® is a "first in class" drug candidate developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, prevention against the nerve damage that can occur in conjunction with chemotherapy treatment. The results from a completed Phase IIb trial (PLIANT), where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx®, indicates that the patients who received PledOx® had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. The presence of the investigator reported sensory nerve damage, the primary endpoint, was after treatment 38% lower in the group of patients treated with PledOx® compared with the placebo group ($p = 0.16$). This was not statistically significant,

but a difference of this magnitude is considered to be clinically relevant. After completion of chemotherapy, the patient-reported incidence of moderate and severe neuropathy was 77% lower in patients treated with PledOx® compared to the placebo group (exploratory analysis; p = 0.014). This is considered valuable for the success of the forthcoming POLAR studies, where patient-reported symptoms after completion of treatment will be the primary efficacy parameter. No apparent negative effect on the efficacy of the cancer treatment was observed.

About chemotherapy induced peripheral neuropathy (CIPN)
Peripheral neuropathy symptoms are caused by damages to sensory nerves, most commonly in hands and feet. Certain chemotherapies, including oxaliplatin, can cause such damages, which is then called chemotherapy induced peripheral neuropathy (CIPN). This can be a debilitating adverse reaction of the cancer treatment and may occur at any time after the initiation of chemotherapy. The symptoms often increase as the chemotherapy treatment continues and may often causes discontinuation of the chemotherapy. In many patients, the symptoms are resolved after discontinuing the chemotherapy, but up to 40-60% of the patients have sustained symptoms such as numbness, tingling and pain in hands and feet. Patients with CIPN may have difficulties with fine motor skill, such as buttoning buttons, challenges using a computer key board and become hypersensitive to cold. The sensory loss in the feet's may increase the risk of falls. There is currently no approved drug to prevent or treat CIPN.

About PledPharma
PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. The company's most advanced project PledOx® is being developed to reduce nerve damage associated with chemotherapy. A phase IIb study has been conducted and will serve as the basis for the continued development. The drug candidate Aladote® is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see www.pledpharma.se