



PledPharma

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Press Release

Go-ahead for PledPharma to proceed with PLIANT study patient recruitment

PledPharma has received green light from the DSMB (Drug Safety Monitoring Board), an independent panel of experts) to continue patient recruitment for the phase IIb study PLIANT. The study will evaluate whether pretreatment with PledPharma's drug candidate PledOx™ reduces the severe side effects caused by the chemotherapy FOLFOX in patients treated for metastatic colorectal cancer.

DSMB has analyzed the test results from the first patient that was enrolled in the study two weeks ago. The study is in the initial stage, the so-called dose-escalation phase. The dosages of PledOx follow a strict protocol for when evaluating a new compound for the first time in a clinical trial. With the approval to proceed with the study, the first patient is to receive the second dose of PledOx, while the next two patients to be included in the study in parallel can receive the first low dose of PledOx. When all three patients received at least one cycle of therapy, and the first patient received three cycles DSMB will re-evaluate the data to give approval for this procedure to be repeated for the higher dose of PledOx.

It is the Department of Oncology at Uppsala Academic Hospital which has included the first patient in PLIANT study. This is one of four centers in Sweden and the United States that include patients for dose-escalation phase. As a second step after the dose-escalation phase is completed, which is expected to take approximately 4-5 months, the study will be scaled up and include 126 patients from at least 28 centers in Europe and the U.S.

About PledOx™

PledOx™ (calmangafodipir) is a compound that, among other things prevents the side effects of chemotherapy in cancer treatment. PledOx has been shown in studies to protect against "oxidative stress" - a condition in which the cell's most important protection is not sufficient against the levels of reactive oxygen species generated as a result of the chemotherapy treatment. By mimicking the enzyme superoxide dismutase (SOD), PledOx boosts the cells endogenous protection and thereby prevents side effects that would otherwise arise as a result of the "oxidative stress".



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About colorectal cancer

Colon cancer is the third most common cancer-related cause of death in the Western world. Standard treatment for advanced colorectal cancer is the chemotherapy FOLFOX but severe and sometimes life-threatening side effects such as reductions in the white blood cell count and painful peripheral sensory nerve disorders especially in the hands and feet, lead to that fewer than half of the patients complete the treatment with the initial dose of chemotherapy. Depending on the side effect, the first step before reducing the chemotherapy dose is to postpone next dose once or several times. The adverse events affect the patients' quality of life negatively, with the risk of long-term symptoms even after stopping treatment.

About PLIANT-study

PLIANT study is divided in two parts, a dose-escalation phase, in order to determine the correct dose level and a randomized phase with the goal to establish PledOx's effect. The dose-escalation phase comprises of 9-12 patients from three selected medical centers in Sweden and one in the U.S. – the Oncology clinic at Uppsala University Hospital, Karolinska University Hospital, Department of Oncology, Linköping University Hospital and the Cancer Therapy & Research Center at The University of Texas Health Science Center in San Antonio, USA. Next phase, the randomized phase, planned for 126 patients from at least 28 centers in Europe and the United States, the patients will be divided into three equal groups to receive either placebo or PledOx in two different doses.

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About PledPharma

PledPharma is a Swedish specialty pharma company that develops PledOx™ (calmangafodipir) for prevention of severe chemotherapy-induced side effects in cancer patients. Due to these side effects optimal treatment cannot be carried out. The current market for supportive cancer care is some SEK 72 billion. PledOx protects normal cells against oxidative stress. It belongs to a group of compounds named lowMEM (low Molecular Enzyme Mimetics), and mimics the enzyme Manganese SuperOxide Dismutase (MnSOD) – the most important endogenous cellular protectant against devastating oxidative stress. Oxidative stress is a condition caused by harmful oxygen/nitrogen molecules, e.g., as a result of chemotherapy treatment. The company is also evaluating opportunities of using PLED substances in other diseases. PledPharma (STO:PLED) is listed on NASDAQ OMX First North. Erik Penser Bankaktiebolag is the Certified Adviser. For further information, please visit

www.pledpharma.se