

# Positive data from an additional 5 patients in the first part of the PLIANT study

In total 11 patients have been treated in the open part of the study and preliminary analysis of the raw data indicated that PledOx<sup>®</sup> reduced the severe chemotherapy-induced side effects.

The new data showed that PledOx was well tolerated by the additional 5 patients treated with the antibody Avastin (bevacizumab) in combination with FOLFOX chemotherapy.

With this, the open part of the study with a total of 11 patients is reported. The open part of the study was performed in order to determine tolerability and the correct dose level.

Nine of these 11 patients underwent at least 6 cycles of FOLFOX and none of these patients showed a grade 2 or worse neuropathy against an expected outcome of at least two patients.

These data also indicated a reduction of serious blood-related side effects with the 5 µmol/kg dose of PledOx.

The combination with the antibody bevacizumab as adjunctive therapy to chemotherapy is common especially in the United States, but occurs in all countries participating in the study.

## About PledOx®

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

#### **About Bevacizumab**

Brand name Avastin<sup>®</sup>, (Genentech / Roche) is an angiogenesis inhibitor that slows the growth of new blood vessels. Bevacizumab specifically blocks a growth factor in blood vessels. This reduces the growth of blood vessels in the tumor, which shuts off the supply of blood to the tumor. Bevacizumab is used in the treatment of metastatic cancer of various origin including colorectal, mammary, kidney, and lung cancer.

#### About colorectal cancer

Colorectal cancer is the third most common cancer related cause of death in the western world. Annually 450,000 people become ill in colorectal cancer on the seven largest markets in the Western world. First line treatment in colorectal cancer is a combination treatment called FOLFOX (FOLinate, 5-Fluorouracil (5-FU), and OXaliplatin). FOLFOX gives rise to a better outcome than previous treatments, but severe side-effects constitute a significant problem. The side-effects result in that the planned chemotherapy dose cannot be



administered. Less than half of the patients do not receive the prescribed dose. Thus, there is a huge medical need to reduce the side-effects of FOLFOX.

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### **About PledPharma**

PledPharma is a Swedish pharmaceutical company that develops new therapies for the treatment of life threatening diseases. The initial objective is to develop a drug, PledOx®, which reduces severe side-effects associated with chemotherapy. The current market for supportive cancer care is some USD 10 billion. PledPharma also evaluates an existing medicines possibility to reduce the damage that occurs on the heart muscle when patients suffer from acute myocardial infarction. In addition to these projects, the company is also evaluating opportunities of using our technology platform in additional areas where there is a significant unmet medical need. PledPharma has the potential to offer patients valuable and unique treatments for serious life-threatening diseases where there is an opportunity fast registration in the US through "breakthrough therapy" designation. This means that the company has the potential to offer shareholders a good return on their investment. PledPharma (STO:PLED) is listed on NASDAQ OMX First North. Erik Penser Bankaktiebolag is the Certified Adviser. For further information, please visit <a href="https://www.pledpharma.se">www.pledpharma.se</a>