PledPharma

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**Press Release**

# PledPharma Broadens Patient Base for the PLIANT Study

**The recruitment of patients for the Phase IIb study PLIANT is ongoing. To broaden the patient population and to ensure that the end result is optimal for clinical practice a request for extension of the eligibility criteria for the study has been submitted to the Swedish Medical Products Agency. The study is also expanded with an additional center, the Department of Oncology, Linköping University Hospital. Thus the patient population broadens and recruitment conditions improve.**

Colorectal cancer is the third most common cancer-related cause of death in the Western world. Standard treatment for metastatic colorectal cancer is the chemotherapy FOLFOX but serious side effects lead to that less than half of the patients receive the recommended dose, and thus are unlikely to fully benefit from the treatment.

The PLIANT study is based on a patient population receiving the chemotherapy FOLFOX in the first line of the spread (metastatic) colorectal cancer. Information from authorities and study investigators reveal that due to the severe side effects (nerve damage) that comes with FOLFOX approximately 70% of the patients are treated with FOLFIRI, with fewer serious side effects, as the first-line treatment despite the fact that FOLFIRI is not as effective as FOLFOX. This shift to FOLFIRI varies from country to country and from clinic to clinic in Sweden. As the study originally only was aimed for patients receiving FOLFOX in the first line setting it has become clear that certain patients were not available for inclusion in the study. With the altered inclusion criteria patients treated with FOLFOX in the second and third line will also be eligible to participate in the study.

- FOLFOX is a proven effective treatment that more patients would benefit from, and we now see that the medical need to reduce the side effects of FOLFOX is greater than we previously estimated. Our ambition is that the PLIANT study will show that PledOx™ allows for a more effective treatment with fewer side effects, says Jacques Näsström, CEO PledPharma.

**About the PLIANT-study**

The phase IIb study PLIANT will investigate PledPharma's substance PledOx possibility to reduce side effects of treatment with the chemotherapy FOLFOX in patients with metastatic colorectal cancer.

The PLIANT study is divided in two parts. A dose escalation phase in order to determine the correct dose and after that a randomization phase with the goal to establish the effect of PledOx. In the dose escalation phase, 6-9 patients from two selected medical centers in Sweden, The Oncology Clinic, Uppsala University Hospital and Karolinska University Hospital, Solna, are included together with the new site, the Oncology Clinic at Linköping University Hospital. The next phase, randomization, is carried out on 126 patients from at least 28 centers in Europe and USA. Patients are randomized 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 a new medicine, PledOx™, for prevention of the severe side effects that patients develop as a consequence of chemotherapy treatment of cancer. Many times the treatment cannot be carried out as planned due to very difficult side effects. The current market for supportive cancer care is some SEK 72 billion. PledOx is a medicine within the patent protected substance class PLED, which protects the body's normal cells against oxidative stress. Oxidative stress is a condition where an overabundance of harmful oxygen molecules (free oxygen radicals) has been formed. We are also evaluating opportunities with PLED substances for 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