



PledPharma

PRESS RELEASE

PledPharma PledOx[®] clinical trial application approved

Stockholm, 2012-08-01 - PledPharma (STO:PLED) today announced that its PledOx[®] phase IIb clinical trial application, PLIANT, was approved by the Swedish Medical Products Agency (MPA). The PLIANT study will examine the effect of PledOx pre-treatment on the side effects of FOLFOX in patients with metastatic colorectal cancer.

Patients will be randomized to receive PledOx in a dose of 2 or 10 µmol/kg, or placebo. The randomization phase of the study will be preceded by a dose-escalation phase with the aim of determining PledOx clinical safety, tolerability and pharmacokinetic and pharmacodynamic properties (effects of the body on the drug, and of the drug on the body).

The primary outcome measure will be the change in absolute neutrophil count (number of white blood cell subtype). Secondary outcomes will include effects on the occurrence of febrile neutropenia (sign of infection associated with loss of white blood cell subtype) and sensory neuropathy (pain and discomfort originating from peripheral nerve affection).

The estimated enrolment of patients in the randomization phase of the study is 126 (42 in each of the 3 groups). 6-12 patients will be enrolled in the dose escalation phase. Professor Glimelius, at Uppsala University Hospital, is the principal investigator. The study will be done at several sites in Europe and North America. For more details please see www.ClinicalTrials.gov.

“We are very happy about the positive assessment of the Swedish MPA. We continue to be on track with respect to the timelines of the study and expect to recruit the first patient during the third quarter and present top line results in the end of 2013. This is a further step towards bringing an innovative medicine to patients in high need of improved treatment”, says CEO Jacques Näsström.

For further information please contact:

Jacques Näsström, CEO, cell: +46 73 713 0979

Erik Kinnman, Investor relations, cell: +46 73 422 1540

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 more information, please visit www.pledpharma.se