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Press Release

FDA has approved IND application for clinical trial with PledOx in the U.S.

PledPharma (STO: PLED) announced today that their PledOx™ Phase IIb clinical trial, PLIANT, is approved by the U.S. Food and Drug Administration (FDA). The goal of the PLIANT study is that pretreatment with PledOx reduces serious side effects of the chemotherapy FOLFOX in patients treated for advanced colorectal cancer.

Patients will be randomized to receive two different doses PledOx, the compound developed by PledPharma, or placebo. The estimated number of patients included in the randomized phase of the study is 126 (42 in each of the 3 groups). The study is planned to be carried out in several centers in Europe and the U.S. For further details see www.ClinicalTrials.gov.

"We are very pleased with the positive assessment by the FDA. Since the U.S. is perhaps the single most important market, it is particularly encouraging that we received approval for our study there. In addition, an Investigational New Drug (IND) approval by the FDA is a sign of quality and something that is seen as positive by both other agencies and businesses," says CEO Jacques Näsström.

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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