



PRESS RELEASE
PledPharma AB
Stockholm, November 17, 2017

PledPharma's Phase IIb study with PledOx[®] (PLIANT) published in Acta Oncologica

PledPharma AB today announces that data from the Phase IIb study PLIANT has been published in the well renowned scientific journal Acta Oncologica. The results indicate that PledOx[®] can prevent the occurrence of patient reported symptoms of chemotherapy-induced peripheral nerve damage (CIPN) during and after treatment of colorectal cancer with oxaliplatin. The sufficiently strong effect, and absence of any apparent evidence of a tumor protective effect from the chemotherapy treatment, warrants initiation of Phase III studies.

The randomized, double-blind, placebo-controlled Phase IIb study (PLIANT) included 173 patients with advanced colorectal cancer who received treatment with PledOx[®] or placebo in conjunction with the FOLFOX chemotherapy. Treatment with PledOx[®] resulted in that the incidence of investigator reported nerve damage decreased during treatment by 38 percent ($p=0.16$) compared with placebo. Patient-reported symptoms six months after end of treatment were approximately 75 percent lower in the PledOx[®] group compared with placebo ($p < 0.01$). In addition, the results indicated that the symptoms occur later and disappear faster after pre-treatment with PledOx[®]. The anti-cancer effect of the FOLFOX chemotherapy was not apparently affected by the PledOx[®] treatment, and no differences in serious adverse events were seen between the treatment groups. In addition to PledOx[®] effect on CIPN, a statistically significant reduction ($p < 0.05$) of all degrees of neutropenia was observed with PledOx[®] treatment.

"We are pleased to announce the publication of these unique results for PledOx[®] in the well renowned scientific journal Acta Oncologica. The results support the recently communicated clinical development plan, and we look forward to continuing the project into Phase III studies" says PledPharma's CEO Nicklas Westerholm.

Nerve damage associated with chemotherapy treatment may cause serious disabling conditions, such as increased cold sensitivity, fine motor disorders, and loss of sensation in hands and feet, which can lead to problems with the balance and consequential injuries. This is one of the most common dose-limiting side-effects in the treatment of colorectal cancer with FOLFOX. These side-effects often lead to a reduction in the prescribed chemotherapy dose or, in the worst-case treatment discontinuation.

"The effects of PledOx are sufficiently strong and the lack of any indications of a tumor protective effect reassuring, motivating initiation of conclusive phase III trials" says the Principal investigator of the PLIANT study, Professor emeritus Bengt Glimelius.



PledPharma

The scientific article "Persistent prevention of oxaliplatin-induced peripheral neuropathy using calmagafodipir (PledOx[®]): a placebo-controlled randomized phase II study (PLIANT)" is available on Acta Oncologica's website:

<http://www.tandfonline.com/doi/full/10.1080/0284186X.2017.1398836>

For further information, please contact:

Nicklas Westerholm, CEO

phone: +46 73 354 20 62

Nicklas.westerholm@pledpharma.se

About PledPharma

PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. The company's most advanced project PledOx[®] is being developed to reduce nerve damage associated with chemotherapy. A phase IIb study has been conducted and will serve as the basis for the continued development. The drug candidate Aladote[®] is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see www.pledpharma.se