



PRESS RELEASE

Study drug for the PledOx[®] global phase III program delivered

Stockholm, September 28, 2018. PledPharma AB (publ) announces that the PledOx[®] study drug for the planned phase III program has successfully been produced and delivered. As previously announced, dosing of first patient is expected to commence in the fourth quarter 2018, in-line with previous guidance.

Submitted clinical trial applications to health authorities will be amended with data from the newly produced study drug. In accordance with previous guidance, dosing of first patient will commence in the fourth quarter 2018, assuming necessary approvals from health authorities.

”We have now taken an additional important step forward towards treatment start in the PledOx[®] phase III program – a drug candidate with the potential to reduce chemotherapy induced peripheral neuropathies”, said PledPharma CEO and President, Nicklas Westerholm.

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About PledOx[®]

PledOx[®] is a “first in class” drug candidate developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, prevention against the nerve damage that can occur in conjunction with chemotherapy treatment. The results from a completed Phase IIb trial (PLIANT), where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx[®], indicates that the patients who received PledOx[®] had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. The presence of the investigator reported sensory nerve damage, the primary endpoint, was after treatment 38% lower in the group of patients treated with PledOx[®] compared with the placebo group (p = 0.16). This was not statistically significant, but a difference of this magnitude is considered to be clinically relevant.



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After completion of chemotherapy, the patient-reported incidence of moderate and severe neuropathy was 77% lower in patients treated with PledOx[®] compared to the placebo group (exploratory analysis; $p = 0.014$). This is considered valuable for the success of the forthcoming POLAR studies, where patient-reported symptoms after completion of treatment will be the primary efficacy parameter. No apparent negative effect on the efficacy of the cancer treatment was observed. The phase III program for PledOx[®] consists of two double blinded randomized placebo controlled trials, POLAR-M and POLAR-A. POLAR-M includes 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and planned to be conducted in Asia, Europe and the US. The study compares PledOx[®] at doses of 2 $\mu\text{mol/kg}$ and 5 $\mu\text{mol/kg}$ with placebo. POLAR-A includes 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and planned to be conducted in Asia and Europe. The study compares PledOx[®] at a dose of 5 $\mu\text{mol/kg}$ with placebo.

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 serves as the basis for the initiated global phase III program. The drug candidate Aladote[®] is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. A proof of principle study has been conducted and will serve as the basis for the continued development. 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 <http://www.pledpharma.se/>