



PRESSRELEASE

PledPharma presents PledOx[®]'s phase III program at the Gastrointestinal (GI) Cancers Symposium

Stockholm, January 17, 2019. PledPharma AB (publ) announces that the company's global phase III program, POLAR, has been accepted for a poster presentation during the Gastrointestinal (GI) Cancers Symposium in January 17-19 in San Francisco.

The symposium is one of the most prominent within the field of gastrointestinal (GI) cancers globally with ASCO (American Association of Clinical Oncology) as one of the co-sponsors.

The title of the presentation is: The Global POLAR program: Calmangafodipir used on top of modified FOLFOX6 (5-FU/FA and oxaliplatin) to prevent chemotherapy induced peripheral neuropathy (CIPN). It will be presented by one of the Coordinating Investigators of the POLAR M study, Prof. Per Pfeiffer from Odense University Hospital in Denmark and M.D., Ph.D. Stefan Carlsson, Chief Medical Officer at PledPharma.

"We are proud to have been selected as one of the presenters at ASCO GI. I see presenting the study at one of the world's most prominent Gastrointestinal Cancer symposiums as a confirmation in the interest in PledOx[®]'s potential and the unmet medical need in this patient population." says Nicklas Westerholm, CEO, PledPharma AB.

Meeting information:

Abstract number: TPS722. Poster Board: Q7. Session information: Trials in progress poster session C. Cancer of the Colon, Rectum and Anus

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PledPharma

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. PledOx® showed 38% effect (odds ratio=0.62; p=0.16) on investigator reported sensory nerve damage, the primary endpoint, compared with the placebo group. This was not statistically significant, but a difference of this magnitude is considered clinically relevant. After completion of chemotherapy, PledOx® showed 77% effect (odds ratio=0.23; exploratory analysis: p=0.014) on patient-reported moderate and severe neuropathy compared to the placebo group.. 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 µmol/kg and 5 µmol/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 µmol/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 successfully completed 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 83 00, certifiedadviser@penser.se). For more information, see <http://www.pledpharma.com/>