PledPharma has completed the recruitment for the clinical trial with Aladote®

Stockholm, May 14, 2018. PledPharma AB (publ) has fully recruited all patients in the proof-of-principle study with the drug candidate Aladote® (PP100-01 for Overdose of Paracetamol Trial, “POP”). Aladote® is being developed to prevent acute liver damage caused by paracetamol overdose. Initial results from the study will be presented during the second quarter 2018.

Aladote® is being developed to potentially prevent acute liver damage caused by paracetamol. Paracetamol is the most used drug in the world for the treatment of fever and pain, but also one of the most overdosed drugs – intentional or unintentional. Paracetamol overdose is also one of the most common method in intentional suicide attempts. Today, there are no efficient treatment alternatives for the proportion of patients who seek medical care in the later part of the poisoning process.

The proof-of-principle trial is being conducted in collaboration with the Queen's Medical Research Institute, University of Edinburgh under the supervision of Dr. James Dear. The primary goal of the trial is to evaluate safety and tolerability in combination with N-acetylcysteine (NAC), NAC is current standard of care for the treatment of paracetamol poisoning. In addition, several biomarkers of liver damage will be measured.

In total, 24 patients were recruited to three dose cohorts with eight patients per dose cohort, of which six patients were treated with the combination of Aladote® and NAC and two with NAC only.

“To have successfully recruited all patients to the proof-of-principle study with Aladote® is an important step forward in this project, and we look forward to take part of the upcoming results. Presently there are no efficient treatment for paracetamol poisoned patients who seek treatment in the latter part of the poisoning process, hence the need for new treatment options who can protect the liver is immense”, said Nicklas Westerholm, CEO, PledPharma.
For more information, please contact:

Nicklas Westerholm, CEO, phone: +46 73 354 20 62
nicklas.westerholm@pledpharma.se

Yilmaz Mahshid, CFO, phone: +46 72 231 68 00
yilmaz.mahshid@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 serves as the basis for the initiated phase III program. 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 http://www.pledpharma.se/