



PRESS RELEASE

PledPharma presents results from study on drug candidate Aladote® for paracetamol poisoning at a global toxicology conference

Stockholm, December 13, 2018. PledPharma AB (publ) announces that the company's Aladote® Phase Ib/IIa study results has been accepted for a poster presentation during the "58th Annual Meeting of the Society of Toxicology" in March, 2019. The principal investigator Dr James Dear will be speaker and present the positive study results.

One of the largest global conferences in toxicology is organized by the Society of Toxicology and takes place March 10-14, 2019 in Baltimore, Maryland. Dr James Dear, an internationally leading paracetamol toxicity expert, was the Principal Investigator for the Proof of Principle Phase Ib/IIa study, conducted at the Royal Infirmary of Edinburgh and the Queen's Medical Research Institute, University of Edinburgh.

Aladote® is a first-in-class drug candidate, developed to reduce liver damage due to paracetamol poisoning. The proof of principle Phase Ib/IIa study was completed in September 2018. The results showed that Aladote® is safe and tolerable when given together with NAC (N-acetylcysteine, standard of care). The results also indicate that Aladote® can reduce liver damage in the current patient population based on analyses of the predefined exploratory biomarkers Keratin-18 (K18) and microRNA-122 (miR-122) in blood samples. PledPharma is now preparing an orphan drug application to the Federal Drug Administration, FDA, while planning for the next step of clinical trial is being finalised.

"Paracetamol/Acetaminophen poisoning is very common but the current therapeutic options are limited to NAC. In patients who start NAC treatment more than 8 hours after overdose this antidote loses its effectiveness. There is an unmet need for new therapeutic options and Aladote represents an exciting new potential therapy" says Dr James Dear, University of Edinburgh.

"We are extremely proud, being selected as one of the speakers at the Society of Toxicology Meeting. It is a sign of the great interest in our drug candidate. I see presenting the study at one of the world's largest toxicology conferences is a confirmation of the quality of the study and the drug's potential." says Nicklas Westerholm, CEO, PledPharma AB.



PledPharma

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About Aladote®

Aladote® is a “first-in-class” drug candidate with the potential to prevent the development of acute liver failure caused by paracetamol overdose. Aladote® has shown good efficacy in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment is no longer is effective. A proof of principle study in patients with paracetamol poisoning has been successfully completed. 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. When excessive amounts of paracetamol are broken down in the liver, the harmful metabolite NAPQI is formed, which can cause acute liver failure. The current standard of care for paracetamol poisoning (NAC) is effective if the patient seeks medical care within 8 hours of ingestion. However, NAC is substantially less effective if started more than 8 hours after overdose.

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 80 00). For more information, see <http://www.pledpharma.se/>