PledPharma

PRESS RELEASE
PledPharma AB

The Lancet EBioMedicine publishes Aladote® study results

Stockholm, July 15 2019. The results of PledPharma's proof of principle study with Aladote®, a drug candidate intended to reduce liver damage associated with paracetamol poisoning, are published in the Lancet's journal EBioMedicine, one of the most prominent biomedical research journals.

Dr James Dear is the lead author of the article titled "Principal results of a randomised open label exploratory, safety and tolerability study with calmangafodipir in patients treated with a 12 h regimen of N-acetylcysteine for paracetamol overdose (POP trial)" Dr. James Dear is an internationally leading expert in the treatment of paracetamol poisoning and was the principal investigator of the proof of principle phase Ib/IIa study conducted at the Royal Infirmary of Edinburgh and The Queen's Medical Research Institute, the University of Edinburgh.

"In this clinical study we explored the safety and tolerability of Aladote® co-treatment with N-acetylcysteine (NAC – the only current treatment option). The combination of NAC and Aladote® was safe and tolerated. There was evidence from measurement of conventional and exploratory biomarkers that this combination treatment may reduce liver injury more than NAC alone after paracetamol overdose. There is a clear unmet need for a new treatment for paracetamol overdose because NAC is largely ineffective when given more than 8 hours after the overdose and there is no other medicine available to prevent acute liver failure. Aladote® is the only medicine in this clinical space and this trial demonstrates its potential as an effective new therapy." says Dr James Dear.

"We are pleased to learn that Lancet has chosen to publish the Aladote® proof of principle-study and its results. The Lancet EBioMedicine sets very high standards for publishing and selects only the most important research results based on its quality and scientific impact. An article in a Lancet journal contributes to the awareness of Aladote® and strengthens our future opportunities. The need for improved treatment of paracetamol poisoning is important and it is our goal to meet this need with Aladote®. " says Nicklas Westerholm, CEO of PledPharma.

EBioMedicine is a biomedical open access journal, published by The Lancet.

Follow this link to the article in the Lancet's EBioMedicine.

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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. The study results established the safety and tolerability of the combination of Aladote® and NAC. Further, the results indicate that Aladote® may reduce liver injury in this patient population. Aladote® has been granted Orphan Drug Designation in the US.

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 is an innovative, unique and integrated pharmaceutical drug development company, focusing on improving treatments for diseases with substantial unmet medical need. The company's most advanced project PledOx® is being developed to reduce nerve damage associated with chemotherapy. A global phase III program is ongoing. The drug candidate Aladote® is being developed to reduce the risk of acute liver injury associated with acetaminophen poisoning. A proof of principle study has been successfully completed and the design of the next study is being finalised. Aladote® has been granted Orphan Drug Designation in the US. 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/