PRESS RELEASE
PledPharma AB
Stockholm July 11, 2019

Aladote® – regulatory interactions

Stockholm, July 11, 2019. Following a meeting request and submission of regulatory documents to U.S. Food and Drug Administration (FDA) in May , PledPharma has been granted a meeting with the FDA at the end of October for advice and discussion on the next Aladote study and the path to a possible market approval. Advice from the European Medicines Agency, EMA, is expected during the same period.

The meeting in October concerns the next clinical study for Aladote and the path to a possible market approval of Aladote, a drug candidate intended to reduce liver damage due to paracetamol poisoning. In March this year, the FDA granted Aladote an Orphan Drug Designation (ODD). The ODD status is considered to potentially result in shorter development time and a total lower development cost. Furthermore, it includes dedicated support from the FDA during the drug development and seven years of market exclusivity.

In parallel, PledPharma will have a corresponding interaction with the European Medicines Agency, EMA..

"Interactions with the FDA and EMA are important steps for us to optimize the path to market approval. It's very positive that we have been granted a meeting with the FDA and can now look forward to finalizing the design of the next clinical study. This is an important step towards meeting the medical need of those suffering from paracetamol poisoning and is one of many project activities that we will achieve in the near future, " says Nicklas Westerholm, CEO of PledPharma.

For further information, please contact:
Nicklas Westerholm, CEO
Tel. +46 (0)73 354 20 62
nicklas.westerholm@pledpharma.se

Yilmaz Mahshid, CFO
Tel. +46 (0)72 231 68 00
Yilmaz.mahshid@pledpharma.se

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/