



PRESS RELEASE  
PledPharma AB  
Stockholm, June 25, 2018

## PledPharma establishes a Scientific Advisory Board for the continued clinical development of Aladote®

**PledPharma (publ) announces today that internationally leading experts will join a newly established Scientific Advisory Board to support the continued global clinical development of Aladote® – a drug candidate being developed to prevent acute liver failure caused by paracetamol/acetaminophen intoxication.**

The purpose of the Scientific Advisory Board (SAB) is to provide PledPharma guidance in the strategy and design of the remaining clinical studies for Aladote®. The objectives of the SAB are to optimize the potential of the drug candidate and maximize the likelihood of market approval in order to provide a treatment option for patients who have overdosed paracetamol/acetaminophen and are at risk of acute liver failure.

The SAB will consist of the following international leading experts:

**Dr. Richard C. Dart, MD**, is a physician specializing in emergency medicine and toxicology. Since 1992 he has served as the Director of the Rocky Mountain Poison and Drug Center at University of Colorado hospital in Denver, CO, USA. He is the Executive Director of Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System. He has published more than 250 scientific papers as well as served as editor for several books. In 2002 he was recognized with a special citation from the Commissioner of the U.S. Food and Drug Administration. Dr Dart currently serves as a Deputy Editor of the medical journal *Annals of Emergency Medicine* and is past-president of the American Association of Poison Control Centers.

**Professor Laura James, MD** is Associate Vice Chancellor for Clinical and Translational Research and Professor of Pediatrics at the University of Arkansas for Medical Sciences (UAMS) and Arkansas Children's Hospital System, USA. She also serves as the Director of the Translational Research Institute at UAMS, which houses the institution's Clinical and Translational Sciences Award (CTSA). Professor James has 24 years' experience in clinical pharmacology and toxicology. She and colleagues developed Acetaminophen Toxicity Diagnostics, LLC to develop a rapid assay for the detection of acetaminophen protein adducts. Professor James has published over 170 peer-reviewed publications.

**Professor Peter De Paepe, MD**, is professor in clinical pharmacology at the Heymans Institute of Pharmacology at Ghent University, and is currently head of the emergency department of the Ghent University Hospital in Belgium. He is a member of the National Council for Emergency Medical Services, while also serving as the program director of the residency curriculum in emergency medicine and instructor of



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the Master of Medicine in emergency medicine at Ghent University. His fields of interest and research focus lie in clinical toxicology, pharmacology in critically ill patients and resuscitation. Professor De Paepe has more than 60 original international publications.

"I am grateful and proud that we have attracted these internationally recognized experts in the field of paracetamol intoxication, toxicology and emergency medicine to PledPharma's Scientific Advisory Board, which also confirms the significant need for a drug that can prevent liver damage in the time-window where NAC is no longer effective. I look forward to their and Dr. James Dear's (University of Edinburgh and leading investigator of the POP-trial) advice and insights in our continued efforts to further Aladote<sup>®</sup> towards market registration" says PledPharma's CEO Nicklas Westerholm.

**For more information, please contact:**

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**About Aladote<sup>®</sup>**

Aladote<sup>®</sup> is a "first-in-class" drug candidate with the potential to prevent the development of acute liver failure caused by paracetamol overdose. Aladote<sup>®</sup> has shown good efficacy in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment is no longer effective. A proof of principle study in patients with paracetamol poisoning is ongoing at the Royal Infirmary of Edinburgh.

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<sup>®</sup> 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<sup>®</sup> is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. A proof of principle study has been conducted and will serve as the basis for the continued development. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the



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company's Certified Adviser (tel +46 8 463 80 00). For more information, see <http://www.pledpharma.se/>