PledPharma

PledPharma's drug candidate Aladote® granted Orphan Drug Designation

Stockholm, March 18, 2019. PledPharma AB (publ) today announces that the U.S. Food and Drug Administration (FDA) has granted an Orphan Drug Designation (ODD) to the drug candidate Aladote®, in development for reducing liver damage due to paracetamol overdose.

Today's treatment for overdose of paracetamol, N-acetylcysteine (NAC), is most effective if given within eight hours of the overdose. Patients arriving later to the hospital, and for those with a severe overdose, there is a need for more efficacious treatment options. Aladote® is a first-in-class drug candidate in development to reduce liver damage due to paracetamol overdose. The scientific rationale as well as clinical results from the completed proof-of-principle study indicate that Aladote® in combination with NAC has the potential to reduce liver damage in the specified patient population. PledPharma intends to conduct regulatory interactions to determine the next step in development of Aladote®.

"We are very positive and proud to receive Orphan Drug Designation for Aladote®. This confirms our development strategy to serve this unmet medical need. The ODD status can benefit patients by potentially resulting in shorter development time and for us also lead to lower development costs. In addition, we will receive further dedicated support from the FDA during the drug development process and seven years of market exclusivity." says Nicklas Westerholm, CEO PledPharma AB.

Further information about ODD is presented at www.fda.gov.

Contacts

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 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 Us

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 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 83 00, certifiedadviser@penser.se). For more information, see http://www.pledpharma.com/

This information is information that is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2019-03-18 08:00 CET.

Attachments

PledPharma's drug candidate Aladote® granted Orphan Drug Designation , Aladote ODD Status Final ENG