PledPharma

Press Release
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PledPharma presents a new project against acetaminophen-induced poisoning, aimed to be financed by a rights issue

PledPharma has during the year worked on a new project with expected great commercial potential based on the proprietary PLED-platform. Project PP-100 aims at reducing or preventing severe liver damage as a result of acetaminophen overdosing, one of the most common poisonings. In order to take PP-100 through clinical Phase II and a potential licensing deal, PledPharma plans a rights issue with the right to subscribe one new share for every existing five at 16 SEK, which can provide the company with up to approximately 75 million SEK. The largest shareholders are supportive of the rights issue and the Board of Directors intends to shortly convene an Extraordinary General Meeting to consider the Board's proposals regarding the rights issue. The plan is that the rights issue will be carried out before the end of the year.

Acetaminophen is the most widely used drug in the world for the treatment of painful conditions and it is available both as an over-the-counter and as a prescription drug. Acetaminophen overdose is also one of the most frequent causes of drug poisonings either intentionally or unintentionally. Intentional overdose of acetaminophen is the most common method of attempted suicide among young people age 10-19 years, where girls dominate.

The unplesant thing with acetaminophen poisoning is that acetaminophen is generally considered as the gentlest among pain medications, furthermore, it can be difficult to detect poisoning at the onset for those that have inadvertently overdosed acetaminophen since the difference between normal and harmful dose is small and the symptoms can be quite vague or absent during the first 24h. Overdose of acetaminophen can among other things lead to acute liver failure, which in turn may result in the need for a liver transplant and in the worst case, result in death.

The problem with acetaminophen overdose is huge worldwide. In Sweden, the number of questions about acetaminophen poisoning at Poisons Information Center has grown three-fold since 2000. In the United States acetaminophen overdose is behind 56,000 emergency room visits, 2,600 hospitalizations and 500 deaths annually.

The existing treatment for overdose of acetaminophen (N-acetylcysteine) is effective if the patient seek medical care within 8 hours after ingestion of acetaminophen. Late arriving patients lack well-functioning treatments despite an increased risk of liver damage. About a quarter of those who overdose on acetaminophen come in to the emergency room later than 8 hours after the overdose.

Preclinical results clearly demonstrate that the PP-100 compound, PP 100-01A, with its unique formulation, can normalize the elevation of certain liver enzymes that are indicators of liver failure long after the N-acetylcysteine stopped working.

Jacques Näsström, CEO PledPharma:
"Our preclinical results demonstrate that we have an opportunity to help late arriving patients. An extended treatment window will be able to save lives, reduce suffering and save significant healthcare costs. Data from IMS Health Capital allows us to estimate the commercial potential of the project to the same magnitude as for PledOx in treatment of colorectal cancer with FOLFOX. "

Because the compound in the PP-100 project is based on the same platform as PledOx, existing safety documentation can be used and the company believes that the project can go directly from preclinical stage to a Phase II study in patients. The compound is subject to the same composition of matter patent application as PledOx, with an expected patent protection up to 2033. PledPharma will also seek orphan drug status in both the EU and USA for this product.

Mechanism of action
N-acetylcysteine acts as antidote by replenishing glutathione stores. Acetaminophen metabolites bind to glutathione after which the conjugate is excreted via the kidneys. More recent research has indicated that the hepatotoxic effects of acetaminophen is due to that when the glutathione stores in the liver are depleted, acetaminophen metabolites bind to proteins in the liver, which induces severe oxidative stress that can lead to acute liver failure. Since PledPharma’s PLED compounds are potent low molecular enzyme mimetics (low MEM) of the body's own manganese-containing superoxide dismutase (MnSOD), these compounds can by their mechanism of action reduce the oxidative stress in the liver and thereby prevent acute liver failure.

Orphan drugs
Orphan drugs, are drugs aimed to treat serious and rare disease-areas of significant medical interest. Orphan drug designation conveys a number of advantages, including market exclusivity for a certain period of time, certain tax credits, assistance with applications and accelerated market approval.

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About Pledpharma

PledPharma is a Swedish pharmaceutical company developing novel therapies for life-threatening diseases. Our initial goal is to develop a drug, PledOx®, which reduces the serious side effects associated with chemotherapy. Project PP-099 is based on limiting the damage that occurs to the myocardium in patients suffering from acute myocardial infarction. In project PP-100, the most recent addition, the ability of PledPharma compound (PP100-01A) to reduce or prevent acute liver failure as a result of acetaminophen poisoning will be evaluated. We have the potential to provide patients with valuable and unique treatments for severe, life-threatening diseases where there is also an opportunity for faster registration process in the United States through breakthrough therapy designation. The current market for prevention of chemotherapy-induced side-effect is about US$ 10 billion. PledPharma (STO: PLED) is listed on NASDAQ OMX First North. Erik Penser Aktiebolag is Certified Adviser. For more information, see www.pledpharma.se