

PledPharma's clinical myocardial infarction study restarted after approval from the Medical Products Agency

Stockholm, 2011-12-15 - PledPharma (STO:PLED) today announced that the new production of mangafodipir clinical trial substance has been approved by the Swedish Medical Products Agency. The clinical phase Ila study will consequently be restarted early 2012. In the (MANAMI) study mangafodipir's ability to improve the treatment outcome in acute myocardial infarction patients treated with angioplasty.

Patient recruitment was discontinued since there was no available clinical trial substance as GE Healthcare stopped its production of Teslascan, a contrast agent used in magnetic resonance imaging (MRI). Recipharm has manufactured new trial substance and this has passed an approval process at the Swedish Medical Products Agency since the manufacturer is new.

"The restart of the MANAMI study is very positive. This is a great opportunity to help myocardial infarction patients who are treated with angioplasty to an even better function by reducing the size of the infarction further. Furthermore, we are expecting to have two clinical phase II studies ongoing next year, since we are in the final stage of the preparatory work ahead of our clinical phase IIb study in colorectal cancer patients", says CEO Jacques Näsström.

About the MANAMI study

Mangafodipir is given just prior to angioplasty treatment in connection with treatment of acute myocardial infarction. The study will include in total 20 patients, whereof 10 patients will receive active substance and 10 patients will receive placebo. 8 patients are included so far. The mangafodipir effect is assessed through measurement of enzyme levels and magnetic resonance imaging (MRI) analysis. The study is done in the County hospital Ryhov under the supervision of Senior Consultant and PhD Jan-Erik Karlsson. Previous pre-clinical studies have shown that PLED-derivates can reduce the size of the remaining infarction after reperfusion of an acute myocardial infarction.

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About PledPharma

PledPharma is a Swedish specialty pharma company, which develops new treatments of life threatening diseases. PledPharma currently runs two projects in clinical development phase II with the patented drug substance class, PLED-derivatives. The preventive effect of PLED-derivatives on adverse effects of chemotherapy in colon cancer is examined in one trial. Another trial investigates the ability of PLED-derivatives to reduce reperfusion injuries in myocardial infarction patients undergoing percutaneous coronary intervention (PCI). PLED-derivatives protect the body's normal cells against oxidative stress, which is a condition due to overproduction of free oxygen radicals. PLED-derivatives have in previous pre-clinical trials been shown to protect against oxidative stress. Moreover, the PLED-derivative mangafodipir protected against the side effects of chemotherapy in colorectal cancer. PledPharma (STO:PLED) is listed on NASDAQ OMX First North. Erik Penser Bankaktiebolag is the Certified Adviser. For more information, please visit www.pledpharma.se