PledPharma

Press Release
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The PLIANT study is fully recruited and the final futility analysis approved

All 126 patients have now been included in PledPharma's colorectal cancer study PLIANT and results are expected by the end of Q1 next year.

The DSMB reports that the third and last futility analysis that included 30 patients, in addition to those 60 patients already analyzed, has been completed and that no negative impact on the anticancer effect of the chemotherapy has been observed.

The analysis covers the first 90 patients in the study who have completed four treatment cycles with the chemotherapy mixture FOLFOX after pretreatment with either PledOx® or placebo. The approval means that PledOx did not weaken the anticancer effect of FOLFOX and that the PLIANT trial be concluded as planned.

" We have now completed the recruitment for the PLIANT study. In the recent months, the recruitment rate has been high and the last patient needed has been included in Part 2 of the study. In total 165 patients have been randomized and have initiated their treatment in the PLIANT study. These patients have in total received more than 600 doses of PledOx to date. Our plan is to present the overall study results at the end of the first quarter of 2015. The results presented will include the effect of PledOx on FOLFOX induced peripheral neuropathy and other dose-limiting side effects. One important goal is to demonstrate that PledOx does not negatively impair the anticancer effect. Therefore, it is of particular importance that DSMB announced that no further analysis needs to be carried out on the remaining patients", said CEO Jacques Näsström

About the PLIANT study
The PLIANT-study investigates PledOx's ability to reduce serious FOLFOX-induced side effects during treatment of colorectal cancer. The primary objective is to evaluate the reduction of adverse events related to a decrease in white blood cells (neutrophils) and sensory nerve disorders (neuropathy). The PLIANT study is divided into two parts with an initial dose-escalation part, in order to determine the correct dose-level, and a randomized part, with the goal to establish PledOx's effect.

In the randomized part, aiming at roughly 126 patients from approximately 30 centers in Europe and the United States, the patients will be divided into three equal groups to receive either placebo or PledOx in two different doses (2 µmol/kg or 5 µmol/kg). For further details please see www.clinicaltrials.gov

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About PledPharma
PledPharma is a Swedish pharmaceutical company that develops new therapies for the treatment of life threatening diseases. The initial objective is to develop a drug, PledOx®, which reduces severe side-effects associated with chemotherapy. The current market for supportive cancer care is some USD 10 billion. PledPharma also evaluates an existing medicines possibility to reduce the damage that occurs on the heart muscle when patients suffer from acute myocardial infarction. In addition to these projects, the company is also evaluating opportunities of using our technology platform in additional areas where there is a significant unmet medical need. PledPharma has the potential to offer patients valuable and unique treatments for serious life-threatening diseases where there is an opportunity fast registration in the US through "breakthrough therapy" designation. This means that the company has the potential to offer shareholders a good return on their investment. PledPharma (STO:PLED) is listed on NASDAQ OMX First North. Erik Penser Bankaktiebolag is the Certified Adviser. For further information, please visit www.pledpharma.se