PledPharma

Press release
PledPharma AB
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# PledPharma reports constructive meeting with the European Medicines Agency (EMA)

**PledPharma AB (publ) today announced that the company has completed a constructive meeting with the European Medicines Agency (EMA) for the remaining development and potential market introduction of PledOx® - a drug candidate that reduces the incidence of chemotherapy induced nerve damage. The meeting was also attended by representatives from NICE in the UK and NOMA in Norway, two national authorities who are responsible for health economic evaluations of new drugs.**

The meeting was held within the framework of the pan-European cooperation HTA Parallel Scientific Advice, where the EMA along with selected national authorities, responsible for health economic evaluations, support pharmaceutical companies in the development of new therapies. At the meeting the design of the remaining part of the development program for PledOx® (calmangafodipir) was discussed.

In addition, the types of health economic evaluations that should be conducted to facilitate future decisions on inclusion in the national pharmaceutical reimbursement systems were discussed. The authorities' assessment of PledOx® potential role in the future treatment of cancer patients and their suggestions are in line with PledPharma's own opinion.

The meeting was attended by representatives of the British NICE (National Institute for Health and Care Excellence) and the Norwegian NOMA (Norwegian Medicines Agency).

"It is with great comfort that we note that the European Medicines Agency shares our view regarding the structure and scope of the final clinical development of PledOx®. The comments received from national authorities, commissioned to evaluate new drug therapies, strengthens our view that PledOx® can play a valuable role in the future treatment of cancer patients, "says Jacques Näsström, CEO, PledPharma."

PledPharma has previously completed a so-called end-of-Phase II/pre-Phase III meeting with the FDA. This meeting was also held in a constructive and positive spirit and altogether has the contact with the authorities established a clear regulatory strategy for the two largest markets, the US and Europe and a good basis for the continued development. PledPharma's view is that these meetings have created an attractive foundation for the way forward towards a market approval.

A large proportion of patients undergoing chemotherapy suffers from symptoms (tingling, numbness and pain) caused by nerve damage that have occurred in connection with the chemotherapy. After completing the treatment, it is common that these symptoms linger and that, in many cases, they become more severe. The results from the phase IIb study PLIANT shows that PledOx® reduce the incidence and intensity of chemotherapy induced nerve damage in a statistically significant and clinically meaningful way without negatively interfering with the anticancer effect of chemotherapy on colorectal cancer.

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**About PledPharma**
PledPharma develop new drugs that protect the body against oxidative stress - a potentially disabling and sometimes life-threatening condition that can be caused by chemotherapy and acetaminophen poisoning. The company's most advanced project PledOx® reduces nerve damage associated with chemotherapy. Positive results from phase IIb study PLIANT were presented in the spring of 2015. The drug candidate Aladote® is developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. The project PP-099 aims to limit the damage that occurs to the heart muscle during a heart attack. PledPharma (STO:PLED) is listed on Nasdaq First North. Erik Penser Bank is the Certified Adviser. For further information, please visit www.pledpharma.se