PRESS RELEASE
PledPharma AB

PledPharma places dosing of patients in the POLAR program on hold

Stockholm, March 1, 2020. PledPharma AB (STO: PLED) today announced the decision to place dosing of patients in the pivotal clinical phase III POLAR program for the lead candidate PledOx® on hold. The decision follows interactions with the French regulatory authority, ANSM, and the previously communicated clinical hold issued by the FDA.

Following this decision, recruitment and dosing of patients in the POLAR program is paused at all sites in all countries. Patients currently enrolled in the POLAR program will continue with their scheduled study visits and procedures, while not receiving study drug.

The phase III POLAR program for PledOx consists of two double blinded randomized placebo-controlled trials, POLAR-A and POLAR-M. POLAR-A is conducted in patients undergoing adjuvant chemotherapy treatment for colorectal cancer and was fully recruited in December 2019. POLAR-M is conducted in patients undergoing chemotherapy treatment for metastatic colorectal cancer, where recruitment will now be placed on hold.

After the Food and Drug Administration (FDA) issued a Clinical Hold on January 22, 2020, the company continued the review of data and interactions with regulatory authorities in countries participating in the POLAR program. On February 14, 2020, the independent Drug Safety Monitoring Board (DSMB) for the POLAR program recommended that the POLAR studies continue as planned, following their review of the accumulating data from the POLAR program.

The French regulatory authority, ANSM, has requested and reviewed unblinded safety data from the POLAR program. On February 28, 2020 ANSM expressed the same concern as the FDA on a few numbers of observed adverse events and requested that recruitment and dosing of patients should stop in France. Altogether, based on the views of the FDA and ANSM, PledPharma has taken a decision to place dosing of patients in the POLAR program on hold in all countries.

"The safety of patients in our clinical studies is our most important responsibility. To date in clinical studies, more than 3,000 doses of calmangafodipir have been administrated in more than 500 patients. We will work with the FDA and ANSM to clarify the right path forward for the POLAR program, as we believe nerve damage associated with chemotherapy remains an unmet medical need" said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

PledPharma will host a telephone conference on March 2, 2020, at 14.00 CET. Follow the link below for call-in details:
Weblink - https://financialhearings.com/event/12752

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About PledPharma

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 paracetamol/acetaminophen poisoning. A proof of principle study has been successfully completed and the design of the next study is being finalised. Aladote® has been granted Orphan Drug Designation in the US. PledPharma (STO: PLED) is listed on the Nasdaq Stockholm main market. For more information, see http://www.pledpharma.com/

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