PledPharma

PRESS RELEASE
23 January 2020 08:46:00 CET

PledPharma provides update on the clinical POLAR program, clinical hold in the US

PledPharma AB (STO: PLED) today announced that the US Food and Drug Administration (FDA) has issued a clinical hold in the US of the phase III POLAR program for the lead candidate PledOx®. The implication is that recruitment and dosing of patients in the POLAR-M study is halted in the US. Based on the evaluation of the independent Drug Safety Monitoring Board (DSMB), PledPharma's position is that the overall safety profile for PledOx® supports the continuation of the POLAR program and both studies will continue as planned in Europe and Asia.

The global 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 Europe and Asia in patients undergoing adjuvant chemotherapy treatment for colorectal cancer and was fully recruited in December 2019. POLAR-M is conducted in Europe, Asia and the US in patients undergoing chemotherapy treatment for metastatic colorectal cancer, where recruitment is ongoing. The clinical hold of the POLAR program issued by the *FDA means that* recruitment and dosing of patients in the POLAR M study is halted in the US. Patients currently enrolled in the US will continue with their scheduled study visits and procedures except for the dosing of study drug. Both POLAR studies will continue as planned in Europe and Asia.

The decision by the FDA is due to safety reasons based on a few numbers of observed adverse events. The independent Drug Safety Monitoring Board (DSMB) for the POLAR program has reviewed the same adverse events and has recommended that the POLAR studies can continue as planned. In order to ensure the safety of patients in our clinical trials PledPharma has conducted an extensive review of all available clinical and pre-clinical data and concludes that the overall safety profile of PledOx supports the continuation of the POLAR program. Thus, both POLAR studies will continue to recruit, and dose patients as planned in Europe and Asia, allowing for additional data to be collected on the benefit-risk profile of PledOx.

PledPharma will continue to work with the FDA to provide the necessary information to lift the clinical hold as soon as possible. Other regulatory authorities involved in the POLAR program will be informed about the US clinical hold.

"The safety of patients in our clinical studies is our most important responsibility. To date in clinical studies, approximately 2,700 doses of calmangafodipir have been administrated in about 500 patients. Our review of available clinical and pre-clinical data supports the continuation of the POLAR program and this view is shared by the DSMB. We will work diligently with the FDA to provide the necessary information to allow the recruitment of US patients in the POLAR-M study to continue as soon as possible." said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

PledPharma will host a telephone conference today at 14.00 CET. Find call-in details and links below:
Weblink - https://tv.streamfabriken.com/press-conference-23-jan
Participant dial-in number:
SE: +46 856642651
UK: +44 3333000804
US: +1 6319131422
JP: +81 344556492
Participant Pin code: 61464234#

PledPharma

PRESS RELEASE
23 January 2020 08:46:00 CET

Contacts

Nicklas Westerholm, CEO, phone: +46 73 354 20 62
nicklas.westerholm@pledpharma.se

Yilmaz Mahshid, CFO, phone: +46 72 231 68 00
yilmaz.mahshid@pledpharma.se

About Us

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 acetaminophen/paracetamol 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 since October 31, 2019. For more information, see http://www.pledpharma.com/

This information is information that PledPharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-01-23 08:46 CET.

Attachments

PledPharma provides update on the clinical POLAR program, clinical hold in the US