Japanese Medical Agency (PMDA) supports the expansion of the Phase III program for PledOx® to include Japanese patients

Stockholm, June 13, 2018. PledPharma AB and Solasia Pharma K.K. (Solasia) today announced that the Japanese Pharmaceuticals and Medical Devices Agency, PMDA, following a meeting with PledPharma and Solasia, has expressed its support for an expansion of the Phase III program (POLAR studies) with the drug candidate PledOx® to include Japanese patients.

The Phase III program for PledOx® consists of two international double-blind, randomized, placebo-controlled studies, POLAR-M (300 patients) and POLAR-A (200 patients), conducted in the US and EU. Based on the discussion with the PMDA, the intention is to submit clinical trial applications to extend the program with an additional 200 patients to cover a total of approximately 700 patients in the POLAR-A and POLAR-M studies. The process of submitting applications for study start will commence immediately in Asian countries including Japan. The expansion of the study program will be financed in full by PledPharma’s partner Solasia, in-line with the licensing agreement announced in November 2017.

The Japanese Medicines Agency’s positive opinion is based, among other things, on the positive outcome of the SUNCIST Phase 1 study that was communicated in February 2018. The study investigated the safety, tolerance and pharmacokinetics of PledOx® in Caucasian and Japanese healthy volunteers.

"We are delighted for the constructive dialogue and the supportive comments from the Japanese Medicines Agency. This is a very important milestone in extending the POLAR studies to Asian patients aiming at realising the global commercial potential of our drug candidate. Furthermore a broadened patient selection in the POLAR studies will increase the robustness of the clinical program and enable an even more thorough assessment of the benefits and risks with PledOx®." said PledPharma CEO and President, Nicklas Westerholm.

For more information, please contact:

Nicklas Westerholm, CEO, phone: +46 73 354 20 62
nicklas.westerholm@pledpharma.se
About PledOx®
PledOx® is a “first in class” drug candidate developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, prevention against the nerve damage that can occur in conjunction with chemotherapy treatment. The results from a completed Phase IIb trial (PLIANT), where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx®, indicates that the patients who received PledOx® had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. The presence of the investigator reported sensory nerve damage, the primary endpoint, was after treatment 38% lower in the group of patients treated with PledOx® compared with the placebo group (p = 0.16). This was not statistically significant, but a difference of this magnitude is considered to be clinically relevant. After completion of chemotherapy, the patient-reported incidence of moderate and severe neuropathy was 77% lower in patients treated with PledOx® compared to the placebo group (exploratory analysis; p = 0.014). This is considered valuable for the success of the forthcoming POLAR studies, where patient-reported symptoms after completion of treatment will be the primary efficacy parameter. No apparent negative effect on the efficacy of the cancer treatment was observed.

About chemotherapy induced peripheral neuropathy (CIPN)
Peripheral neuropathy symptoms are caused by damages to sensory nerves, most commonly in hands and feet. Certain chemotherapies, including oxaliplatin, can cause such damages, which is then called chemotherapy induced peripheral neuropathy (CIPN). This can be a debilitating adverse reaction of the cancer treatment and may occur at any time after the initiation of chemotherapy. The symptoms often increase as the chemotherapy treatment continues and may often causes discontinuation of the chemotherapy. In many patients, the symptoms are resolved after discontinuing the chemotherapy, but up to 20–30% of the patients have sustained symptoms such as numbness, tingling and pain in hands and feet. Patients with CIPN may have difficulties with fine motor skill, such as buttoning buttons, challenges using a computer key board and become hypersensitive to cold. The sensory loss in the feet’s may increase the risk of falls. There is currently no approved drug to prevent or treat CIPN.

About PledPharma
PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. The company’s most advanced project PledOx® is being developed to reduce nerve damage associated with chemotherapy. A phase IIb study has been conducted and will serve as the basis for the continued development. The drug candidate Aladote® is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company’s Certified Adviser (tel +46 8 463 80 00). For more information, see http://www.pledpharma.se/
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