PledOx® shows favorable safety and tolerability profile in the SUNCIST Phase I study in Japanese subjects

Stockholm, Sweden / Tokyo, Japan, [February 9th 2018] - PledPharma AB ("PledPharma") (STO: PLED) and Solasia Pharma K.K. ("Solasia") (TSE: 4597) today jointly announce the completion of a Phase I clinical study (SUNCIST) of PledOx® in 24 Japanese and 24 Caucasian healthy volunteers. The study was performed by PledPharma, and first patient in was reported on December 1, 2017. PledOx® showed a favorable safety and tolerability profile, which merits further clinical development in Asian patients.

The Phase I study included 24 Japanese and 24 Caucasian healthy volunteers, which were randomly assigned to study treatment with PledOx® in a single dose of 2-, 5- or 10 µmol/kg, or placebo. The objective of the study is to gain sufficient safety, tolerability and pharmacokinetic data for an expansion of the Phase III program to include Asian patients.

In November 2017, Solasia acquired exclusive development and marketing rights for PledOx® in Japan, China (including Hong Kong and Macau), Korea and Taiwan from PledPharma. PledPharma has been conducting clinical development of PledOx® in the US and Europe focusing on the use for prevention of chemotherapy induced peripheral neuropathy as its initial indication. Based on the result from the PLIANT Phase II clinical trial conducted by PledPharma, the effect of improvement of peripheral neuropathy in patients with advanced colorectal cancer in FOLFOX therapy*1 has been confirmed while maintaining the FOLFOX therapy's treatment effect. The US FDA, the central ethics committee in the US and the health authority in the UK, MHRA, have recently accepted the design of a phase III program, which is estimated to commence in the second half of 2018. Solasia will continue preparing for the participation in these global phase III clinical trials by including patients in Japan as well as other Asian countries, subject to approvals from concerned regulatory authorities.

"We are very excited to have reached this first milestone in our collaboration with Solasia. The study has been carried out with exceptional delivery focus in a very short time. I'm looking forward to our continued collaboration and the potential for extending the POLAR studies to include Asian patients," said Nicklas Westerholm, CEO, PledPharma.

** 1: FOLFOX therapy refers to cancer chemotherapy using three agents, fluorouracil, folinic acid, and oxaliplatin. It is adopted as standard therapy in postoperative adjuvant chemotherapy for Stage III colorectal cancer and systemic chemotherapy for Stage IV recurrent colorectal cancer.*

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/

About Solasia

Solasia is a specialty pharmaceutical company based in Asia, with a mission of "Better Medicine for a Brighter Tomorrow". In order to address the unmet medical needs within the oncology area, we develop innovative medicines to contribute to the patient's healthy living and to provide treatment options for the healthcare providers. Additional information is available at http://www.solasia.co.jp/en/

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