Announcement Concerning the Development Plan of PledOx®

Stockholm, Sweden / Tokyo, Japan, June 13th 2018 – PledPharma AB ("PledPharma") (STO: PLED) and Solasia Pharma K.K. ("Solasia") (TSE: 4597) today announced the future development plan of PledOx® in Asian region including Japan.

Phase III clinical trials in Asian region including Japan, will start in the second half of 2018 as an extension of the Phase III clinical trial that will be conducted under the initiative of PledPharma. Asian region including Japan will now be part of Phase III International joint clinical trial.

PledPharma has completed a Phase II clinical trial in Europe and the United States as well as Phase I clinical trial including the Japanese healthy volunteers in the United States.

After the consultation with the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), and the Pharmaceuticals and Medical Devices Agency (PMDA), the outline of the Phase III clinical development plan has been set as follows

Study description:
- Phase III, International, multicenter, double-blind, randomized, placebo-controlled study

Purpose of the study:
- The effect of suppressing the peripheral neuropathy associated with administration of oxaliplatin by PledOx® administration compared with placebo.

Study design:
- POLAR-M study: Colorectal cancer patients who undergo FOLFOX therapy (*1) with distant metastases are included.

- POLAR-A study: Colorectal cancer patients who undergo FOLFOX therapy as an adjuvant therapy for postoperative surgery are included.

Primary outcome measures:
- Both the POLAR-M and POLAR-A studies will include subjects with moderate or higher chronic peripheral neuropathy at 9 months after (first day of FOLFOX therapy) the initial administration of PledOx® is evaluated.

Estimated enrollment:
- POLAR-M study: 420 patients (of which 120 patients in Asian region)

- POLAR-A study: 280 patients (of which 80 patients in Asian region)

About chemotherapy induced peripheral neuropathy (CIPN) in Japan

Cancer chemotherapy has side effects such as nausea and vomiting and onset of stomatitis, but peripheral neuropathy is also a serious side effect. Peripheral neuropathy is known to be markedly expressed in major drugs of cancer chemotherapy such as plant alkaloid preparations and platinum preparations (*2). FOLFOX therapy including oxaliplatin, is a combination of a chemotherapy for advanced and recurrent cancer and a typical anticancer drug for postoperative adjuvant chemotherapy as a treatment for colorectal cancer, which is difficult to heal surgically. Almost all patients (85% - 95%) of oxaliplatin prescribed patients develop peripheral nerve disorder, and the disorder brings about the following symptoms (*2).

- *Acute symptoms: abnormal sensations such as hands, feet and lip peripheral parts, strangulation of pharyngeal larynx accompanied with dyspnea and dysphagia*
- *Chronic symptoms: numbness in the periphery of the limbs, decreased sensation, decreased tendon reflexes, sensory ataxia*

When such side effects occur, it is considered that some symptom improvement is seen in 80% of patients due to discontinuation of medicine and completely recovered in 6 to 8 months in 40% of cases (*2). However, discontinuation of the drug results in discontinuation of cancer treatment or change in treatment regimen which is an important medical issue. There is currently no approved drug to prevent or treat CIPN.

** 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.*

** 2: Reference: Ministry of Health, Labor and Welfare "Corresponding manual for severe side effects disease Peripheral neuropathy"*

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 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/

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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