PRESS RELEASE
PledPharma AB
Stockholm December 16, 2019

Global phase III study POLAR-A fully recruited

Stockholm, December 16, 2019. PledPharma AB (STO: PLED) and Solasia Pharma K.K. ("Solasia") (TSE: 4597) today jointly announced that the global Phase III study POLAR-A with PledPharma's lead candidate PledOx® is now fully recruited and top line results expected approximately one year later.

The now fully recruited POLAR-A study is the first study of the Global Phase III POLAR program for PledOx, which is developed to prevent nerve damage associated with chemotherapy. It is a double-blind, randomized, placebo-controlled trial involving 280 patients with colorectal cancer undergoing adjuvant chemotherapy and conducted in Asia and Europe.

"We are excited to have successfully completed the recruitment in the POLAR-A study and to be able to do it within the intended time plan. This year we started screening the first patient in the study and what better way to end the year than screening the last one. Top line results are expected approximately one year later. I want to thank everybody who has been and still is involved in this important study, which takes us one step closer to a treatment that can truly help the patients optimize their cancer treatment and improve their quality of life," said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

"We are extremely excited to achieve this great milestone in the POLAR-A study. As we continue to work together with our partner, PledPharma, advancing our enrollment in the POLAR-M study, we will move another step closer to the completion of the Global Phase III program " said Yoshihiro Arai, President and Chief Executive Officer, Solasia.

As was communicated in each report, for the third quarter 2019, the second study in the POLAR program, POLAR-M, conducted in 420 patients with metastatic colorectal cancer, is expected to be fully recruited in Q2 2020, and it is anticipated that PledPharma and Solasia will have top line results approximately a year later.

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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/

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. PledOx® showed 38% effect (odds ratio=0.62;

p=0.16) on investigator reported sensory nerve damage, the primary endpoint, compared with the placebo group. This was not statistically significant, but a difference of this magnitude is considered clinically relevant. After completion of chemotherapy, PledOx® showed 77% effect (odds ratio=0.23; exploratory analysis: p=0.014) on patient-reported moderate and severe neuropathy compared to the placebo group. 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. The phase III program for PledOx® consists of two double blinded randomized placebo-controlled trials, POLAR-M and POLAR-A. POLAR-M includes 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and is being conducted in Asia, Europe and the US. The study compares PledOx® at doses of 2 µmol/kg and 5 µmol/kg with placebo. POLAR-A includes 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and is being conducted in Asia and Europe. The study compares PledOx® at a dose of 5 µmol/kg with placebo.

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 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. For more information about the company, please visit https://www.solasia.co.jp/en/