PRESS RELEASE

GLOBAL PHASE III STUDY POLAR-A FULLY RECRUITED

Stockholm and Tokyo, 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 for 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 POLAR-A 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 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." 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 more progressed disease, 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.

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

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, please see http://www.solasia.co.jp/en/

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.

About the POLAR program

The Phase III POLAR program for PledOx, which is developed to prevent nerve damage associated with chemotherapy, comprises two double-blind, randomized, placebo-controlled trials – POLAR-A and POLAR-M. The first patient was enrolled in November 2018.

POLAR-A involves 280 patients with colorectal cancer undergoing adjuvant chemotherapy and is conducted in Asia and Europe. The trial compares PledOx at a dose of 5 µmol/kg with a placebo.

POLAR-M includes 420 patients with metastatic colorectal cancer undergoing chemotherapy and is conducted in Europe, Asia and the US. The trial compares PledOx at doses of 2 µmol/kg and 5 µmol/kg, respectively, with a placebo.

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