PRESS RELEASE
PledPharma AB

Results from the prematurely closed PledOx POLAR program

Stockholm, Sweden / Tokyo, Japan, December 15, 2020. PledPharma AB ("PledPharma") (STO: PLED) and Solasia Pharma K.K. ("Solasia") (TSE: 4597) today jointly announce that PledOx® did not meet the efficacy endpoint in the prematurely closed Phase 3 POLAR program. Based on further evaluation of the results from the POLAR studies, the strategic next steps for PledOx will be determined together with Solasia.

In the efficacy analysis, based on patient-reported symptoms of moderate or severe CIPN by the validated FACT/GOG-NTx instrument, combining data from both the POLAR-A study and the POLAR-M study, PledOx 5 µmol/kg in combination with chemotherapy did not reduce the risk of moderate to severe chemotherapy induced peripheral neuropathy (CIPN) at 9 months after the first cycle of chemotherapy versus chemotherapy alone.

The occurrence and type of adverse events observed were generally consistent with the expected toxicity caused by the chemotherapy and the patient populations studied. No negative effect on the anti-cancer effect of chemotherapy were observed with PledOx on progression-free survival (PFS), overall survival (OS) and disease-free survival (DFS), albeit based on a limited number of events. As previously identified by the independent drug safety monitoring board (DSMB) at the time when the POLAR program was prematurely stopped, an increased risk of allergic-hypersensitivity reactions was observed, with a small number of patients experiencing a serious adverse event (SAE) on PledOx in combination with chemotherapy. The severe allergic-hypersensitivity reactions occurred only after repeated treatment cycles.

Full results will be presented at a forthcoming scientific conference.

"The negative result in the efficacy analysis of the POLAR program is very disappointing, as we believe nerve damage associated with platinum-based chemotherapy is an important unmet medical need. Based on further evaluation of the results, we will conclude on the strategic next steps for PledOx together with Solasia. Our full focus is on building a specialized late-stage orphan drug development company with Emcitate® and Aladote® and their respective pivotal studies, as previously communicated", said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

"We are disappointed that the efficacy endpoint for CIPN could not be achieved in the combined analysis of the POLAR M and POLAR A studies. Regarding future development strategies, we plan to evaluate and discuss the study results in detail with our partner PledPharma". said Yoshihiro Arai, President and Chief Executive Officer, Solasia

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This information is information that PledPharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2020-12-15, 08:00 CEST.

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 drug candidate Aladote® is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol poisoning. A proof of principle study has been successfully completed and the design of the upcoming pivotal Phase IIb/III study for Aladote has been finalized after completed interactions with FDA, EMA and MHRA. Aladote® has been granted Orphan Drug Designation in the US. Through the acquisition of Rare Thyroid Therapeutics (RTT), the clinical portfolio also includes Emcitate®, for the treatment of MCT8 deficiency, a rare disease with high unmet medical need and no available treatment. A pivotal Phase IIb/III early intervention

study was initiated in Dec 2020 with the first patient dosed. Emcitate has been granted Orphan Drug Designation in the US and EU. The Phase III POLAR program for the drug candidate PledOx® was prematurely stopped in Q2 2020. Results from the POLAR program communicated in December 2020 shows that Pledox did not meet the efficacy endpoint. Based on further evaluation of the results from the POLAR studies, the strategic next steps for PledOx® will be determined together with our partner Solasia. The company is undergoing a name change to Egetis Therapeutics based on the resolution at the EGM on December 11, 2020.

PledPharma (STO: PLED) is listed on the Nasdaq Stockholm main market since October 31, 2019. For more information, see www.pledpharma.com.

About PledOx® and the POLAR program

PledOx® is a "first in class" drug candidate developed to provide prevention against the nerve damage that can occur in conjunction with chemotherapy for colorectal cancer patients that are receives adjuvant treatment after surgery or treatment for metastatic colorectal cancer.

The phase III program for PledOx® consists of two double blinded randomized placebo-controlled trials, POLAR-M and POLAR-A. The POLAR-A and POLAR-M studies were initiated in late 2018. POLAR-A was fully recruited in December 2019 and randomized 301 patients undergoing adjuvant chemotherapy for CRC to either 5 µmol/kg of PledOx or placebo in Europe and Asia. The POLAR-M study intended to randomize 420 patients undergoing chemotherapy for metastatic CRC to 2 µmol/kg of PledOx, 5 µmol/kg of PledOx or placebo. In April 2020 PledPharma and Solasia decided to prematurely stop the POLAR phase III program. The decision was taken after a recommendation from the independent Drug Safety Monitoring Board (DSMB) and followed the clinical holds issued by the French regulatory authority, ANSM, and the US Food and Drug Administration (FDA) earlier this year. Therefore, POLAR-M was not fully recruited, but randomized only a total of 291 patients. Patients enrolled in the POLAR program continued with their scheduled study procedures, while not receiving the study drug, until the data cut-off in the third quarter 2020 when all patients eligible for at least 6 cycles of active treatment had completed the primary efficacy data collection nine (9) months after initiation of chemotherapy. Due to the fewer than planned number of randomized patients in the POLAR-M study and the reduced dosing of patients in both studies, the efficacy analysis for the POLAR program was defined to be conducted across the two studies.