NEWS RELEASE

Solasia Announces Development Strategy for Expanded Indication of PledOx® and Amendment of License Agreement

Tokyo, Japan, October 9th, 2019 – Solasia Pharma K.K. (TSE: 4597, hereinafter "Solasia")'s clinical program, SP-04 (PledOx®, active ingredient name: Calmangafodipir, Indication: Chemotherapy Induced Peripheral Neuropathy) was licensed from PledPharma AB (STO: PLED, hereinafter "Pled"). Pled and Solasia have agreed to explore indication expansion. We are announcing our development strategy regarding indication expansion as follows.

Chemotherapy Induced Peripheral Neuropathy (CIPN) is a major cause induced by platinum-based compounds (oxaliplatin, cisplatin, etc.), Taxanes (paclitaxel, etc.), Vinca alkaloids, and proteasome inhibitors. However, there are currently no drugs approved for the indication of CIPN. Solasia and Pled are currently developing PledOx® for colorectal cancer patients who receive combination chemotherapy mFOLFOX6 *[1] which includes oxaliplatin. In 4Q 2018, an international joint phase III clinical trial was initiated in Europe, the US, and Asian countries including Japan and top line results is expected before year end 2020.

The incidence of peripheral neuropathy caused by oxaliplatin, which is currently under clinical development, and the main clinical symptoms such as paralysis, numbness, and pain may be observed in the same way even when Taxanes are administered*[2]. PledOx® is a superoxide dismutase analog that is an enzyme that breaks down active oxygen generated in cells and protects nerve cells from damage caused by drug-induced oxidative stress such as antineoplastic drugs. Based on this assumed mechanism of action, as part of PledOx®'s strategy to expand the indication, Pled has initiated pre-clinical studies to evaluate the expression suppression effect in collaboration with University of Milan Bicocca, Italy.

Solasia believes that the expansion of targets to CIPN caused by cancer chemotherapy other than oxaliplatin (hereinafter referred to as "indication expansion") will address the unmet medical needs in clinical practice and contribute to further increasing the potential of PledOx®.

In November 2017, PledOx® was licensed (hereinafter "existing contract") to Solasia from Pled and has led to jointly promote development and explore indication expansion. The amendment of this agreement will not change Solasia's licensed territory i.e. Japan, China, South Korea, Taiwan, Hong Kong and Macau. Among the economic conditions established by existing contract, the maximum amount of milestone due to Pled will increase by ¥ 1.8 billion from ¥ 9.3 billion in accordance with contract payments, development progress and achievement of certain sales. However, there is no change in the royalty rate.

*[1]: *mFOLFOX6 therapy is a typical regimen of FOLFOX therapy (cancer chemotherapy that uses fluorouracil, folinic acid, and oxaliplatin in combination), and is a postoperative adjuvant chemotherapy for high-risk Stage II or Stage III colorectal cancer. It has been adopted as standard therapy in systemic chemotherapy for Stage IV recurrent colorectal cancer.*

*[2]: *Reference: Seretny, M., et al: (2014). Incidence, Prevalence and Predictors of Chemotherapy Induced Peripheral Neuropathy. Pain, 155 (12), 2461-2470.*

About PledOx®

PledOx® (calmangafodipir) is a "first-in-class" drug candidate, designed to prevent nerve damage caused by chemotherapy without reducing its anticancer effects. The Phase III program for PledOx consists of two double-blinded, randomized, placebo-controlled trials – POLAR-M and POLAR-A. The first patient was enrolled in 4Q 2018.

POLAR-M comprises 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.

POLAR-A comprises 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.

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 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 prevent 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 acetaminophen poisoning. A proof of principle study has been successfully completed and two. Aladote® has been granted Orphan Drug Designation in the US. PledPharma (STO: PLED) is listed on Nasdaq First North Growth Market. Erik Penser Bank acts Certified Adviser (www.penser.se). For further information, please see www.pledpharma.se

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For further information, please contact:

Solasia Pharma K.K.
Rie Toyoda, Public Relations and Investor Relations,
Tel. +81 3 5843 8049
info@solasia.co.jp