



Solasia

PledPharma and Solasia enter license agreement to develop and commercialize PledOx® in Asia

Stockholm, Sweden / Tokyo, Japan, [November 20th 2017] - PledPharma AB (“PledPharma”) (STO: PLED) and Solasia Pharma K.K. (“Solasia”) (TSE: 4597) today jointly announce that they have entered a license agreement pertaining to the clinical development and commercialization of PledOx® in Japan, China, Hong Kong, Macau, South Korea and Taiwan.

Under the terms of this agreement, PledPharma grants exclusive development and commercialization rights to PledOx® in the territories mentioned and Solasia will pay upfront, development, regulatory and sales milestones of up to JPY 9.3 billion (approximately USD 83 million). In addition, Solasia will pay industry standard royalty rates on sales applicable for a deal pertaining to an in-licensed asset in Phase III development. Solasia will also fully finance an expansion of the Phase III program to include Asian patients subject to regulatory consultations.

The license agreement is initially focused on the use of PledOx® as prevention of chemotherapy induced peripheral neuropathy in colorectal cancer patients. The agreement with Solasia facilitates an expansion of the recently announced global Phase III-program for PledOx® with Asian patients, subject to regulatory consultations, aiming to gain sufficient documentation for regulatory approvals in the major Asian markets. In addition, a Phase I study in Japanese and Caucasian Healthy Volunteers with focus on safety, tolerability and pharmacokinetics will be conducted. Following potential regulatory approvals, Solasia will be responsible for the commercialization of PledOx® in Japan, China, Hong Kong, Macau, South Korea, and Taiwan.

“We are very excited to announce our partnership with Solasia – an ideal partner during the development, regulatory process and commercialization of PledOx® in this very important region. The collaboration will ensure an optimized expansion of the Phase III program to include Asian patients, aiming at further realising the global commercial potential of our drug candidate,” said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

“We are convinced that PledOx®, as a novel first in class therapy, will play an important role in fulfilling the significant unmet medical need of preventing chemotherapy induced peripheral neuropathy. Solasia is ideally equipped to support PledPharma during the remaining clinical development and local regulatory processes in Japan, and to effectively launch the product in key Asian markets,” said Yoshihiro Arai, President and Chief Executive Officer, Solasia.

As Pledpharma announced earlier in November, following interactions with the regulatory authorities, EMA and FDA, the company has finalized the design of the global Phase III program for the drug candidate PledOx®. It is anticipated to be initiated at the end of 2017 with top line Phase III results expected during 2020.

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 side-effects of chemotherapy can lead to a reduction of the planned dose or, in worst case, treatment discontinuation. Unfortunately, it appears that the chemotherapy can induce permanent nerve damage. Patients may, for example, experience discomfort and numbness in the hands and feet, difficulty with balance with risk of falling and problems with sensation that can last for the rest of their lives.

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 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/>

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/>

For further information, please contact:

Nicklas Westerholm, Chief Executive Officer, PledPharma AB
Tel. +46 73 354 20 62
nicklas.westerholm@pledpharma.se

Rie Toyoda, Investor Relations, Solasia Pharma K.K.
Tel. +81 3 6721 8332
info@solasia.co.jp