PledPharma and Solasia enter a second license agreement for the development and commercialisation of PledOx® in Asia, targeting neuropathy caused by taxanes and any other chemotherapy

Stockholm, Sweden / Tokyo, Japan, October 9, 2019 - PledPharma AB ("PledPharma") (STO: PLED) and Solasia Pharma K.K. ("Solasia") (TSE: 4597) today jointly announced that the companies have entered a second license agreement for PledPharma's lead candidate PledOx® in Japan, China, Hong Kong, Macau, South Korea and Taiwan, covering chemotherapy induced peripheral neuropathy (CIPN) by any chemotherapy. The agreement includes development and regulatory milestones to PledPharma of up to approximately SEK 165 million (USD 17 million)*, as well as sales milestones and royalties.

The new agreement is a comprehensive extension of the original license agreement announced in November 2017. The extension covers the use of PledOx as prevention of CIPN by any chemotherapy in any cancer type. Most notably, this includes CIPN caused by taxanes with a high unmet medical need similar to that of CIPN caused by oxaliplatin. Taxanes have a significant use in clinical practice across several different cancer types (e.g. breast and ovarian cancer) with approximately 400,000 patients treated yearly in the US, EU5 and Japan.

According to the new agreement, PledPharma will receive development and regulatory milestones of up to approximately SEK 165 million (USD 17 million)* in Japan and China for the extension of the PledOx rights of prevention of CIPN caused by any chemotherapy. This is on top of the first agreement from November 2017, which included development and sales milestone payments of up to approximately SEK 700 million (USD 83 million)*. To date, PledPharma has received in total approximately SEK 56 million (USD 5.6 million)* from Solasia in upfront and milestone payments, and in addition, Solasia is paying for the recruitment of patients to the POLAR program in Asia.

In the new agreement, the terms for the sales milestones is altered to be based on the total sales of PledOx in Japan and China irrespective of chemotherapy. Royalty rates on sales will remain the same as in the first license agreement.

PledPharma and Solasia will share all development costs in the areas covered by the second agreement. The new agreement follows PledPharma's initiated indication expansion program in CIPN caused by taxanes, where preclinical studies are already underway to guide further development in a clinical stage.

"There is a large unmet medical need preventing CIPN caused by taxanes, where we see a huge potential for PledOx. This is a key step in broadening PledPharma's pipeline of development projects. We are very pleased with this important license agreement, which give us an opportunity to accelerate the development and deepen our collaboration with our partner Solasia." 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 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.

* Contract based on JPY, the amount given in USD and SEK is subject to exchange rates.

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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 keyboard and become hypersensitive to cold. The sensory loss in the feet may increase the risk of falls. There is currently no approved drug to prevent or treat CIPN.

About Us

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 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 Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 83 00, certifiedadviser@penser.se). For more information, see http://www.pledpharma.com/

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 2019-10-09 08:31 CEST.

Attachments

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