PRESS RELEASE
PledPharma AB
Stockholm December 10, 2019

PLEDPHARMA'S ASIAN PARTNER SOLASIA ENTERS AGREEMENT WITH JAPANESE MARUHO FOR COMMERCIALIZATION OF PLEDOX®

Stockholm, December 10, 2019. PledPharma AB (STO: PLED) today announced that its Asian partner Solasia Pharma KK ("Solasia") has entered into an exclusive license agreement with the Japanese pharmaceutical company Maruho Co Ltd ("Maruho") for commercialization of PledPharma's therapeutic agent PledOx® (calmangafodipir) for the treatment of chemotherapy induced peripheral neuropathy (CIPN) in Japan.

Under the license agreement, Maruho will commercialize PledOx exclusively in Japan after Solasia and PledPharma completes development of the product in Japan. The global Phase III program in CIPN with PledOx® is ongoing and consists of two studies.

"This agreement between Solasia and Maruho is a strong validation of the potential for PledOx to address chemotherapy induced nerve damage, a large unmet medical need. Maruho will bring a strong and experienced Sales & Marketing team for commercialization of PledOx to maximize the value of the asset", said Nicklas Westerholm, Chief Executive Officer and President, PledPharma.

Link to Solasia's PR.

The Phase III POLAR program for PledOx comprises two double-blind, randomized, placebo-controlled trials – POLAR-A and POLAR-M.

POLAR-A, which is expected to be fully recruited before yearend 2019, includes 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. It is expected to be fully recruited in Q2 2020, and it is anticipated that PledPharma will have top line results approximately a year later.

In October 2019, PledPharma and Solasia entered a second license agreement for PledOx in Japan, China, Hong Kong, Macau, South Korea and Taiwan, covering chemotherapy induced peripheral neuropathy (CIPN) by any chemotherapy. This agreement is a comprehensive extension of the original license agreement between PledPharma and Solasia, announced in November 2017.

For further information, please contact:
Nicklas Westerholm, CEO
Tel. +46 (0)73 354 20 62
nicklas.westerholm@pledpharma.se

Yilmaz Mahshid, CFO
Tel. +46 (0)72 231 68 00
Yilmaz.mahshid@pledpharma.se

The information was submitted for publication, through the agency of the contact persons set out above, at 2019-12-10, 09:00 CET.

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. 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 about the company, please visit https://www.solasia.co.jp/en/