Solasia

April 6, 2020

To: All Concerned Parties

Update on SP-04 (PledOx®) (3rd Report)

Tokyo, Japan, April 6, 2020 – Solasia Pharma K.K.(TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter "Solasia")'s clinical program, SP-04 (PledOx®, active ingredient name: calmangafodipir, indication: peripheral neuropathy associated with cancer chemotherapy) was licensed from PledPharma AB (hereinafter "Pled"). Solasia and Pled have made the following decisions regarding the development of ongoing Phase III global clinical trial (hereinafter "the study") of SP-04.

- For this study, the originally planned process will be changed, and the early cut-off of data collection (hereinafter "data cut-off") will be made in the third quarter of 2020, after which this study will be closed. The number of subjects enrolled in the studies have been 590 cases compared to the initially planned 700 cases.

- Solasia and Pled will conduct a detailed and robust evaluation of the safety and efficacy, focusing on the information obtained after the termination of this study, and formulate a plan for SP-04 thereafter.

- The decision was made after a recommendation from the independent Drug Safety Monitoring Board (DSMB) to stop new patient enrollment and SP-04 dosing in the studies due to a number of severe allergic reactions and hypersensitivity, which have been observed after repeated dosing of SP-04 in combination with Oxaliplatin.

On March 2nd, Solasia and Pled decided to place recruitment and dosing of patients in the POLAR program on hold. The decision followed interactions with the French regulatory authority, ANSM, and the clinical hold issued by the US Food and Drug Administration (FDA) earlier in the year and was due to a few numbers of observed CNS related adverse events. Solasia and Pled maintain its position that these events are not related to SP-04, a position which is also supported by the DSMB and an additional independent external evaluation of these cases. On the other hand, in new safety data evaluation in March, the DSMB recommended that the program should be stopped due to a number of severe allergic reactions and hypersensitivity observed after repeated dosing of SP-04 in combination with Oxaliplatin.

"Allergic reactions are not uncommon in relation to platinum-based chemotherapy. However, the DSMB recommendation implies that there is an increased risk with SP-04. We are currently working to better understand why these allergic reactions occur with coadministration of oxaliplatin and why they occur after repeated dosing.", said Stefan Carlsson, M.D., Ph.D., Chief Medical Officer, Pled.

Patients currently enrolled in the POLAR program will continue with their scheduled study procedures, while not receiving the study drug, until the data cut-off targeted for the third quarter. The POLAR program with SP-04, developed to reduce nerve damage associated with chemotherapy, consists of two studies, POLAR-A and POLAR-M, with the aim of randomizing 700 patients. POLAR-A is conducted in patients undergoing adjuvant chemotherapy treatment for colorectal cancer and was fully recruited in December 2019. POLAR-M is conducted in patients undergoing chemotherapy treatment for metastatic colorectal cancer and is not fully recruited. A total of 590 patients have been randomized in the POLAR program, of which 420 have completed more than six cycles of treatment and about 250 more than nine cycles. The

total data will enable an efficacy and safety evaluation and an assessment of the benefit/risk of SP-04 to evaluate if further activities to find a path forward for SP-04 to treat nerve damage associated with chemotherapy are motivated.

"The safety of patients in our clinical studies is our most important responsibility. Of course, the early closure of the POLAR program is a major setback for us., We will now concentrate on collecting the remaining data in the challenging COVID-19 environment and how we can best use the robust data from the POLAR studies to potentially support future clinical trials, as we believe nerve damage associated with chemotherapy remains an unmet medical need", said Nicklas Westerholm, Chief Executive Officer and President, Pled.

"The most important part of conducting a clinical trial is securing the safety of the patients. Pled and Solasia have decided to suspend new patient enrolment and SP-04 dosing in POLAR studies according to the clinical hold in connection with a few central nervous system adverse events by the regulatory authorities. Prior to making this decision, many subjects have participated in the studies. Pled and Solasia have agreed to assess the usefulness of SP-04 for cancer chemotherapy-induced peripheral neuropathy based on obtained robust data so far and maximize its use in future SP-04 development and new drug applications. In addition, we will continue our efforts to elucidate the causes and how to cope with allergic reactions suspected to increase risk in combination of SP-04 an Oxaliplatin for securing more safety of patients based on the DSMB's recommendations on allergic reactions." said Yoshihiro Arai, President and CEO, Solasia.

The impact of this matter on the consolidated financial forecast for the fiscal year ending December 2020 is expected to be minor and will not be revised.

At 21:00 JST (14:00 CET) today, Pled will host a teleconference on the matter (in English). Follow the link below for call-in details:

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