Solasia

NEWS RELEASE

Solasia Announces License and Capital Alliance for SP-04 (PledOx®) with Maruho

TOKYO, December 10, 2019 - Solasia Pharma K.K. (TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter “Solasia”) announced today that it has entered into an exclusive license agreement with Maruho Co., Ltd. (Headquarters: Osaka, Japan, President & CEO: Koichi Takagi, hereinafter “Maruho”) for commercialization of Solasia’s product SP-04 (PledOx®, hereinafter “product”), a therapeutic agent for chemotherapy induced peripheral neuropathy (currently undergoing Phase III clinical trials; active ingredient name: calmangafodipir) in Japan.

Under the license agreement, Maruho will commercialize the product exclusively in Japan after Solasia completes development of the product. Based on the license agreement, Solasia will supply the product exclusively to Maruho, and Maruho will pay Solasia an upfront payment of 1.0 billion yen and milestone payments based on progress in development and marketing up to a total of 18.0 billion yen.

In addition to the above license agreement, Solasia and Maruho have entered into a capital alliance agreement whereby Maruho acquires Solasia shares by a third-party allotment with a view to maintain a close business relationship going forward.

Capital alliance format:	Acquisition of newly issued Solasia shares by Maruho in third-party allotment
Pay-in date:	December 26, 2019
Number of shares issued:	11,324,000 Solasia common stock
Issue price per share:	151 yen (closing price on December 9, 2019)
Total issue amount:	1,709,924,000 yen
Shareholding ratio after issue:	Maruho will hold 9.70% of outstanding shares in Solasia
Lock-up agreement:	Maruho must obtain prior consent from Solasia if transferring its shareholding before the day following the date of the initial announcement of the clinical trial results and others by Solasia after completion of the two Phase III trials of the product currently under way. Solasia’s top shareholder, ITOCHU Corporation must obtain prior consent from Solasia if transferring its shareholding within one year of the pay-in date stated above.

Use of proceeds:	For in-licensing and development of new pipeline product SP-05.

Maruho specializes in dermatology and has contributed to improving the quality of life (QOL) of patients suffering from skin disorders caused by cancer treatment. This time, in order to further contribute to cancer patients and their families, Maruho decided to obtain the rights to commercialize the product. Solasia specializes in oncology in Asia, and 3 of their 4 existing and development products include drugs that treat the side effects of anticancer drugs. Solasia is yet to establish an in-house sales force in Japan. Therefore, in light of the steady progress of the phase III clinical trial for the product, Solasia decided to derive the commercialization rights to Maruho who share the common philosophy of the importance of improving patient QOL.

Koichi Takagi, President and CEO of Maruho, commented as follows:
“Solasia is a specialty pharmaceutical company in oncology. The company supports patients undergoing cancer treatment and their families by developing not only anticancer drugs, but also cancer supportive care products to improve patient QOL. In collaboration with Solasia, we will continue to do our best to help cancer patients and their families further by combining Solasia’s extensive knowledge in oncology with the experience we have gained in improving patient QOL.”

Yoshihiro Arai, President and CEO of Solasia, commented as follows:
“Maruho is a leading company in Japan in the dermatology area that has gained from many years’ experience with cancer and other patients the insight that improving patient QOL is as important as treating the underlying disease. We are confident that Maruho, with its wealth of knowledge and experience in patient QOL, is the best partner for Solasia, as we can broadly share the expectations and importance of our development product SP-04 in the treatment of chemotherapy-induced peripheral neuropathy and work together to improve patient QOL.”.

About Maruho

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,930 consolidated employees (as of the end of September 2018), and consolidated net sales were approximately 85.29 billion yen in its fiscal year ending September 30, 2018. Pursuing its long-term corporate vision of “Excellence in Dermatology,” Maruho is striving to improve the health and quality of life of people all over the world.
For more information, please visit https://www.maruho.co.jp/english/

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

Chemotherapy Induced Peripheral Neuropathy

Cancer chemotherapy has side effects such as nausea, vomiting, and stomatitis. Chemotherapy-induced peripheral neuropathy (CIPN) is another major side effect caused by platinum-based agents (oxaliplatin, cisplatin, etc.), Taxanes (paclitaxcel, etc.), Vinca alkaloids, and proteasome inhibitors*1. However, there are currently no drugs approved for the indication of CIPN (based on Solasia survey).

SP-04 (PledOx®)

SP-04 (PledOx®) is an agent created and developed by Swedish company PledPharma AB (STO: PLED, Head office: Stockholm, Sweden, hereinafter "Pled"). A superoxide dismutase analog, which is an enzyme that breaks down active oxygen generated in cells, it is believed to inhibit the onset of peripheral neuropathy by protecting nerve cells from damage caused by drug-induced oxidative stress such as antineoplastic drugs.
Solasia acquired exclusive development and marketing rights for SP-04 in Japan, China, South Korea, Taiwan, Hong Kong, and Macau from Pled. Solasia and Pled are currently engaged in global Phase III clinical trials in the United States, Europe, and Asia (including Japan) of SP-04 with colorectal cancer patients undergoing mFOLFOX6*2 combination chemotherapy, which includes a platinum-based antineoplastic agent oxaliplatin.

*1: *Reference: Ministry of Health, Labor and Welfare "Corresponding manual for severe side effects disease Peripheral neuropathy*
*2: *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.*

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