

News Release

December 10, 2019
Maruho Co., Ltd.

Maruho Enters an Exclusive License Agreement in Japan for SP-04, a Therapeutic Agent for Chemotherapy Induced Peripheral Neuropathy, and a Capital Alliance with Solasia

Osaka (Japan), December 10, 2019 – Maruho Co., Ltd (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announced today that it has entered into a license agreement with Solasia Pharma K.K. (“Solasia”, Head Office: Tokyo, Japan, President and CEO: Yoshihiro Arai) for Maruho to exclusively commercialize Solasia’s product (currently undergoing Phase 3 clinical trials) “SP-04”, a therapeutic agent for chemotherapy induced peripheral neuropathy (active ingredient name: calmangafodipir, hereinafter referred to as the “product”) 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 make an upfront payment and may also make milestone payments depending on achievement of development and commercialization milestones.

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

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 3 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.



The product was created and developed by PledPharma AB ("Pled", STO: PLED, Head Office: Stockholm, Sweden), and Solasia received exclusive clinical development and commercialization rights in Japan, China, South Korea, Taiwan, Hong Kong and Macau from Pled. The product is a superoxide dismutase analog that is an enzyme that is thought to break down active oxygen generated in cells and protect nerve cells from damage caused by drug-induced oxidative stress such as antineoplastic drugs. Cancer chemotherapy has side effects such as nausea and vomiting and onset of stomatitis, but peripheral neuropathy is also a serious side effect. Peripheral neuropathy is known to be markedly expressed in major drugs of cancer chemotherapy such as plant alkaloid preparations and platinum preparations. Cancer chemotherapy has side effects such as nausea, vomiting and stomatitis, but peripheral neuropathy is one of the serious side effects *1.

Chemotherapy Induced Peripheral Neuropathy (CIPN) is a major side effect caused by platinum based compounds (oxaliplatin, cisplatin, etc.), Taxanes (paclitaxel, etc.), Vinca alkaloids, and proteasome inhibitors. However, there are currently no drugs approved for the indication of CIPN (according to Solasia survey). Solasia and Pled are currently developing the product in Europe, the US, and Asian countries including Japan for colorectal cancer patients who receive combination chemotherapy mFOLFOX6*2 which includes 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.*

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 1,512 employees (as of the end of September 2018), and net sales were approximately 78.57 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/>

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