

Solasia Announces Patient Registration Reached Target Number of Cases for Darinaparsin Phase 2 Pivotal Study for T-Cell Lymphoma

TOKYO, JAPAN, September 17, 2019 – Solasia Pharma K.K. (TSE:4597, Headquarters: Tokyo, President & CEO: Yoshihiro Arai, hereinafter “Solasia”), a specialty pharmaceutical company based in Asia, today announced that patient registration reached the target number of cases for the darinaparsin Phase 2 study.

The Phase 2 study is being conducted as a multinational, multicentre, single-arm, open-label, non-randomized study to evaluate the efficacy and safety of darinaparsin monotherapy in relapsed or refractory patients with peripheral T-cell lymphoma (hereinafter “PTCL”) in Japan, South Korea, Taiwan and Hong Kong. Patients would receive maximum 6 cycles of darinaparsin, and the efficacy would be measured with tumor response as primary outcome measure.

This study is a pivotal (final) study for PTCL based on prior consultation with the authority. At present, Solasia expects to announce the study results in 2020.

Solasia holds an exclusive worldwide license to develop and commercialize darinaparsin. For Japan market, Solasia has already entered into an exclusive license agreement with Meiji Seika Pharma Co., Ltd., for the commercialization of darinaparsin, and for Latin America, with HB Human BioScience SAS. Going forward, Solasia will actively seek licensing partners outside of Asia.

Through the active development of darinaparsin, Solasia will continue to strive for providing new treatment option for PTCL patients. Furthermore, Solasia will continue to pursue the possibility for developing other indications in cancer field following PTCL.

About darinaparsin

Darinaparsin is a novel mitochondrial-targeted agent (organoarsenic) being developed for the treatment of various hematologic and solid cancers. In a US Phase 2 study, darinaparsin demonstrated evidence of clinical activity in lymphoma, in particular PTCL. Furthermore, the Phase 1 study done in US, and the Pan-Asian Phase 1 study both demonstrated positive efficacy and safety. Darinaparsin has been granted orphan drug designation in US and EU. For more information, please see at <https://www.solasia.co.jp/en/pipeline/sp-02.html>

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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