

Solasia Announces Submission of New Drug Application for Anti-cancer Drug DARINAPARSIN for Peripheral T-Cell Lymphoma in Japan

- ***NDA filed in Japan ahead of anywhere else in the world***
- ***New anti-cancer drug with a novel mechanism of action***
- ***Darinaparsin is designated Orphan Drug in the US and EU as a treatment of peripheral T-cell lymphoma (PTCL)***

TOKYO, JAPAN, June 30, 2021 – Solasia Pharma K.K. (TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter “Solasia”) today announced submission of a New Drug Application (NDA) for its new anti-cancer drug darinaparsin (generic name, development code: SP-02) as a treatment for relapsed or refractory peripheral T-cell lymphoma to the Ministry of Health, Labour and Welfare (MHLW). Based on positive results of R&D on darinaparsin, centered primarily on the results of the Asian Multinational Phase 2 Study (study results released in June 2020), Solasia filed an NDA for the drug with the regulatory authority in Japan ahead of anywhere else in the world.

Solasia expects to obtain regulatory approval in 2022 and to also launch in the same year. If approved and launched, darinaparsin would be the third drug Solasia successfully developed and brought to market since its founding and is expected to contribute to the treatment of PTCL.

Mr. Yoshihiro Arai, President and CEO of Solasia, commented as follows:
“No standard treatment has been established for relapsed or refractory PTCL as of yet. I firmly believe that darinaparsin, with its novel mechanism of action that differs from those of already approved drugs, will contribute to patients and healthcare providers at clinical sites as a new treatment option for relapsed or refractory PTCL. Since founding, Solasia has conducted R&D on five pipeline drugs. Of the five, we have successfully developed and brought to market two drugs, i.e., began providing them to patients, and today, we submitted an NDA for our first anti-cancer drug. Under our mission to provide patients with ‘Better Medicine for a Brighter Tomorrow’, we will continue aiming to contribute to patients’ treatment and enhanced quality of life.”

About darinaparsin (SP-02)

Darinaparsin, an organoarsenic compound with anticancer activity, is a novel mitochondrial-targeted agent being developed for the treatment of various hematologic and solid tumors. The proposed mechanism of action of the drug involves the disruption of mitochondrial function, increased production of reactive oxygen species, and modulation of intracellular signal transduction pathways. Darinaparsin is believed to exert anticancer effect by inducing cell cycle arrest and apoptosis. Darinaparsin has been granted orphan drug designation in the US and EU.

For more information, please visit at <https://solasia.co.jp/en/pipeline/sp-02.html>

About Asian Multinational Phase 2 Study

The Asian Multinational Phase 2 Study was a multinational, multicenter, single-arm, open-label, non-randomized study to evaluate the efficacy and safety of darinaparsin monotherapy in patients with relapsed or refractory PTCL conducted in Japan, Korea, Taiwan, and Hong Kong. (CT.gov Identifier: NCT02653976).

Solasia plans to present the results of the study at an international academic conference to be held in the near future.

About peripheral T-cell lymphoma (PTCL)

PTCL is a type of malignant lymphoma. Malignant lymphoma is largely classified into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL), and non-Hodgkin lymphoma is further divided into two main categories of B-cell lymphoma and T-cell lymphoma. PTCL is a subtype of T-cell lymphoma with a relatively high incidence rate among other subtypes of T-cell lymphoma. No standard treatment has been established for PTCL, and the National Comprehensive Cancer Network guidelines recommend as front-line treatment participation in clinical trials or multidrug chemotherapy such as CHOP therapy.

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For relapsed or refractory PTCL patients, in addition to participation in clinical trials, multidrug chemotherapy or recently approved drugs are recommended. However, as with the newly diagnosed cases, no standard therapy has been established. As prognosis for PTCL may be poor and its treatment difficult, it is one of the diseases with high unmet medical needs for which the development and introduction of new therapies and drugs are much anticipated.

About Solasia

Solasia is a specialty pharmaceutical company based in Asia, with a mission to provide "Better Medicine for a Brighter Tomorrow." To address the unmet medical needs in the oncology field, Solasia develops innovative medicines to contribute to the better health and brighter future of patients. Please visit the company website at <https://solasia.co.jp/en/> for more information.

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