June 20, 2022

To: All Concerned Parties

Company Name: Solasia Pharma K.K.
Representative: Yoshihiro Arai, President & CEO
(Code number: 4597, TSE Growth Section)
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DARVIAS® Injection 135mg
(generic name: DARINAPARSIN /development code: SP-02) approved in Japan

TOKYO, JAPAN, June 20, 2022 – Solasia Pharma K.K. (TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter "Solasia") officially announced today that an organoarsenic drug "DARVIAS® Injection 135mg" (SP-02, hereinafter DARVIAS®) has been approved for relapsed or refractory Peripheral T-Cell Lymphoma (hereinafter "PTCL") by the Ministry of Health, Labor and Welfare (MHLW). Solasia filed an NDA with the MHLW in Japan in June 2021. In October 2021, Nippon Kayaku Co., Ltd. (TSE: 4272, Headquarters: Tokyo, Japan, President: Atsuhiro Wakumoto) secured a license agreement with DARVIAS® for marketing rights in Japan.

DARVIAS®, 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. DARVIAS® is believed to exert an anticancer effect by inducing cell cycle arrest and apoptosis. This approval is based on the result of an Asian Multinational phase II study of SP-02 in patients with relapsed or refractory PTCL, Japan being the first country in the world where it was approved.

Mr. Yoshihiro Arai, President and CEO of Solasia, commented for this approval as follows:

Since its founding, we have been focusing on developing new treatment options that solve the quality of life of patients in the treatment of cancer that affects one in two Japanese people. The two products, episil® Oral Solution and Sancuso®, which have been successfully developed so far, are not for the treatment of cancer itself, but used as supportive care such as suppression of nausea / vomiting and alleviation of pain associated with oral mucositis caused by chemotherapy and radiotherapy. DARVIAS® is our first NDA approved anticancer drug. Nippon Kayaku is our commercial partner with strengths in the field of oncology. We are very pleased to have this opportunity to deliver DARVIAS® to nationwide medical institutions providing new cancer treatment by utilizing Nippon Kayaku's extensive experience in oncology and contribute to the treatment of patients suffering from PTCL.