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Solasia initiates Phase III programme for PledOx

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Solasia Pharma K.K. has announced the initiation of Phase III clinical trial for PledOx in Japan.

In November 2017, Solasia acquired exclusive development and commercialization rights for PledOx in Japan, China, Hong Kong, Macau, South Korea and Taiwan from PledPharma.

This Phase III clinical trial in Asia (Japan, South Korea, Taiwan and Hong Kong) is an expansion of the Global Phase III trial led by PledPharma in the rest of the world where the first patient was included in the United States in November. The Asian region including Japan is now officially part of this Global Phase III clinical trial.
Following Japan, Solasia will also initiate in South Korea, Taiwan and Hong Kong successively.

This trial is for colorectal cancer patients treated with mFOLFOX6 (*1) which contains antioxidant drug “oxaliplatin” and to examine the effect of suppressing the development of peripheral neuropathy by administering PledOx. Oxaliplatin is a platinum-based drug and is indicated for colorectal cancer, pancreatic cancer, gastric cancer etc.

Peripheral neuropathy is known as one of the serious side effects caused by administration of oxaliplatin, and one of the causes is that neurons develop by being damaged due to oxidative stress induced by the drug. Peripheral neuropathy is also known as the main side effect of other platinum-based drugs such as cisplatin. There are currently no drugs approved for the treatment of chemotherapy induced peripheral neuropathy. PledOx is a superoxide dismutase analogue that is an enzyme that degrades active oxygen generated in cells and has the effect of protecting nerve cells from damage caused by drug-induced oxidative stress.

The initiation of this trial is a significant milestone for Solasia as this trial is positioned as a registration trial and its success is expected to contribute to patients suffering from peripheral neuropathy due to cancer chemotherapy.