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On **June 13, 2018**, Solasia Pharma announced it has entered into a committed credit line agreement.

The company announced it has resolved in the Board of Directors meeting held on the same day to enter into a committed credit line agreement with Sumitomo Mitsui Banking Corporation (SMBC).

Solasia has been meeting its needs for working capital under a financial strategy of utilizing cash and cash equivalents (JPY2.8 bn as of March 31, 2018) and overdraft facilities (total of JPY2.6 bn; signed in November 2017). Regarding the signing of the committed line of credit, after discussions with SMBC and the bank's assessment of Solasia's businesses, the company was able to secure an additional loan capacity without collateral. Solasia thinks the agreement will be beneficial to its financial strategy from the standpoint of further diversification and financial resource enhancement.

#### Terms of the agreement

Contracting party: Sumitomo Mitsui Banking Corporation

Maximum loan amount: JPY1.0bn

Contract date: June 15, 2018

Maturity date: December 30, 2019

Collateral: None

The impact of this agreement on earnings is negligible, and the company has not changed its consolidated FY12/18 earnings forecasts announced on February 9, 2018.

On **the same day**, the company announced a development plan for pipeline product SP-04 (drug for cancer chemotherapy induced peripheral neuropathy, brand name: PledOx®).

Solasia announced a development plan for SP-04 in Japan, South Korea, Taiwan, and Hong Kong as follows.

The licensor PledPharma AB (headquartered in Stockholm, Sweden; Stockholm Stock Exchange: PLED) has already completed Phase II clinical trials for SP-04 in Europe and the US as well as Phase I clinical trials in the US that included Japanese healthy volunteers.

Of the regions where Solasia holds development rights, the company will begin Phase III clinical trials in Japan, South Korea, Taiwan, and Hong Kong in 2H FY12/18. These trials will be a part of the global Phase III clinical trials led by PledPharma, which have evolved from the latter's Phase III clinical trials to begin in the US and Europe.

The overview of the Phase III clinical development plan has been set as follows, based on the consultation with the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), and the Pharmaceuticals and Medical Devices Agency (PMDA).

#### Trials overview

- ▷ Description: Phase III, global, multicenter, double-blind, randomized, placebo-controlled study
- ▷ Purpose: Study the effect of suppressing peripheral neuropathy associated with administration of oxaliplatin (via PledOx® administration) in comparison with a placebo
- ▷ Study design
  - POLAR-M study: Targets colorectal cancer patients who undergo FOLFOX therapy with distant metastases
  - POLAR-A study: Targets colorectal cancer patients who undergo FOLFOX therapy as an adjuvant therapy for postoperative surgery

- ▷ Primary outcome measures: For both the POLAR-M and POLAR-A studies, evaluate the ratio of subjects with moderate or higher chronic peripheral neuropathy at 9 months after the administration of SP-04 (first day of FOLFOX therapy)
- ▷ Estimated enrollment: 420 patients for POLAR-M study (120 patients in Solasia's regions), 280 patients for POLAR-A study (80 patients)

The impact of this development has been factored into Solasia's consolidated FY12/18 earnings forecasts announced on February 9, 2018. The forecasts remain unchanged.

This note is the most recent addition to the [full report](#).

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