

Solasia Announces Option Agreement for New Drug Candidate with GeneCare Research Institute

Tokyo, Japan, July 15, 2020 – Solasia Pharma K.K. (TSE: 4597, Headquarters: Tokyo, Japan, President & CEO: Yoshihiro Arai, hereinafter "Solasia"), a specialty pharmaceutical company based in Asia, today announced that it had entered into an option agreement with GeneCare Research Institute Co., Ltd. (Headquarters: Kamakura, Kanagawa Prefecture, President & CEO: Naoya Takahashi, hereinafter "GC") based on the assumption that Solasia in-licenses GC's nucleic acid drug candidate and technologies , as summarized below.

- ✓ Solasia will acquire option rights to RECQL1-siRNA, a nucleic acid drug candidate, and related technologies.
- ✓ Solasia will decide whether to exercise its option rights after detailed analysis of progress with, and results of non-clinical studies or Phase I clinical trials for RECQL1-siRNA.
- ✓ RECQL1-siRNA is expected to be used in the treatment of peritoneal metastases (disseminated metastases developing in the peritoneum) of gastrointestinal cancer and ovarian cancer, and related malignant ascites.

RECQL1 is an enzyme that plays a key role in DNA repair (repair of damage to DNA that occurs in the process of replication). Excessive expression of the enzyme is found in actively multiplying cancer cells. This suggests that their repair mechanism is dependent on RECQL1 under the deficient cell-cycle checkpoint regulation caused by p53 mutations and other genetic abnormalities. RECQL1-siRNA selectively suppresses the expression of RECQL1, which is believed to prevent the full repair of DNA damage in cancer cells, resulting in cell death at the mitosis (M) stage of cell division.

GC discovered RECQL1-siRNA and related technologies based on technologies in-licensed from US company Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), a world leader in RNA interference (RNAi) technologies. Although still in the non-clinical study stage, the antitumor effects of RECQL1-siRNA have been demonstrated in several studies. It is expected that RECQL1-siRNA can be used in the treatment of peritoneal metastases (disseminated metastases developing in the peritoneum) of gastrointestinal cancer and ovarian cancer, and related malignant ascites, for which there are few treatment options and is thus an area of high unmet medical need.

Solasia has a track record in successful development of products for cancer treatment such as SP-01 (Sancuso®), SP-02 (darinaparsin), and SP-03 (episil® oral liquid). Solasia believes that maintaining the success rate of product development is a management priority so that we can contribute toward frontline medical treatment. Therefore, our drug candidate portfolio has mainly consisted of products in or after the clinical development stage. We plan to maintain this basic concept going forward. We also believe that work on new modalities* with the potential to satisfy high clinical needs or solve medical problems is consistent with our mission of delivering better medicines to patients to brighten their future, even if the drug candidates are at the early, preclinical stages of development.

The impact of this matter on the consolidated financial forecast for the fiscal year ending December 2020 is expected to be minor and the forecast will not be revised.

* Modality: Refers to methods of medical treatment such as low molecular compounds, peptide drugs (medium molecular weight compounds), protein-based drugs including antibody drugs, nucleic acid drugs, cell therapies, and regenerative medicines.

About Peritoneal Metastases

In peritoneal metastases, cancer cells in the abdominal cavity spread to the peritoneum due to progression of cancers such as ovarian cancer, and fluid builds up in the abdominal area (malignant ascites). In this condition, cancer cells are scattered around the abdominal cavity and are difficult to treat

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by surgery or radiotherapy, and thus the treatment of choice is chemotherapy. Malignant ascites causes abdominal bloating, making it difficult for patients to eat and induces fatigue, severely impacting on their QOL. Consequently, it can affect the possibility of continuing chemotherapy and other cancer therapies. Treatment options for malignant ascites are symptomatic, such as abdominal paracentesis and cell-free and concentrated ascites reinfusion therapy (CART), but the fluid is likely to build up again quickly, because they do not treat the underlying cause. For this reason, a new treatment is anticipated in the clinical setting, such as a way to suppress ascites by treating the underlying cause (i.e., peritoneal metastasis) with cancer therapies.

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 about the company, please visit https://www.solasia.co.jp/en/

About GeneCare Research Institute

GeneCare Research Institute is a drug discovery startup founded in 2000 with headquarters in Kamakura, Kanagawa Prefecture. The company focused on a group of DNA repair helicases that are effective against a broad spectrum of cancer cells and function as superior molecular targets, and engaged in research and development of anticancer drugs that combine their effects with superior properties of siRNA. For RECQL-siRNA, the company used National Cancer Center Hospital's consultation service for healthcare startups that covers various issues that arise in clinical research, clinical trials, etc. GeneCare is committed to developing drugs as quickly possible to help cancer patients. For more information about the company, please visit <u>http://www.genecare.co.jp/ja/index.html</u>

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(Contact) **Solasia Pharma K.K.** Rie Toyoda, Public Relations and Investor Relations Tel: +81 3 5843 8049 (Japan) info@solasia.co.jp

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