August 11, 2021

To: All Concerned Parties


Company Name: Solasia Pharma K.K.
Representative: Yoshihiro Arai, President & CEO
(Code number: 4597, TSE Mothers Section)
Contact: Toshio Miyashita, CFO
Tel: 81-3-5843-8049
Website: https://solasia.co.jp/en/


# Business Overview of Pipeline Products
## (Second Quarter of the Fiscal Year Ending December 31, 2021)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Six Months of the Fiscal Year Ending December 31, 2021. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

[Launched Products]

| Products Name (Pipeline Code) | Indication | Area | Pre-clinical | Clinical Study P 1 | Clinical Study P 2 | Clinical Study P 3 | NDA | Approval Launch | Progress | Out-licensed Partner (Region) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Sancuso®** **(SP-01)** | Chemotherapy Induced Nausea and Vomiting (CINV) | China | | | | | | | Launched in 2019 | Solasia (BJ,SH,GZ), Lee's Pharma (China w/o 3 cities) |
| | | TW, HK etc. | | | | | | | (Launched by Kyowa Kirin) | Kyowa Kirin [Sublicensee] |
| **episil® oral liquid** **(SP-03)** | Pain associated oral mucositis [Medical Device] | Japan | | | | | | | Launched in 2018 | Meiji Seika Pharma (Japan) |
| | | China | | | | | | | Launched in 2019 | Solasia (BJ,SH,GZ), Lee's Pharma (China w/o 3 cities) |
| | | South Korea | | | | | | | Launched in 2020 | Synex (South Korea) |

[Pipelines Under Clinical Development]

| Pipeline Code | Target Indication | Area | Pre-clinical | Clinical Study P 1 | Clinical Study P 2 | Clinical Study P 3 | NDA | Approval Launch | Progress | Out-licensed Partner (Region) |
|---|---|---|---|---|---|---|---|---|---|---|
| **SP-02** | Peripheral T-Cell Lymphoma (PTCL) | Japan | | | | | | | Submitted NDA | Meiji Seika Pharma (Japan) |
| | | KR,TW, HK | | | | | | | Pivotal P2 study completion, preparation for NDA filing | HB Human BioScience (Latin America) |
| | | China | | | | | | | Phase 2/3, preparation | |
| | | US | | | | | | | Phase 2A, completion | |
| | | EU | | | | | | | Pre-clinical, completion | |
| **SP-04** | CIPN | Japan etc. | | | | | | | Pre-clinical in taxane-induced peripheral neuropathy | Maruho (Japan) |
| **SP-05** | Colorectal Cancer | Japan | | | | | | | Global Phase 3 study | – |

## 1. Launched Products:

### ➢ Sancuso® (SP-01): Granisetron transdermal delivery system (Indication: Chemotherapy-induced nausea and vomiting)

- The Company holds rights in China, etc. In China, the Company pursues direct sales and sales through its partner Lee's Pharmaceutical (HK) Limited ("Lee's").

China - Current status

- The Company launched in March 2019.
- The first new Guideline was published by CSCO, recommended Sancuso® as a new standard of care for CINV (Chemotherapy induced nausea and vomiting) treatment in June 2019.


Sancuso® Chinese Product Package

Building of distribution channels in China;

- The Company has entered into a sales distribution agreement for China with Itochu Corporation ("Itochu") and has built sales channels utilizing Itochu and the Itochu Group.
- The Company is conducting sales in-house in Beijing, Shanghai, and Guangzhou, and builds the sales structure.
- In other parts of China, Lee's launched on the basis of sales and licensing agreements between the Company.
- The Company's direct sales partner is Itochu Group.

➢ **episil® oral liquid (SP-03): The protection and relief of oral pain associated with oral mucositis/stomatitis caused by chemotherapy and radiotherapy for cancer (Indication: Oral mucositis/stomatitis caused by chemotherapy and radiotherapy)**

- The Company holds rights in Japan, China (including Hong Kong and Macau), and South Korea.

Japan - Current status

- Meiji Seika Pharma Co., Ltd. ("Meiji") launched in May 2018, based on a license and collaboration agreement for episil®.

China - Current status

- The Company launched in July 2019.

South Korea - Current status

- Synex Consulting Ltd. Launched in September 2020, based on a license and collaboration agreement for episil®.


episil® Japanese Product

Building of distribution channels in China;

- Same as Sancuso®, the Company has entered into a sales distribution agreement for China with Itochu and has built sales channels utilizing Itochu and the Itochu Group.
- The Company is conducting sales in-house in Beijing, Shanghai, and Guangzhou, and builds the sales structure.
- In other parts of China, Lee's launched on the basis of sales and licensing agreements with the Company.
- The Company's direct sales partner is Itochu Group.

## 2. Pipelines Under Clinical Development:

➢ **SP-02 (darinaparsin): Mitochondria-targeted apoptosis inducer (Target Indication: Relapsed or Refractory Peripheral T-Cell Lymphoma)**

- The Company holds worldwide rights.
- The Company out-licensed marketing and other rights in Japan to Meiji and rights in Latin America to HB Human BioScience SAS.

Current status

- This product achieved the primary endpoint (antitumor effect) in the Asian multinational phase II clinical study in patients with relapsed or refractory peripheral T-cell lymphoma in Japan, South Korea, Taiwan, and Hong Kong.
- The Company submitted a New Drug Application(NDA) in June 2021.

Plans

- The Company expects to obtain a regulatory approval and to launch in 2022.
- Other clinical trial countries, South Korea, Taiwan and Hong Kong are planning for a NDA filling after concluding out-licensing agreement in each countries.

Line-Extension

- Currently, the Company is conducting non-clinical studies on other hematologic cancers (ATLL: Adult T-Cell Leukemia/Lymphoma, AML: Acute Myeloid Leukemia).

➢ **SP-05 (arfolitixorin): Increase in antitumor efficacy, folic acid compound (Target Indication: Increase in antitumor efficacy of fluorouracil**

- The Company holds development and commercialization rights in Japan.

US&EU - Current status

- Global Phase III clinical study (AGENT study) in patients with advanced colorectal cancer is conducted in Japan, North America (US, Canada), Europe, and Australia.
- Based on the results of the interim analysis, the target number of patients for the AGENT study is set 440. Furthermore, the number of patients enrolled in the study reached 440 in December 2020.

Japan - Current status

- In August 2020, the Company obtained the development and commercialization rights for arfolitixorin in Japan from Isofol Medical AB.
- After obtaining rights for arfolitixorin, the Company took over the AGENT study in Japan.
- In May 2021, the AGENT study completed the recruitment of Japanese patients in accordance with the regulatory requirements by the PMDA (the Japanese Medicines Agency) to reach market approval in Japan.

Plans

- The Company expects the top line results for the AGENT study to be available during H1 FY2022, afterwards, expects to submit for NDA in H2 FY2022.

## 3. Pipelines Under Pre-Clinical:

➢ **SP-04 (PledOx®): Intracellular superoxide removing agent (Target Indication: Chemotherapy-induced peripheral neuropathy)**

- The Company holds rights in Japan, China (including Hong Kong and Macau), South Korea and Taiwan.
- The Company out-licensed marketing and other rights of PledOx® in Japan to Maruho Co., Ltd.

Current status

- The Company confirmed that the primary endpoint of the Global Phase III clinical trial of PledOx® targeting oxaliplatin-induced peripheral neuropathy

conducted in Japan, South Korea, Taiwan and Hong Kong, in addition to the US and EU, had not been achieved in December 2020.

Plans

- Based on the results of the above-mentioned trial, the Company has decided to park the development for a platinum-based agent, oxaliplatin-induced peripheral neuropathy; instead, has determined to conduct additional animal studies to investigate the product's potential in targeting taxane-induced peripheral neuropathy.

## 4. New Drug Candidates:

### ➢ Drug discovery business utilizes RNA editing technology

- In 2019, the Company concluded a joint research and development agreement with EditForce, Inc., a biotech company originating from Kyushu University. For the Company, the initiative is a means of acquiring candidate products for long-term development. Specifically, it furthers the Company's plans to develop new gene therapy drugs in the field of oncology based on RNA editing technology.

### ➢ Nucleic acid drug candidate for peritoneal metastases

- In 2020, the Company entered an agreement with GeneCare Research Institute Co., Ltd ("GC"). for exclusive negotiating rights (option rights) to in-license their nucleic acid drug candidate RECQL1-siRNA and related technologies. 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.
- Based on development progress of the drug candidate from the non-clinical study stage onward, the Company will decide whether to exercise the option rights to in-license the drug candidate.

## 5. In-house sales structure in China:

In-house sales strategy

- Within China, the Company is conducting in-house sales and marketing activities for Sancuso® and episil® in Beijing, Shanghai, and Guangzhou, in the interest of maximizing profits from product sales and controlling fixed costs.

Bases

- Solasia Medical Information Consulting (Shanghai) Co. Ltd., a wholly owned subsidiary, is taking charge of the Company's sales and marketing activities in China.
- The Company established the bases in Shanghai, Beijing and Guangzhou.

Organization of personnel

- The Company is conducting an in-house sales structure with a total of 40 medical representatives (MRs) in Beijing, Shanghai, and Guangzhou.

## 6. Impact of the COVID-19 pandemic on the Company's business activities and efforts to prevent the spread of infection:

Japanese business

- The Company adopted a telework system for all employees of the Tokyo office as of today.

Chinese business

- The COVID-19 pandemic significantly is restrained marketing activities of the

Group's and sales partners' medical representatives (MRs), including their access to medical sites. This in turn has an impact on the prescription and delivery volumes of the products.

Product supply

- The Company's products are manufactured in Europe and the United States. At present, provision almost continues uninterrupted.

Clinical development

- The spreading pandemic is having a limited impact on clinical development activities. To ensure the safety of subjects and lessen the burden on the medical systems, visits to medical institutions by subjects and employees handling clinical studies have been curtailed to some extent, and we are utilizing online methods of communication instead.

Business alliances

- Restrictions on overseas travel are impeding discussions with potential alliance partners necessary for negotiations on in- and out-licensing. The Company is instead using online alternatives and working through local distributors.

The Company is a specialty pharma company, specializing in the development and commercialization of products in the oncology field. In the United States, which is home to numerous successful biopharma venture companies, the majority of those companies post losses on a single-year basis. (According to research by Solasia Pharma, of the companies that make up the NASDAQ Biotechnology Index, 143 companies have market capitalization of more than ¥100 billion. Of those, 110 are posting operating losses as of July 31, 2021.) We believe that this situation exists because the market places more importance on making proactive upfront investments in promising drug development than on assessing such companies on the basis of their single-year gains and losses. At present, the Company is operating in accordance with this sort of business strategy. In addition to the operating results and other financial information in our earnings reports, we believe in the importance of disclosing to investors information about our key pipeline products to a certain level of detail. We have disclosed such information on this report.