Solasia

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To: All Concerned Parties

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Business Overview of Pipeline Products
(first six months of the Fiscal Year Ending December 31, 2022)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for first six months of the Fiscal Year Ending December 31, 2022. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

1. Commercial 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 sales through its partner Lee's Pharmaceutical (HK) Limited ("Lee's").

China - Current status

- The Company launched in March 2019.
- The Company dissolved its own sales structure covering Beijing, Shanghai, and Guangzhou, China (hereafter the "three cities") as of July 31, 2022, and on August 1 of the same year, transferred its sales functions to sales partner Lee's Pharmaceutical
- In the first six months of the fiscal year under review, the shipment volume of Sancuso ® came to 12,586 units, down 6% year-on-year, due to the impact of the COVID-19 pandemic as explained in below.

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

- The Company holds worldwide rights.

Japan - Current status

- The Company out-licensed for marketing and other rights in Japan to Nippon Kayaku, and the company will conduct sales activities in the future.
- On June 20, 2022, the Company obtained marketing approval from the Ministry of Health, Labour and Welfare for DARVIAS ® Injection 135mg for the treatment of relapsed or refractory peripheral T-cell lymphoma. The Company expects sales to begin in August 2022.

Other - Current status

- The Company out-licensed for marketing and other rights in Latin America to HB Human BioScience SAS. which plans to file for regulatory approval.
- The commercialization of the product in regions other than Japan and South America will be pursued through the establishment of a sales partner.

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Plans

- 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.

➢ **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)**

- On July 8, 2022, the Company obtained worldwide rights, including manufacturing rights, to episil ® oral liquid from Camurus AB. The Company will continue supplying the product in Japan, China, and Korea. The business transfer from Camurus AB, primarily manufacturing and regulatory procedures for the product, is expected to be completed by May 2024, and Solasia plans to make a decision regarding development of the business in other regions by then.

Japan - Current status

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

China - Current status

- Sales of episil ® oral liquid began in July 2019. The Company dissolved its own sales structure covering Beijing, Shanghai, and Guangzhou, China, as of July 31, 2022, and on August 1 of the same year transferred its sales functions to sales partner Lee's Pharm. Currently, Lee's Pharm is conducting sales activities for the product throughout China.
- In the first six months of the fiscal year under review, the shipment volume of episil ® oral liquid in the three cities was 1,514 down 33% year-on-year, hurt by the impact of the COVID-19 pandemic as explained in below.

South Korea - Current status

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

2. Pipelines Under Clinical Development:

➢ **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 held development of SP-04 for the treatment of oxaliplatin-induced peripheral neuropathy based on the results of global Phase III clinical trials, and is instead investigating the possibility of developing the pipeline product for the treatment of taxane-induced peripheral neuropathy. To this end, the Company is conducting animal studies with licensor Egetis Therapeutics (formerly PledPharma).

- **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.

Current status

  - Global Phase III clinical trials in patients with advanced colorectal cancer were conducted in Japan, the US, Canada, Europe, and Australia. On August 4, 2022, the Company released preliminary results of the study, indicating that no statistically significant difference was found in the outcomes of patients between the arfolitixorin group (5-FU + oxaliplatin + bevacizumab therapy in combination with SP-05 [arfolitixorin]) and the control group receiving standard treatment (5-FU + oxaliplatin +bevacizumab therapy in combination with leucovorin), in terms of overall response rate (ORR), the primary endpoint, and progression-free survival (PFS), one of the secondary endpoints of the study.
  - The Company plans to reanalyze PFS, a secondary endpoint of the Phase III study,and conduct gene expression and other subgroup analyses and safety information analysis in phases, with the goal of releasing the results of these analyses in the fourth quarter of the fiscal year under review. Further, it expects to obtain overall survival (OS) results, a secondary endpoint of the study, in 2023. The Company will determine the future direction of the development for SP-05 based on the results of these analyses and the discussion with licensor Isofol Medical AB.
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3. 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.

4. Organizational structure and capital relationship:

Dissolution of the China Vending Structure

  - Solasia began operating its own sales structure in the three cities in China in 2019. Shipment volumes of Sancuso ® to hospitals and pharmacies in the three cities expanded from 10,000 units in FY2019 to 15,000 units in FY2020 and 30,000 units in FY2021 supported by the Company's sales activities,

and shipment volumes of episil ® were also on a growth trajectory. However, prolonged impacts of the COVID-19 pandemic and the lockdown of Shanghai and other regions since Mach 2022 have depressed sales volumes, which together with other factors, resulted in the sales volumes lagging the necessary amount to reach the breakeven point. Further, maintaining the Company's own sales structure requires about 1 billion yen each year, primarily for marketing activities and personnel expenses. As a result, profitability of China operations continued to suffer, and costs for maintaining the sales structure had become a key factor behind the Group's losses.

- In light of these factors, the Company dissolved its own sales organization in China as of July 31, 2022, curtailing personnel expenses for sales staff and suspending expenditures on marketing activities. As a result, the number of employees on a consolidated basis fell from 77 at the end of March 2022 to around 27, and the Company anticipates this to contribute to cost reductions of approximately 1 billion yen for the full year.

Capital and business alliance with Nippon Kayaku

- On June 28, 2022, Solasia entered into a capital and business alliance agreement with Nippon Kayaku Co., Ltd., a pharmaceutical company with an extensive track record and sales experience in the oncology field. Based on the terms of the agreement, on July 14, the Company issued 12,000,000 shares of its common stock to Nippon Kayaku and raised funds of 1.02 billion yen. As a result of the share issue, Nippon Kayaku became the second largest shareholder of Solasia with a 7.7% stake in the Company.
- Based on the terms of the alliance agreement, the Company granted Nippon Kayaku the preferential negotiating rights to in-license the Company's pipeline products, as well as the preferential negotiating rights for the manufacture of the Company's commercialized and pipeline products.

5. 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

- Sales activities of the Group's and sales partners' medical representatives, including their visits to medical institutions, were restrained due to thespread of COVID-19, negatively affecting the prescription and shipment volumes of the Company's products.
- Throughout the second quarter of the fiscal year under review, about 80%of medical institutions that were the main targets for the Company's sales activities were closed in Shanghai due to the lockdown of the city since March 2022. This resulted in a substantial drop in treatment opportunities for cancer patients, the main targets of the Company's products,subsequently depressing the prescription volume of these 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, 140 companies have market capitalization of more than ¥100 billion. Of those, 98 are posting operating losses as of August 09, 2022.) We believe that this situation exists because the marketplaces 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 our business information on this report.