Solasia

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To: All Concerned Parties

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Business Overview of Pipeline Products
(The Fiscal Year Ending December 31, 2023)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Fiscal Year Ending December 31, 2023. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

【Commercial Products】

Product (Development code)	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
Sancuso® (SP-01)	Chemotherapy induced nausea and vomiting (CINV)	China							Launched in 2019 Obtained approval for new manufacturing facility	Lee's Pharm
DARVIAS® (SP-02)	Peripheral T-cell lymphoma (PTCL) Additional indication under review	Japan							Launched in August 2022 Began searching for additional indications	Nippon Kayaku (Japan) HB Human BioScience (South America)
		South Korea, Taiwan, Hong Kong							Phase II (pivotal) study completed Out-licensing activities ongoing	
		South America							Preparations to file for approval underway in each country based on approval granted in Japan	
		China, US, Europe							Development strategy being drafted based on US study data and approval in Japan; out-licensing activity ongoing	
		overseas countries							NPP strategy being evaluated based on approval in Japan	
episil® oral liquid (SP-03)	Pain associated oral mucositis (medical device)	Japan							Launched in 2018 Preparing to apply for approval of new manufacturing facility	Meiji Seika Pharma
		China							Launched in 2019	Lee's Pharm
		South Korea							Launched in 2020	Synex

Note: For the development status of DARVIAS® in South America, China, US and Europe, are based on past US trials and Japanese approval status.

【Under Development】

Pipeline Code	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, etc.							Pre-clinical study in taxane-induced peripheral neuropathy ongoing* *PIII study of oxaliplatin-induced peripheral neuropathy completed; results not achieved	Maruho (Japan)

Note: SP-05 has been removed from the above table based on Phase III trial results

【New Drug and Technology Candidates】

GeneCare Project:	Aims to treat peritoneal metastasis (peritoneal dissemination) associated with various gastrointestinal cancers, ovarian cancer, etc. and accompanying ascites with the novel nucleic acid drug RECQL1-siRNA.
EditForce Project:	Aims to discover gene therapies for cancer using RNA editing that uses the PPR (pentatricopeptide repeat) protein platform technology.
HikariQ Project:	Aims to develop innovative immunoassays and discover the next-generation antibody-drug conjugates (ADC), using the novel Q-body technology that embeds fluorescent dyes and drugs inside antibodies.
Goryo Chemical Project:	Aims to jointly commercialize navigation drugs for cancer surgery, among others, using functional fluorescent probe technology

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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").
  - Ongoing investigation of hospitals in China to combat corruption is having an impact on the prescription volume of the drug.

China - Current status

  - The Company launched in March 2019.
  - The Company dissolved its own sales structure as of July 31, 2022, and on August 1 of the same year, transferred its sales functions to sales partner Lee's Pharmaceutical.
  - Currently, procedures are underway to change the manufacturing site of the drug in a bid to lower manufacturing costs, and we expect prescription volume of the drug to fall temporarily until the procedures are complete.
  - In the first half of the fiscal year ended December 2023 (July-December 2023), the number of prescriptions for Sancuso® was affected by the investigation of hospitals by the Chinese authorities in efforts to combat corruption, but this impact has subsided as of the release of this document.
  - At the end of 2023, the Company obtained approval from the Chinese regulatory authority for the relocation of its manufacturing facility aimed at curbing manufacturing costs. Because the Company built up inventory of Sancuso® manufactured at the former manufacturing facility to prevent stock outs during the transitional period until it fully relocates to the new facility, the sales volume of the drug produced at the new facility is expected to be low, albeit temporarily, for some time.

- **DARVIAS® Injection 135mg (development code: SP-02, generic name: darinaparsin): organic arsenic compound (indication: 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.
  - In June 2022, the Company obtained marketing approval from the Ministry of Health, Labor and Welfare for DARVIAS® Injection 135mg for the treatment of relapsed or refractory peripheral T-cell lymphoma. Nippon Kayaku began selling the product in August 2022, and its MRs are promoting the product to medical institutions.

Other - Current status

  - In 2018, the Company out-licensed marketing rights to DARVIAS® in South America to HB Human BioScience SAS. HB Human Bioscience is preparing to apply for regulatory approval in South America based on the approval status in Japan. In Columbia, marketing application was accepted by the country's regulatory authority in December 2023.
  - In regions other than Japan and South America, we intend to commercialize the drug by establishing sales partners, and are currently focused on out-licensing marketing rights in China.

Named Patient Program (NPP) and other

  - The Company will make DARVIAS® available through the Named Patient Program (NPP) in countries and regions where it does not yet have a sales partner or where the drug has yet to be approved or covered by medical

insurance (i.e., no reimbursement price has been set). The program covers Europe, India, South America and some parts of China.

- We are currently working on expanding indications for the drug to include cancer types other than relapsed and refractory peripheral T-cell lymphoma in collaboration with domestic sales partner Nippon Kayaku.

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

- In July 2022, the Company acquired 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 2024.
- The Company is diligently making preparations to relocate its manufacturing facility to curb manufacturing costs, and expects to apply for and obtain necessary regulatory approval by the end of 2024 in Japan.

Japan - Current status

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

China - Current status

- Sales of episil® oral liquid began in 2019. The Company dissolved its own sales structure 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.
- The Company is diligently making preparations to relocate its manufacturing facility to curb manufacturing costs, and expects to apply for and obtain necessary regulatory approval by the end of 2024 in Japan.

South Korea - Current status

- Synex Consulting Ltd. launched episil® in 2020, based on a license and collaboration agreement with the Company.

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 halted the development of SP-04 as a treatment for peripheral neuropathy caused by multidrug chemotherapy containing oxaliplatin, based on the results of the global Phase III study of the drug for the said indication. We are currently conducting animal studies, using rat models of taxane-induced peripheral neuropathy, in collaboration with licensor Egetis Therapeutics (formerly PledPharma) to investigate the possibility of developing the drug for the treatment of taxane-induced

peripheral neuropathy. Results of animal studies conducted thus far suggest potential efficacy of the drug in suppressing the onset of peripheral neuropathy, but the effect was not clearly demonstrated enough. The Company plans to conduct new animal studies in collaboration with Egetis Therapeutics with an eye to resuming clinical development of SP-04.

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

- Global Phase III clinical trials (Agent study) in patients with advanced colorectal cancer were conducted in multiple countries including Japan, to compare the outcomes of patients in the arfolitixorin group (administered 5-FU + oxaliplatin + bevacizumab combination therapy + SP-05 [arfolitixorin]), with those of the standard therapy group (received 5-FU + oxaliplatin + bevacizumab combination therapy + leucovorin). In November 2022, the Company confirmed through the final topline results of the study that no statistically significant difference was found in the primary and key secondary endpoints between the outcomes of the arfolitixorin (SP-05) group and the standard therapy group.
- In March 2023, the drug's licensor, Isofol, announced a detailed analysis of the results of the studies to date and a plan for conducting non-clinical studies with a view to resuming clinical development of SP-05. In addition, Isofol announced in July 2023 the re-analysis of Phase III clinical trial data suggesting potential antitumor effects obtained by adjusting the dosage and administration method of arfolitixorin. Isofol also announced the initiation of non-clinical studies, the results of which are expected to be confirmed as early as this summer. The Company will closely monitor and review the results of these studies.
- In July the same year, Isofol announced that the dosage of arfolitixorin may not have been sufficient based on detailed analysis of the Phase III clinical trial data, and that by adjusting the dosage and dosing regimen, it may be able to demonstrate antitumor effects of the drug. Further, Isofol announced its plan to commence nonclinical trials, and we plan to closely monitor and review the trial results going forward.
- In December 2023, Isofol released interim results of non-clinical studies conducted using organoids collected from colorectal cancer patients, stating that the studies confirmed additional efficacy of arfolitixorin that was not demonstrated by leucovorin. Isofol announced its plans to obtain more detailed data and conduct further analysis. The Company intends to closely monitor the results of the studies and will continue discussing future direction of the development with Isofol.

3. New Drug /Technology Candidates:

Development candidates and technologies below are early-stage projects in the research or pre-clinical development stages. They have potential to become our next pipeline products, and we are working on research and development together with each partner company.

➢ **Nucleic acid drug candidate for peritoneal metastases**

- In 2020, the Company entered into an agreement with Japan-based GeneCare Research Institute Co., Ltd. ("GC") for exclusive negotiating rights (option rights) to in-license the latter's nucleic acid drug candidate RECQL1-siRNA and related technologies. We are currently engaged in joint development with GC, and will decide whether to practice the option rights to in-license the drug candidate, taking into consideration progress

in non-clinical studies and new formulation development going forward.

- RECQL1-siRNA is an siRNA (small interfering, double-stranded RNA) and a nucleic acid drug discovered by GC based on technologies in-licensed from US-based Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), a world leader in RNA inference (RNAi) technologies. The drug is believed to have a novel mechanism of action to induce cell death by selectively suppressing the expression of the DNA repair enzyme helicase RECQL1, which is found to be overexpressed in cancer cells. In multiple pharmacological studies, the drug was shown to suppress the growth of various types of cancer and prolong survival in animal models of peritoneal dissemination associated with advanced-stage ovarian or gastric cancer.
- Currently, the Company is examining various conditions necessary for the expression of the effects of new, potentially more effective siRNA sequences discovered in collaboration with Ui-Tei Laboratory of the Graduate School of Science, the University of Tokyo, with a view to product development. The Company and GC are conducting pharmacological studies and the development of new formulations to advance the novel siRNA sequences to the clinical development stage.

  *Peritoneal dissemination is a type of metastasis observed in ovarian or gastric cancer patients, where cancer cells migrate to the peritoneal cavity and spread like seeds scattered and sown in the soil. As the condition progresses, it may be accompanied by malignant ascites, and the prognosis is said to be poor. Systemic chemotherapy has not been sufficiently effective in treating peritoneal dissemination, and novel local treatments, such as intraperitoneal administration of drugs, are also being tried.

➢ **Drug discovery utilizing RNA editing technology (gene therapy)**

- 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 its core RNA editing technology.
- The Company has selected a potential target disease and gene mutations causing the disease, and is preparing and examining various matters necessary to conduct non-clinical studies to confirm the efficacy of the pentatricopeptide repeat (PPR) candidate discovered using the RNA editing technology of EditForce.

➢ **Drug discovery using novel antibody modification technology**

- In April 2022, the Company entered into a capital and business alliance agreement with HikariQ, Inc., a startup with roots in Tokyo Institute of Technology. The agreement mainly outlines the Company's investment in HikariQ.
- The fundamental technology of HikariQ's Q-body involves attaching a fluorescent dye to the Q-body, an antibody, and quenching the fluorescence of the dye so the Q-body does not emit fluorescence when it is not bound to the target antigen. However, when the antibody binds to the target antigen, the fluorescent dye is ejected and emits fluorescence. In this way, the Q-body acts as a biosensor whose fluorescence intensity changes according to the target antigen concentration. Immunoassays utilizing this technology are expected to be much simpler and less costly than existing immunoassays that rely on immune reactions. Further, a preliminary review regarding the discovery and development of the next-

generation antibody-drug conjugates (ADC) using the Q-body technology is also underway.

- **Joint commercialization of functional fluorescent probe technology**
  - In 2023, the Company entered into an agreement to explore joint commercialization opportunities with Goryo Chemical, Inc., to conduct joint business and clinical development of navigation drugs for cancer surgery, among others in the pharmaceutical business, using its functional fluorescent probe technology.
  - As the first phase of the joint effort, the Company and Goryo Chemical began exploring the possibilities for the development and commercialization of GCP-006, a navigation drug targeting breast cancer.

4. <u>Other:</u>

- **The fiscal Year Ended December 31, 2023**
  - From the middle of the fiscal year under review, shipments of Sancuso® (SP-01) and episil® (SP-03), which primarily rely on sales in China, were affected by the relocation of manufacturing facilities aimed at curbing manufacturing costs and anti-corruption campaigns in China, which hindered regular sales activities. Further, the Company was not able to reach an agreement to out-license DARVIAS® (SP-02) in China by the end of the fiscal year. As a result, sales revenue declined 475 million yen year on year, falling significantly below the initial forecast.
  - R&D expenses were down 479 million yen year on year, mainly because no clinical trial was conducted for pipeline products.
  - SG&A expenses declined 1,176 million yen year on year, as the Company continued working on reducing fixed costs as it did in the previous fiscal year, mainly through dissolving its in-house sales structure in China, including laying off personnel.
  - As a result of the above, operating loss and net loss narrowed 1,331 million yen and 1,435 million yen year on year, respectively.

- **Major shareholders information**
  - The largest shareholder of the Company as recorded in the Shareholder Registry as of December 31, 2023 was Nippon Kayaku Co., Ltd. (6.9% stake in the Company; partner for DARVIAS® in Japan), followed by Maruho Co., Ltd. (6.5% stake; partner for SP-04 in Japan). The Company concluded an agreement with Nippon Kayaku, requiring the latter to obtain prior written consent from the Company if it is to sell the Company's shares during the two-year period from July 14, 2022.

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, 155 companies have market capitalization of more than ¥100 billion. Of those, 118 are posting operating losses as of February 7, 2024.) 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.

Disclaimer:

The forward-looking statements, including earnings forecasts, contained in this press release are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Such statements should not be construed as representing commitments on the part of the Company. Please be aware that actual performance may differ for a variety of reasons. Major factors affecting the Company's actual performance include the economic conditions in which it operates, exchange rate fluctuations, the competitive situation and other factors. Information contained in this press release is for informational purposes only and should not be considered as investment solicitation. Information with regard to pharmaceuticals and medical devices (including products under development) is not provided for the purposes of advertising or medical advice. We do not have any obligation to update or revise any information in this press release, and any update or revision may occur anytime without notice.