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To: All Concerned Parties

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Business Overview of Pipeline Products
(Third Quarter of the Fiscal Year Ending December 31, 2024)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the third quarter of the Fiscal Year Ending December 31, 2024. The Company hereby supplements this information by providing notice of the status of its major pipeline 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 Completed manufacturing site change	Lee's Pharm
DARVIAS® (SP-02)	Peripheral T-cell lymphoma (PTCL) Additional indication under review	Japan							Launched in August 2022 Exploring 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							New drug application has been filed in Colombia	
		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 Approval for the manufacturing site change has been obtained	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
PledOx® **(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)
Arfolitixorin® **(SP-05)**	Colorectal Cancer	Japan							Has been decided to resume clinical development *P3 completed in 2022: Endpoints not met	-

【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

Solasia

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 began selling Sancuso® in China 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.
- At the end of 2023, the Chinese regulatory authorities granted approval for the application to change the manufacturing facility, aimed at reducing production costs. Local sales partners accumulated inventory of the drug manufactured at the former site to prevent stockouts during the transition to the new site, resulting in a decline in the sales volume of the drug in the fiscal year under review.

- **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, the Company's marketing application was accepted by the country's regulatory authority in December 2023. The Company is also preparing to apply for regulatory approval in other South American countries.

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 investigating the possibility of expanding indications for this drug to include cancers other than relapsed and refractory peripheral T-cell lymphoma. We are also continuing out-licensing efforts for this product overseas.

*Named Patient Program (NPP) allows marketing authorization holders to provide specified patients with drugs that have not yet been approved in

their country for life-threatening conditions,when no alternative treatment exists, after completing the necessary procedures.

- **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.
  - In Japan, we received approval on August 13, 2024, for the application we submitted to the Ministry of Health, Labor and Welfare for a partial change to the medical device manufacturing and marketing approval for episil® (to add a new manufacturing site). We will also be diligent in carrying out the necessary regulatory procedures in other markets where the drug is approved for sale.

Japan - Current status

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

China - Current status

- In August 2022, the Company transferred its sales functions to local sales partner Lee's Pharm. Currently, Lee's Pharm is selling 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.

Other - Current status

- In regions other than those discussed above, the Company is conducting out-licensing activities.

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 (including Japan) Phase III study of the drug for the said indication (POLAR-A and POLAR-M studies). 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. Although completed animal studies did not confirm a clearly

suppressive effect on the onset of the condition SP-04, effectiveness was bserved in several trial endpoints, suggesting its potential to suppressi the onset of peripheral neuropathy. Based on animal study results obtained thus far, we are conducting preclinical studies on taxane-induced peripheral neuropathy.

- **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), 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.
  - Since March 2023, Isofol, the licensor of the drug, has requested detailed post-hoc analyses of the AGENT study results to external experts and commenced nonclinical studies. The overall evaluation of these efforts suggested that SP-05 may demonstrate clinical efficacy in a dosage regimen different from that used in the AGENT study. Further, Furthermore, Isofol has announced plans to undertake small-scale clinical trials using a new dosage regimen to demonstrate the clinical efficacy of SP-05 compared to standard treatment, with an initial focus on time- and cost-efficient methodologies.
  - In light of Isofol's decision to resume clinical development of arfolitixorin, the Company decided to join efforts to define details of the clinical development program led by Isofol, with a view to participating in future clinical trials.
  - In July 2024, Isofol announced the results of post-hoc analyses of the AGENT study conducted by external experts, along with the results of nonclinical trials on the dose responsiveness of SP-05. The post-hoc analyses indicated that even in the AGENT study, where SP-05 was administered at a potentially suboptimal dose, the SP-05 group demonstrated quantitatively superior results compared with the control group, supporting Isofol's strategy of conducting future clinical trials with a higher dose than that used in the AGENT study (in the view that an optimized dose and administration regimen could lead to a higher efficacy). This strategy is expected to increase the likelihood of obtaining favorable data from the Phase Ib/II clinical trial slated to begin by the end of 2024.

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 planning 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 continues to prepare and examine the 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.

- HikariQ is engaged in joint R&D with other companies as well in its immunoassay business. The Company, jointly with Hikari Q, has begun a preliminary review of the next-generation antibody drug conjugate (ADC) discovery using the Q-body technology.

➢ **Joint commercialization of functional fluorescent probe technology**

- In 2023, the Company entered into an agreement with Goryo Chemical, Inc. to explore joint commercialization opportunities. Specifically, the two companies aim to explore and evaluate the feasibility of joint business development and clinical development opportunities in the pharmaceutical business, including for navigation drugs for cancer surgery using Goryo Chemical's functional fluorescent probe technology.
- As the first phase of the joint effort, the Company and Goryo Chemical continue to explore the possibilities for the development and commercialization in Japan and the U.S. of GCP-006, a navigation drug targeting breast cancer.

4. <u>Other:</u>

➢ **Financial results for the nine months of the fiscal year ending December 31, 2024**

- Product sales remained sluggish due to the impact of competing products and China's anti-corruption campaign. In addition, local sales partners in China accumulated inventory of products manufactured at the former site to prevent stockouts during the transition to the new site, resulting in a decline in sales volume for products manufactured at the new facility in the fiscal year under review. As a result, revenue in the said period came to 81 million yen, primarily owed to sales of DARVIAS® (SP-02) and others, and gross profit came in at 5 million yen.
- R&D expenses were 317 million yen. This was mainly due to investments in changing manufacturing sites to reduce product costs, consideration of expanding indications for DARVIAS® (SP-02) and clinical development in China, animal testing of SP-04, and investments in new development candidates. SG&A expenses were 580 million yen, down 229 million yen year-on-year. The result was an operating loss (gross profit minus R&D expenses and SG&A expenses) of 892 million yen, and net loss of 871 million yen.

- **Major shareholders information**
  - The largest shareholder of the Company as recorded in the Shareholder Registry as of June 30, 2024 was Nippon Kayaku Co., Ltd. (6.0% stake in the Company; partner for DARVIAS® in Japan), followed by Maruho Co., Ltd. (5.66% stake; partner for SP-04 in Japan).

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, 147 companies have market capitalization of more than ¥100 billion. Of those, 114 are posting operating losses as of October, 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.