May,14, 2025

To: All Concerned Parties

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Business Overview of Pipeline Products
(First Quarter of the Fiscal Year Ending December 31, 2025)

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for First quarter of the Fiscal Year Fiscal Year Ending December 31, 2025. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

Commercial Products･Under Development

Product	Developme code	Indication	Area	Pre-clinical	Clinical study P1	Clinical study P2	Clinical study P3	NDA	Approva Launch
Sancuso®	SP-01	Chemotherapy induced nausea and vomiting (CINV)	中国等	China					
ダルビアス®	SP-02	Peripheral T-cell lymphoma (PTCL)･･Additional indication under review	全世界	Japan					
エピシル®	SP-03	Pain associated oral mucositis (medical device)	全世界	Japan･China･South Korea,					
PledOx®	SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	日本・中国		※2020: Global Phase III Clinical Trial for Platinum-Induced Peripheral Neuropathy — Primary Endpoint Not Met				
アルボリチキソリン	SP-05	Colorectal Cancer	日本		※2022: Phase III Clinical Trial – Primary				

※Colombia, Peru: Application Submitted、South Korea, Taiwan, HongKong: Preparing for Application
※United States: Phase II clinical trial completed, China: Phase I clinical trial completed

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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.
→ Preparing to file a new patent application for a novel siRNA sequence developed in collaboration with Ui-Tei Laboratory of the University of Tokyo

EditForce Project:
Aims to discover gene therapies for cancer using RNA editing that uses the PPR (pentatricopeptide repeat) protein platform technology.
→ Exploring new drug candidates for genetic mutation-related diseases using PPR technology platform

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.
→ Evaluating the fundamental technology and conditions for novel ADC drug discovery using Q-body technology

Goryo Chemical Project:
Aiming to explore the potential for joint commercialization of navigation drugs for cancer surgery using functional fluorescent probe technology.
→ Assessing the feasibility of filing for approval in Japan and the US for an in vitro diagnostic drug targeting breast cancer

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.
  Meanwhile, sales of Sancuso® sharply declined year-on-year due to shipment constraints following the transfer of manufacturing facility.

➢ 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. It filed for approval in Colombia in December 2023 and in Peru in March 2025, with the regulatory authorities of each respective country. The Company is also preparing to apply for regulatory

approval in other South American countries.

- Non-clinical studies are underway to evaluate the potential for expanding indications to other cancers beyond relapsed or refractory peripheral T-cell lymphoma.

Named Patient Program (NPP) and other

- To provide DARVIAS® in countries and regions where the Company has no sales partners or where the drug has not yet been approved (Europe, India, South America, and parts of China), the Company offers the drug through the Named Patient Program (NPP)*, which allows marketing authorization holders to provide specific drugs directly to physicians upon request, following the necessary procedures in each respective country.
- Nonclinical trials are ongoing to expand indications for the drug to include cancers other than relapsed and refractory peripheral T-cell lymphoma.
- At the Annual Meeting of the Japanese Pharmacological Society in March 2025, research findings were presented, showing that darinaparsin exhibits cytotoxic effects against the glioblastoma cell line U-87 and the breast cancer cell line MCF-7.

*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.**

  - Sales of episil® (SP-03), which primarily rely on the Chinese market, have remained sluggish due to shipment constraints and other issues resulting from the transfer of manufacturing facilities aimed at reducing production costs
  - The Company obtained regulatory approval for the transfer of its manufacturing facility in Japan in August 2024, and has obtained regulatory approval in South Korea and China as of the date of this release.

Japan - Current status

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

China - Current status

- In December 2024, to boost sluggish sales volume, the Company entered into an agreement to change its sales partner in China from Lee's Pharmaceutical (HK) Limited to Changchun GeneScience Pharmaceuticals Co., Ltd..

South Korea - Current status

- Synex Consulting Ltd. launched episil® in 2020, based on a license and collaboration agreement with the Company. Changchun GeneScience Pharmaceuticals began selling episil® from the first quarter of the current fiscal year.

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.
  - Based on the results of the global (including Japan) Phase III clinical trials (POLAR-A and POLAR-M studies), the Company has suspended the development of SP-04 as a treatment for peripheral neuropathy caused by multidrug chemotherapy containing oxaliplatin in colorectal cancer patients. Instead, additional animal studies are being conducted to explore the potential development of SP-04 as a treatment for taxane-induced peripheral neuropathy. In a new animal study conducted in Japan in collaboration with licensor Egetis Therapeutics based on findings from previous animal studies, we obtained positive results in the pathological evaluation of peripheral neuropathic pain and nerve cells in animal models. With future clinical trials in mind, we are conducting additional animal studies to further validate these findings.

- **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 January 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.

- In July 2025, at the Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO) held in the U.S., detailed results from a post-hoc analysis of the AGENT trial were presented. The analysis, which only included data from patients who strictly adhered to the study protocol, demonstrated that the SP-05 treatment group exhibited higher efficacy than the control group receiving leucovorin. This finding further increases the likelihood of obtaining positive data in the Phase Ib/II clinical trial scheduled to begin in the first six months of this fiscal year.
- In March 2025, the German regulatory authority BfArM (Federal Institute for Drugs and Medical Devices) issued approval to initiate a Phase Ib/II clinical trial of SP-05, and the first patient was enrolled on April 28. The Company plans to participate in the trial from the Phase II portion.

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. Other:

➢ Financial results for the first three months of the fiscal year ending December 31, 2025

- Revenue amounted to JPY 25 million (+111.0% year-on-year), driven by sales of DARVIAS® (SP-02) and episil® (SP-03). Gross profit was JPY 6 million.
- R&D expenses amounted to JPY 111 million, mainly reflecting a reduction in

the cost of DARVIAS® (SP-02), a review of indication expansion and clinical development in China, animal studies for SP-04, and investments in new development candidates. SG&A expenses totaled JPY 191 million (-JPY 40 million year-on-year). As a result, the Company recorded an operating loss of JPY 296 million, calculated by subtracting R&D and SG&A expenses from gross profit, and a bottom-line loss of JPY 292 million.

- **Major shareholders information**

  · The largest shareholder of the Company as recorded in the Shareholder egistry as of December 31, 2024 was Nippon Kayaku Co., Ltd. (5.49% stake in the Company; partner for DARVIAS® in Japan), followed by Maruho Co., Ltd. (5.18% 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, 164 companies have market capitalization of more than ¥100 billion. Of those, 113 are posting operating losses as of February, 2025.) 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.