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To: All Concerned Parties

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

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for Second 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	Developm code	Indication	Area	Pre-clinical	Clinical study P1	P2	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						
アルホリチキソリン	SP-05	Colorectal Cancer	日本						

※Colombia, Peru: Application Submitted, South Korea, Taiwan, HongKong: Preparing for Application

※United States: Phase II clinical trial completed, China: Phase I clinical trial completed status

※2020: Global Phase III Clinical Trial for Platinum-Induced Peripheral Neuropathy — Primary Endpoint Not

※2022: Phase III Clinical Trial – Primary

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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
→ Preparing for a new animal study in collaboration with a domestic university laboratory
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
→ The new business project "Development of performance evaluation system for novel synthetic trypsin, and domestic manufacturing and development of human gene sequence-type GMP trypsin" has been selected under the standard category of the Ministry of Economy, Trade and Industry's FY2025 "Go-Tech Project" (Support for Research and Development of Growth-Oriented SMEs, etc.).

1. Commercial Products:

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

- The Company holds rights for this product in China and certain other territories. .

China - Status

- The Company began selling Sancuso in China in March 2019.
- The Company discontinued its in-house sales structure and, effective August 2022, transferred sales operations to its partner, Lee's Pharmaceutical (HK) Limited, which now conducts sales activities throughout China.
- Regulatory procedures related to the change of manufacturing facility have been completed. However, due to the impact of the change, there are currently constraints on product shipments from the Company.

➢ DARVIAS® Injection 135mg (development code: SP-02, generic name: darinaparsin): organic arsenic compound (indication: peripheral T-cell lymphoma)

- The Company holds worldwide rights.

Japan - Status

- The Company out-licensed for marketing and other rights in Japan to Nippon Kayaku.
- In June 2022, the Company obtained manufacturing and marketing approval from the Ministry of Health, Labor and Welfare for DARVIAS Injection 135mg indicated for relapsed or refractory peripheral T-cell lymphoma. Nippon Kayaku began sales in August 2022, and its MRs are promoting the product to medical institutions.

Other area - Status

- In 2018, the Company out-licensed marketing rights to DARVIAS in South America to Human BioScience SAS. Based on the Japanese marketing approval, Human BioScience is preparing regulatory submissions in the region, having filed for new drug approval in Colombia in December 2023 and in Peru in March 2025, Preparations for filings in other South American countries are also underway.
- The Company continuing out-licensing activities for overseas rights. Regarding the clinical development plan for the peripheral T-cell lymphoma indication in China, the Company has been receiving guidance from the Chinese regulatory

authorities.

- In July 2025, the Company entered into a licensing agreement with FIREBIRD BIOLOGICS Pte. Ltd. (headquartered in Singapore) covering 19 countries across Southeast Asia, Oceania, the Middle East, and Africa. FIREBIRD BIOLOGICS is preparing regulatory applications in the licensed countries

Others

- 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.
- At the 65th Annual Meeting of the Japanese Society of Lymphoma held in July 2025, the results of a re-evaluation based on the Lugano Classification of the antitumor effects observed in the international joint Phase II study of darinaparsin in patients with relapsed or refractory peripheral T-cell lymphoma were presented.
- In the same month, at the 52nd Annual Meeting of the Japanese Society of Toxicology, research findings on the mechanism of action of darinaparsin were also presented.

➢ **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.**

- The Company obtained regulatory approval for the transfer of its manufacturing facility in Japan in August 2024 and has also obtained the corresponding regulatory approvals in South Korea and China as of the date of this transfer of manufacturing facility.

Japan - Status

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

China - Status

- In December 2024, the Company contracted with Changchun GeneScience Pharmaceutical Co., Ltd., as a new commercialization partner from Lee's Pharmaceutical (HK) Limited.
- The company commenced shipments to the new partner during the current interim consolidated accounting period.

South Korea - Status

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

Other area- Status

- In regions other than those discussed above, the Company is conducting out-licensing activities.
- In July 2025, the Company entered into a licensing agreement with FIREBIRD BIOLOGICS Pte. Ltd. (headquartered in Singapore) covering 19 countries across Southeast Asia, Oceania, the Middle East, and Africa.
- On July 23, FIREBIRD obtained marketing authorization from the Singapore regulatory authorities and has commenced preparations for sales activities from September 2025. Shipments of the product to FIREBIRD have already initiated.

Others

- It was included in the Clinical Practice Guidelines for the Treatment of Oral Cancer in Elderly Patients, compiled by the Japanese Society for Oral Oncology. This marks the first inclusion of episil® in a clinical practice guideline in Japan.

- It obtained certification for ISO 13485, the international standard for medica device quality management systems (scope: design, development, and distribution of oral lesion and mucosal care sprays).

2. Pipelines Under Development:

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

- The Company holds the rights to this product 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.
- Considering the results from the international Phase III clinical trials (POLAR-A and POLAR-M), including in Japan, targeting peripheral neuropathy induced by multi-agent chemotherapy containing oxaliplatin in patients with colorectal cancer, the Company has suspended development for this indication.
- Instead, it is conducting additional animal studies to explore the potential for development targeting peripheral neuropathy induced by Taxane-based agents. Based on the information obtained from previous animal studies, the Company, in collaboration with the licensor Egetis Therapeutics AB, conducted new animal studies in Japan. These studies demonstrated positive results in the assessment of neuropathic pain and the pathological evaluation of neuronal cells in the test animals. In view of these findings, and with a view toward future clinical trials, further animal studies are being conducted to reinforce these results.

➢ 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 (administered 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 originator licensor of the drug, has requested detailed post-hoc analyses of the AGENT study results to external experts and commenced non-clinical 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. 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 discussion about 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 non-clinical 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.

- In January 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.
- 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. In June of the same year, the first cohort of dose escalation in the Phase Ib part of the trial was completed, and preparations are currently underway to begin patient enrollment for the second cohort. The Company plans to participate in the trial from the Phase II portion.

Others

- The Company invested in Isofol capital, by subscribing to newly issued shares. Through this investment, the Company aims to build a closer relationship with Isofol and strengthen collaboration in future development activities.

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 GeneCare Research Institute Co., Ltd. (“GC”), Japan-based biotech venture company 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 a 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. This siRNA 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 and GC are planning pharmacological studies and the development of new formulations to advance the novel siRNA sequences which was discovered by Ui-Tei Laboratory of the Graduate School of Science, the University of Tokyo to the clinical development stage. in collaboration with a domestic university laboratory.
- *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.
- In July 2025, the company's new business venture, "Development of a performance evaluation system for newly synthesized trypsin and domestic manufacturing development of human gene sequence-type GMP trypsin," was selected for the regular program of the Ministry of Economy, Trade and Industry's "Growth-Oriented Small and Medium-Sized Enterprise Research and Development Support Program (Go-Tech Program)" for fiscal year 2025. The Company is an advisor for this project.

4. Corporate information

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

- Revenue amounted to JPY 49 million, driven by sales of DARVIAS (SP-02) and episil (SP-03). R&D expenses amounted to JPY 232 million, mainly reflecting consideration of indication expansion and clinical development in China for DARVIAS (SP-02), animal studies for SP-04, and investments in new development candidates. SG&A expenses totaled JPY 325 million.
- Through the issuance of stock acquisition rights in April of this year and the

exercise of those rights, the company raised 1,232 million yen by the end of July of this year.

- Major shareholders information
  - The largest shareholder of the Company as recorded in the Shareholder registry as of Jun 30, 2025 was Nippon Kayaku Co., Ltd. (4.98% stake; partner for DARVIAS in Japan), followed by Maruho Co., Ltd. (4.68% 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. We believe that this situation exists because the marketplaces more important 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 business information on this report.