Solasia

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To: All Concerned Parties

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

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for the Fiscal year ended December 31, 2025. The Company hereby supplements this information by providing an update on the status of its major pipeline products.

Commercial Products・Under Development

Product	Development code	Indication	Solasia Territory	Pre-clinical / Clinical Development Stage (P1 / P2 / P3) / NDA / Approval Launch
Sancuso®	SP-01	Chemotherapy induced nausea and vomiting (CINV)	China	China
Darvias®	SP-02	Peripheral T-cell lymphoma (PTCL)□□Additional indication under review	World wide	Japan; Colombia・Peru
episil®	SP-03	Pain associated oral mucositis (medical device)	World wide	Japan, China, Korea
PledOx®	SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, China	※2020: Global Phase III Clinical Trial for Platinum-Induced CIPN — Primary Endpoint Not Met. New non-clinical investigation started in Taxane induced CIPN
Arfolitixorin	SP-05	Colorectal Cancer	Japan	※2022: Phase III Clinical Trial – Primary Endpoint Not Met 2024: New Phase Ib/II study started in Germany

■ Development Candidates / Technology Projects

- Nucleic Acid Medicine Project for Peritoneal Dissemination (GeneCare Research Institute Co., Ltd.)
- Gene Therapy Project Utilizing RNA Editing Technology (EditForce Inc.)
- Drug Discovery Project Using Novel Antibody Modification Technology (HikariQ Health Co., Ltd.)
- Joint Commercialization Project for Functional Fluorescent Probe Technology (Goryo Chemical Inc.)

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1. Marketed Products

■ Sancuso® (Development Code: SP-01, Chinese Product Name: 善可舒®) -Granisetron transdermal delivery system-

- Indication: Chemotherapy-induced nausea and vomiting
- Territory under the Company's Rights: China
- Out-licensing Partner: Lee's Pharmaceutical (HK) Limited （MAAB Group from 2027)

Status in China

- In August 2022, the Company discontinued its own sales structure, and Lee's Pharmaceutical is currently conducting nationwide marketing activities in China.
- Due to the impact of the manufacturing site transfer, product shipments from the Company were temporarily restricted; however, the Company has completed the first shipment from the new manufacturing site.
- In January 2026, the Company entered into a license agreement with MAAB for manufacturing and marketing rights in Mainland China, Hong Kong, Macau, and Taiwan. MAAB has commenced preparations for local production, and commercial sales are scheduled to begin in January 2027.
- In January 2026, results of a Phase III comparative study were published in The Oncologist, demonstrating statistically significant superiority over palonosetron in preventing delayed nausea and vomiting.

■ DARVIAS® (Development Code: SP-02, darinaparsin): Organic arsenic compound

- Indication: Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL)
- Territory under the Company's Rights: Worldwide

Status in Japan

- Out-licensing Partner: Nippon Kayaku Co., Ltd.
- In June 2022, manufacturing and marketing approval was obtained, and product sales were initiated.

Status in South America

- Out-licensing Partner: HB Human BioScience SAS
- The new drug application (NDA) for DARVIAS® was accepted by the health authorities in Colombia in December 2023 and in Peru in March 2025, and preparations for filing an application in Ecuador are currently underway.

Status in Eastern Europe

- Out-licensing Partner: INTEGRIS PHARMA S.A.
- In August 2025, the Company terminated its existing agreement with WEP Clinical Ltd. (U.K.) and newly entered into a license agreement with INTEGRIS PHARMA S.A. (headquartered in Athens, Greece) granting exclusive rights for the commercialization of DARVIAS® in 13 Eastern European countries under the Managed Access Program (MAP) framework.

Other updates

- The Company is currently conducting indication expansion beyond relapsed or refractory PTCL, including EBV-positive B-cell lymphoma and breast cancer.
- In July 2025, the results of the "Re-evaluation of Antitumor Efficacy of Darinaparsin Based on the Lugano Classification in the International Phase II study for relapsed or refractory peripheral T-cell lymphoma" were presented at the 65th Annual Meeting of the Japanese Society of Lymphoreticular Tissue Research. In the same month, "Research findings on the mechanism of action of Darinaparsin" were also presented at the 52nd Annual Meeting of the Japanese Society of Toxicology.

■ episil® oral liquid (Development Code: SP-03): Hydrogel Wound Coating and Protective Material

- Intended Use: Management and relief of oral pain associated with cancer therapy
- Territory under the Company's Rights: Worldwide
- The Company holds worldwide rights for this product and has out-licensed the marketing rights in Japan and other territories.

Status in Japan

- Out-licensing Partner: Meiji Seika Pharma Co., Ltd.

Status in China

- Out-licensing Partner: Changchun GeneScience Pharmaceutical Co., Ltd.
- In December 2024, the marketing partner was changed from Lee's Pharmaceutical (HK) Limited to Changchun GeneScience Pharmaceutical Co., Ltd., and product supply to GeneScience commenced during the current fiscal year.

Status in Korea

- Out-licensing Partner: Synex Co., Ltd.

Status in Brazil

- In August 2025, the Company entered into an exclusive license agreement with Daiichi Sankyo Brasil Farmacêutica Ltda. (headquartered: Brazil, a wholly owned subsidiary of Daiichi Sankyo Co., Ltd.,) granting exclusive commercialization rights for Brazil.

Other updates

- episil® was included in the Clinical Practice Guidelines for the Treatment of Oral Cancer in Elderly Patients, compiled by the Japanese Society for Oral Oncology, and issued in June 2025. This marks the first inclusion of episil® in a clinical practice guideline in Japan.
- The Company obtained certification under ISO 13485, the international standard for medical device quality management systems, covering the design, development, and distribution of oral lesion and mucosal care sprays.

2. Pipelines Under Development

■ SP-04 (PledOx®): Intracellular superoxide dismutase mimetic

- Planned indication: Chemotherapy-induced peripheral neuropathy (CIPN)
- Territory under the Company's Rights: Japan, China, South Korea, Taiwan, Hong Kong, and Macau
- Out-licensing Partner in Japan: Maruho Co., Ltd.
- In 2020, in light of the results of the international Phase III clinical studies (POLAR-A and POLAR-M), which targeted chemotherapy-induced peripheral neuropathy caused by oxaliplatin-containing multidrug regimens in colorectal cancer patients and did not meet the primary endpoints, the Company has suspended development for this indication
- To explore the potential development of PledOx® for chemotherapy-induced peripheral neuropathy caused by taxane-based agents, additional animal studies have been conducted at domestic university laboratories, and the results were presented at the 34th Annual Meeting of the Japanese Society of Pharmaceutical Health Care and Sciences.
- In addition, the Company is currently evaluating efficacy using a two-dimensional cell model of taxane-induced peripheral neuropathy at domestic university laboratories.

■ SP-05 (arfolitixorin): Folate Formulation Designed to Enhance Antitumor Efficacy

- Planned Indication: Enhancement of the Antitumor Effect of 5-Fluorouracil (5-FU)
- Territory under the Company's Rights: Japan
- In 2022, as the final results of the international Phase III clinical study (AGENT study) in colorectal cancer patients, including Japan, revealed that SP-05 did not achieve statistically significant outcomes in the primary or key secondary endpoints, the Company subsequently suspended development. In 2024, Isofol Medical AB, the originator and licensor of the product, decided to resume development of SP-05, and the Company likewise determined to restart development activities in Japan.
- By January 2025, Isofol announced the results of post-hoc analyses from the AGENT study together with non-clinical study results regarding the dose–response relationship of SP-05. The analyses indicated that, although the AGENT study was conducted at a non-optimal dose level and dosing schedule, the SP-05 treatment group showed numerically higher antitumor efficacy compared with the leucovorin control group. In addition, in a subset of patients who strictly adhered to the study protocol, the SP-05 group demonstrated higher efficacy than the leucovorin group. These findings are currently considered to increase the likelihood of obtaining positive data in the ongoing Phase Ib/II clinical study.
- In March 2025, approval to initiate the Phase Ib/II clinical trial of SP-05 was obtained from the German regulatory authority BfArM (Federal Institute for Drugs and Medical Devices), and in April 2025, the first patient was dosed at Charité University Hospital, Berlin. In September 2025, the second cohort of the dose-escalation Phase Ib part was completed, and the third cohort is currently ongoing. In Japan, which is within the Company's licensed territory, participation is planned from the Phase II part of this study in 2026.

Others

- In July 2025, pursuant to Isofol's capital increase through a rights issue and other methods, the Company invested JPY 77 million by subscribing to newly issued shares. As a result, the Company holds a 2.2% equity stake in Isofol. Through this investment, the Company aims to further strengthen collaboration with Isofol in the future development of SP-05.
- Isofol announced that it has received an Intention to Grant from the European Patent Office (EPO) for a new patent related to SP-05 (arfolitixorin). If the patent is granted, the protection period is expected to extend until 2043. The patent covers lyophilized formulation technology, and Isofol plans to pursue patent protection in major markets, including the United States and Japan.

3. Development Candidates / Technology Projects

- The 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"), a Japan-based biotech venture company holding exclusive negotiating rights (option rights) to in-license the latter's nucleic acid drug candidate RECQL1-siRNA and related technologies. The Company is currently conducting joint development with GC and will decide whether to exercise the option rights to in-license the drug candidate, considering progress in non-clinical studies and new formulation development.
- RECQL1-siRNA is a small interfering RNA (siRNA) molecule, a double-stranded nucleic acid drug discovered by GC based on technologies in-licensed from US-based Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), a world leader in RNA interference (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.

- The Company and GC are currently conducting pharmacological studies and the development of new formulations to advance the novel siRNA sequences, which were discovered by the 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. In addition, animal studies using a new lipid nanoparticle (LNP) formulation prototype targeting ovarian cancer are currently being conducted.

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

■ **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 is currently evaluating the applicability of the pentatricopeptide repeat (PPR) technology to Niemann–Pick disease, a rare hereditary and progressive lysosomal disorder characterized by abnormal lipid metabolism, which leads to the accumulation of lipids in the liver, spleen, and brain.

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

- In 2022, the Company entered into a capital and business alliance agreement with HikariQ Health Co., Ltd., a biotechnology venture startup originating from Tokyo Institute of Technology (currently Tokyo Science University), primarily through an equity investment.
- The fundamental Q-body technology involves attaching a fluorescent dye to an antibody and quenching its fluorescence until binding to a target antigen, upon which the dye emits fluorescence. Thus, Q-bodies function as biosensors whose fluorescence intensity varies according to antigen concentration.
- This immunoassay technology is expected to simplify procedures and reduce costs compared to conventional immunoassays. In addition, a preliminary review is currently being conducted on the discovery and development of next-generation antibody drug conjugate (ADC) products using this technology, including the development of a prototype novel darinaparsin ADC based on Q-body technology.
- HikariQ is engaged in joint R&D with other companies as well in its immunoassay business. The Company, jointly with HikariQ, has begun a preliminary review of the next-generation antibody drug conjugate (ADC) discovery using Q-body technology.

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

- In 2023, the Company entered into an agreement with Goryo Chemical, Inc. to evaluate and explore joint commercialization opportunities, including navigation drugs for cancer surgery using Goryo's fluorescent probe technology.
- As the first phase, both companies are currently conducting exploratory development and an evaluation of commercialization possibilities in Japan and the U.S. for GCP-006, a navigation drug targeting breast cancer.
- In July 2025, Goryo's new business, "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 Japanese Ministry of Economy, Trade and Industry's FY2025 Go-Tech Program. The Company serves as an advisor for this project.

4. Corporate information

■ Financial results for the fiscal year ended December 31, 2025

- In the consolidated statement of income for the fiscal year ended December 31, 2025, the Company recorded total revenue of JPY 429 million, mainly driven by sales of Sancuso® (SP-

01), DARVIAS® (SP-02), and episil® (SP-03) products, as well as license revenue from the out-licensing of episil® rights in Brazil. Gross profit amounted to JPY 207 million.

- R&D expenses amounted to JPY 430 million, primarily reflecting cost reduction initiatives for DARVIAS® (SP-02), consideration of indication expansion and clinical development in China, animal studies for SP-04, and investments in new development candidates. Selling, general and administrative expenses amounted to JPY 637 million. As a result, operating loss amounted to JPY 861 million, and net loss amounted to JPY 876 million.

■ Fundraising

- Through the issuance and exercise of new share subscription rights in April 2025, the Company raised approximately JPY 1,613 million by the end of January 2026.

■ Major shareholders information

- As of the end of December 2025 according to the Company's shareholder registry, the largest shareholder was Nippon Kayaku Co., Ltd. (ownership ratio: 4.55%), the domestic partner for DARVIAS®, and the second largest shareholder was Maruho Co., Ltd. (ownership ratio: 4.29%), the domestic partner for SP-04.

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, most of those companies post losses on a single-year basis. We believe that this situation exists because the marketplace places greater importance on making proactive upfront investments in promising drug development than on assessing such companies based on 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 it is important to disclose to investors information about our key pipeline products to a certain level of detail. We have disclosed such business information in this report.