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To: All Concerned Parties

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## Business Overview of Pipeline Products (First Quarter of the Fiscal Year Ending December 31, 2026)

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for the first quarter of the Fiscal Year Ending December 31, 2026. 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			NDA	Approval
					P1	P2	P3		Launch
Sancuso®	SP-01	Chemotherapy induced nausea and vomiting (CINV)	China						China
Darvias®	SP-02	Peripheral T-cell lymphoma (PTCL) Additional indication under review	Worldwide						Japan
									South America
									Eastern Europe
episil®	SP-03	Pain associated oral mucositis (medical device)	Worldwide						Japan, China, Korea
									Brazil
				※Planned to file for approval based on Japanese regulatory approval.					
PledOx®	SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, China	Japan	※In 2020, the Phase III clinical trial for platinum-induced CIPN did not meet its primary endpoint. ※Non-clinical studies for taxane-induced CIPN are currently ongoing.				
Arfolitixorin	SP-05	Colorectal Cancer	Japan		※Failure to meet the primary endpoint in the Phase III clinical trial in 2022.				
				Germany	※Initiation of a Phase Ib/II clinical trial in 2025 with a revised dosing regimen. ※Led by Isofol; Japan participating from the Phase II part. ※Germany: Phase Ib/II.				

※Darvias®

- Marketing authorization applications have been submitted in Colombia and Peru.
- Marketing authorization applications are in the process of submission in Ecuador and Panama.
- Out-licensing conducted under the MAP scheme.

### 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.)

## **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: MAAB Pharma Limited

#### Status in China

- In January 2026, the Company entered into a license agreement with MAAB for manufacturing and marketing rights, MAAB has commenced sales activities following the transfer from Lee's Pharmaceutical in April 2026 and is promoting initiatives toward local production in China, and in addition, MAAB has initiated evaluation and consideration of strategic collaboration with the Company regarding products other than Sancuso®.
- In January 2026, results of a Phase III comparative study were published in The Oncologist, demonstrating statistically significant superiority over palonosetron in preventing long-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 BioSciences 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 and Panama 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 malignancies and malignancies with high expression of the XCT transporter in collaboration with a laboratory at a domestic university and a contracted laboratory in China.
- In March 2026, that laboratory at a domestic university presented the results of a collaborative study on the efficacy of DARVIAS® in treating EB virus-positive B-cell lymphoma (99th Annual Meeting of the Japanese Pharmacological Society).

### ■ 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

#### Status in Japan

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

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## 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 sales by GeneScience commenced in March 2025.

## 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 in São Paulo, Brazil, a wholly owned subsidiary of Daiichi Sankyo Co., Ltd.) granting exclusive commercialization rights for Brazil.

## Other updates

- episil<sup>®</sup> 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<sup>®</sup> 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.

## 1. **Pipelines Under Development**

### ■ **SP-04 (PledOx<sup>®</sup>)**: 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 licensor (Egetis Therapeutics) and the Company have suspended development for this indication
- To explore the potential development of PledOx<sup>®</sup> for chemotherapy-induced peripheral neuropathy caused by taxane-based agents, additional animal studies have been conducted at university laboratories, and the results have been 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 a domestic university laboratory.

## Other updates

- In March 2026, a laboratory at a domestic university presented the results of a collaborative study using animal models on the efficacy of SP-04 against taxane-induced peripheral neuropathy (146th Annual Meeting of the Pharmaceutical Society of Japan).

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

- Planned Indication: Enhancement of the Antitumor Effect of 5-Fluorouracil (5-FU) in colorectal tumor
- 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.

- In 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.

#### Other updates

- Isofol has raised funds for the future development of SP-05 through a rights issue and other methods. In July 2025, the Company invested JPY 77 million by subscribing to newly issued shares under the same conditions, and in March and April 2026, the Company made additional investments of JPY 34 million. As a result, the Company holds approximately a 3.25% equity stake in Isofol. Through these investments, the Company aims to further strengthen collaboration with Isofol in the future development of SP-05 and to partially capture economic value generated from development progress outside Japan.
- In March 2026, Isofol announced that it had expanded its exclusive global license for arfolitixorin to include development and commercialization for autism spectrum disorder.

## **2. 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. HikariQ is engaged in joint R&D with other companies as well in its immunoassay business.
- 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.

## ■ Joint commercialization of functional fluorescent probe technology

- This project aims to evaluate the commercial potential of the technology prior to commencing joint research and development with Goryo Chemical Co., Ltd. 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.

## 3. Corporate information

### ■ Financial results for the first quarter of the fiscal year ending December 31, 2026

- In the first quarter of the fiscal year ending December 31, 2026, the Company recorded revenue of JPY 6 million, mainly driven by sales of episil® (SP-03) products, and gross profit amounted to JPY 4 million. Due to the transition of the China sales partner, no sales of Sancuso® were recorded in the first quarter, and shipments are expected within the second quarter. License revenue from the agreement with MAAB has not yet been recognized, and is expected to be recorded from the second quarter onward.
- R&D expenses amounted to JPY 112 million, primarily reflecting indication expansion of DARVIAS® (SP-02), animal studies for SP-04, and investments in new development candidates.

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- Selling, general and administrative expenses amounted to JPY 198 million, increasing by JPY 7 million compared to the same period of the previous fiscal year. As a result, operating loss amounted to JPY 306 million, and net loss amounted to JPY 307 million.
- Fundraising
  - The 15th series of stock acquisition rights issued on April 9, 2025 were fully exercised on February 25, 2026, and total proceeds amounted to JPY 1,718 million.
- Major shareholders information
  - As of the end of March 2026, according to the Company's shareholder registry, the largest shareholder was Nippon Kayaku Co., Ltd. (ownership ratio: 4.38%), the Japanese partner for DARVIAS<sup>®</sup>, and the second largest shareholder was Maruho Co., Ltd. (ownership ratio: 4.14%), the Japanese 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.

#### 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 about 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.