

To: All Concerned Parties

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## Business Overview of Pipeline Products

### (Second Quarter of the Fiscal Year Ending December 31, 2019)

Solasia Pharma K.K. (hereinafter “the Company”) today announced its Consolidated Financial Results for the Six Months of the Fiscal Year Ending December 31, 2019. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

Pipeline Code Estimated Initial indication	Originator	Pre-clinical	Clinical Study			NDA	Approval	Launch	Out-licensed Partner (Region)
			Phase I	Phase II	Phase III				
<b>SP-01</b> <b>Sancuso®</b> Chemotherapy Induced Nausea and Vomiting	Kyowa Kirin (UK)		China (Launched in Mar. 2019)						- Kyowa Kirin (TW etc.), - Lee's Pharma (China*) *excl. BJ, SH and GZ - Solasia sales force (above 3 big cities in China) Distribution partner; Itochu Corp.
			Taiwan, HK etc. (by Kyowa Kirin)						
<b>SP-02</b> <b>darinaparsin</b> Peripheral T-Cell Lymphoma	ZIOPHARM Oncology (US)		Japan, Korea, TW, HK			(Phase II, pivotal study)			- Meiji Seika Pharma (Japan), - HB Human BioScience (Latin America)
			China			(Phase II/III, pivotal study preparation)			
			US			(Phase IIA, completion)			
			EU			(Pre-clinical, completion)			
<b>SP-03</b> <b>episil®</b> [Medical Device] Pain associated oral mucositis	Camurus (Sweden)		Japan (Launched in May 2018)						- Meiji Seika Pharma (Japan), - Lee's Pharma (China*) *excl. BJ, SH and GZ - Solasia sales force (above 3 big cities in China) Distribution partner; Itochu Corp.
			China (Launched in Jul. 2019)						
			Korea (NDA in Mar. 2019)						
<b>SP-04</b> <b>PledOx®</b> Chemotherapy Induced Peripheral Neuropathy	PledPharma (Sweden)		Japan, Korea, TW, HK			(Initiated Phase III, pivotal study)			—
			China			(Clinical study preparation)			

### 1. SP-01 (Sancuso®): Commercialization in China

#### Granisetron transdermal delivery system (Indication: Chemotherapy-induced nausea and vomiting)

The Company has rights in China etc. The Company out-licensed rights in Hong Kong, Taiwan etc. to Kyowa Kirin.

#### China - Current status

- The Company obtained approval by the Chinese authority in July 2018 and launched (provided to clinical sites) on March 18, 2019.

- The first new Guideline was published by CSCO, recommended Sancuso® as a new standard of care for CINV (Chemotherapy induced nausea and vomiting) treatment in June 2019.

Building of distribution channels;



Sancuso® Chinese Product Package

- The Company has entered into a sales distribution agreement for China with Itochu Corporation (hereinafter “Itochu”) and has built sales channels utilizing Itochu and the Itochu Group.
- The Company is conducting sales in-house in Beijing, Shanghai, and Guangzhou, and is building the sales structure as below.
- In other parts of China, Lee’s Pharmaceutical (HK) Limited (hereinafter “Lee’s”) launched with the basis of sales and licensing agreements between the Company.
- The Company’s direct sales partner is Itochu Group.

## **2. SP-02 (darinaparsin): Development in Japan and other parts of Asia (Japan, South Korea, Taiwan and Hong Kong)**

### **Mitochondria-targeted apoptosis inducer (Estimated Indication: Peripheral T-cell lymphoma)**

The Company has worldwide rights.

The Company out-licensed rights in Japan to Meiji Seika Pharma Co., Ltd. (hereinafter “Meiji”) and rights in Latin America to HB Human BioScience SAS.

Current status

- This product is currently undergoing an Asian multinational phase II clinical study on patients with relapsed or refractory peripheral T-cell lymphoma in Japan, South Korea, Taiwan, and Hong Kong.
- Following discussions with the Pharmaceuticals and Medical Devices Agency (PMDA), the Company is positioning this clinical study as the final study before New Drug Application (NDA). As of today, patient-enrollment is over 95% of the target number of cases.

Plans

- The Company expects to close this clinical study in 2019. If the results of this clinical study are positive, the Company plans to apply NDA to the relevant authorities in 2020.

Line-Extension

- Currently, the Company is conducting non-clinical studies on other hematologic cancers.

## **3. SP-03 (episi<sup>®</sup> oral liquid): Commercialization in Japan and China**

### **The protection and relief of oral pain associated with oral mucositis/stomatitis caused by chemotherapy and radiotherapy for cancer (Indication: Oral mucositis/stomatitis caused by chemotherapy and radiotherapy)**

The Company has rights in Japan, China (including Hong Kong and Macau), and South Korea.

## Japan - Current status

- Meiji began selling the product in May 2018, based on a License and collaboration agreement for episil®.

## China - Current status

- The Company obtained approval by the Chinese authorities in February 2019 and has launched on July 19, 2019.



episil® Japanese Product

## Building distribution channels

- Same as SP-01, the Company has entered into a sales distribution agreement for China with Itochu and has built sales channels utilizing Itochu and the Itochu Group.
- The Company is conducting sales in-house in Beijing, Shanghai, and Guangzhou, and is building the sales structure as below.
- In other parts of China, Lee's has been launched on the basis of sales and licensing agreements with the Company.
- The Company's direct sales partner is Itochu Group.

## South Korea - Current status

- The Company filed a New Medical Device Application to the relevant authorities in March 2019.

## 4. **SP-04 (PledOx®): Development in Japan and other parts of Asia (Japan, South Korea, Taiwan and Hong Kong)**

### **Intracellular superoxide removing agent (Expected Indication: Chemotherapy-induced peripheral neuropathy)**

The Company has rights in Japan, China (including Hong Kong and Macau), South Korea and Taiwan.

#### Current status

- The Company initiated a multinational phase III clinical study on colorectal cancer patients who undergo mFOLFOX6 therapy in December 2018.

#### Plans

- The Company plans to complete the multinational phase III clinical study in 2020.

## 5. **Building of an in-house sales structure in China**

### In-house sales strategy

- Within China, the Company is conducting in-house sales and marketing activities for SP-01 and SP-03 in Beijing, Shanghai, and Guangzhou, in the interest of maximizing profits from product sales and controlling fixed costs.

### Organization of personnel

- The Company appointed the following three business directors and built up the foundation for an in-house sales structure. Furthermore, the

# Solasia

Company has established of an in-house sales structure with totally 30 medical representatives (MRs), comprising around 10 each in Beijing, Shanghai, and Guangzhou. 70% of these people hail from large foreign pharmaceutical companies and on average have two or more years of sales experience in the oncology field. MRs are being put to immediate use in sales activities.

General manager of Chinese business,

Career history: Formerly the head of oncology at Roche in China and a medical doctor (formerly at Shanghai Ninth People's Hospital attached to Shanghai the Second Medical University)

Marketing director of the Company subsidiary in China:

Career history: Formerly at Roche, BMS, and Sanofi and a medical doctor (formerly ER at Shanghai No.1 Peoples Hospital)

Sales director of the Company subsidiary in China:

Career history: Formerly at Roche and BI and a medical doctor (formerly Cardiac Surgeon at Suzhou City Hospital)

- Bases
- Solasia Medical Information Consulting (Shanghai) Co. Ltd., a wholly owned subsidiary, is taking charge of the Company's sales and marketing activities in China.
  - The Company has completed the establishment of bases in Shanghai, Beijing and Guangzhou.

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, 108 companies have market capitalization of more than ¥100 billion. Of those, 76 are posting operating losses as of July 29, 2019.) We believe that this situation exists because the market places 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 information on 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 with regard to 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.