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To: All Concerned Parties

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# Business Overview of Pipeline Products (Third Quarter of the Fiscal Year Ending December 31, 2018)

Solasia Pharma K.K. (the "Company") today announced its earnings results for the nine months of the fiscal year ending December 31, 2018. We hereby supplement this information by providing notice of the status of our pipeline products.

## 1. SP-01: Commercialization in China (Indication: Chemotherapy-induced nausea and vomiting)

Current status

- We obtained approval from the Chinese authorities in July 2018 and are currently preparing for launch, as outlined below.
- Basing on this approval, the Company received milestone payments from Lee's Pharmaceutical (HK) Limited (hereinafter "Lee's") in the third quarter, which was recorded as revenue.

Product manufacturing

- We are in the final commercial product manufacturing stage.

Building of distribution channels

- We have entered into a sales agency agreement for China with Itochu Corporation (hereinafter "Itochu") and are building 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 described below in these areas.
- In other parts of China, the Company is preparing for launch with the basis of sales and licensing agreements between Lee's.

Plans

- The Company's direct sales partner is Itochu. We expect to commence initial product shipment to Itochu in 2018.
- After shipment to Itochu and following Chinese customs proceedings, SP-01 will be provided to clinical sites (launch). We expect to launch in the first quarter of the fiscal year ending December 31, 2019.

## 2. SP-02: Development in Japan and other areas of Asia (Indication: Peripheral T-cell lymphoma, etc.)

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 exceeds 80% of the target number of cases.

Plans

- The status of patients enrolled for the phase II clinical study is described above. On this basis, the Company expects to close this clinical study in 2019. If the results of this clinical study are positive, we plan to apply NDA to the relevant authorities for approval in 2020.

Expansion of indications

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

**3. <u>SP-03: Development and commercialization (Indication: Oral mucositis/stomatitis caused by chemotherapy and radiotherapy for cancer)</u>**

**(a) Japan**

Current status

- This product obtained medical device manufacturing and marketing approval in 2017. Meiji Seika Pharma Co., Ltd. (hereinafter “Meiji Seika Pharma”) began selling the product in May 2018, based on a License and collaboration agreement for episil®.
- The Company ships the product to Meiji Seika Pharma and receives product sales revenue and royalty payments from Meiji Seika Pharma. To stockpile the product through sales channel at the launch period, the Company shipped a certain amount of the product in the second quarter of 2018. Due to this reason, no shipments occurred during the third quarter. Accordingly, only royalty payments were recorded as revenue in the third quarter.

Plans

- We plan to ship the next batch of products to Meiji Seika Pharma in the fourth quarter of the current year.

**(b) China**

Current status

- The authorities are currently reviewing the product for approval. Reviewing is in the final stage, and we are aware of no impediments to approval being obtained.

Plans

- We expect to obtain approval in 2018 and followed by launch in 2019.

**(c) South Korea**

Current status

- Exclusive development and marketing rights for South Korea were obtained in August 2018, and we are currently preparing to apply for approval to the relevant authorities.

Plans

- We plan to apply to the authorities for approval in 2019.

**4. <u>SP-04: Development in Japan and other areas of Asia (Indication: Chemotherapy-induced peripheral neuropathy)</u>**

Current status

- A phase I clinical study was concluded in February 2018. Following consultation with the PMDA, in May 2018 the Company decided on a development strategy of participating into the global phase III clinical study being led by licensor PledPharma AB in Japan, South Korea,

Taiwan, and Hong Kong, which is within the area in which the Company holds rights. We are currently preparing to start this study.

Plans
- We plan to initiate this clinical study in 2018 within the above area where the Company holds rights.

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

In-house sales strategy

- Within China, the Company plans to conduct 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

- We have appointed the following three business directors and building up the foundation for an in-house sales structure. We have also recruited product managers for each product, a medical manager to take charge of post marketing surveillance, and other key members.

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

Business sites

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

Plans
- Prior to the launch of SP-01, scheduled for the first quarter of 2019, we plan to complete the establishment of an in-house sales structure with 30 medical representatives (MRs), around 10 each in Beijing, Shanghai, and Guangzhou.
- We plan to establish our business site in Guangzhou within 2018.

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 such companies post losses on a single-year basis. (According to research by Solasia Pharma, of the companies that make up the NASDAQ Biotechnology Index, 100 companies have market capitalization of more than ¥100 billion. Of those, 70 are posting operating losses as of October 31, 2018.) 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 intend to disclose such information going forward.

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 with regard to pharmaceuticals and medical devices (including products under development) is not provided for the purposes of advertising or medical advice.