February 13, 2019

To: All Concerned Parties

Company Name: Solasia Pharma K.K.
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(Code number: 4597, TSE Mothers Section)
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# Business Overview of Pipeline Products
## (Consolidated Financial Results for the Fiscal Year Ended December 31, 2018)

Solasia Pharma K.K. (the "Company") today announced Consolidated Financial Results for the Fiscal Year Ended December 31, 2018. We hereby supplement this information by providing notice of the status of our major pipeline products.

The Company is a specialty pharma company, specializing in the development and commercialization of products in the oncology domain. 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, 105 companies have market capitalization of more than ¥100 billion. Of those, 78 are posting operating losses as of January 28, 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.

| **Pipeline Code**<br>Estimated Initial indication | Originator / Partner | Pre-clinical | Clinical Study: Phase 1 | Clinical Study: Phase 2 | Clinical Study: Phase 3 | NDA | Approval | Launch |
|---|---|---|---|---|---|---|---|---|
| **SP-01**<br>**Sancuso®**<br>Chemotherapy Induced Nausea and Vomiting | Originator:<br>Kyowa Kirin<br><br>Partner:<br>Lee's Pharma<br>Kyowa Hakko Kirin | China (Approval in July 2018, Preparation for Launch) | | | | | | |
| | | Taiwan, Singapore, HK etc. (by Kyowa Hakko Kirin) | | | | | | |
| | | US, EU, over 10 countries (Sancuso® by other companies) | | | | | | |
| **SP-02**<br>**darinaparsin**<br>Peripheral T-Cell Lymphoma | Originator:<br>ZIOPHARM<br><br>Partner:<br>Meiji Seika Pharma<br>HB Human BioScience | Japan, Korea, Taiwan, HK (Phase II, pivotal study) | | | | | | |
| | | China (Phase II/III, pivotal study preparation) | | | | | | |
| | | US (Phase IIA, completion) | | | | | | |
| | | EU (Pre-clinical, completion) | | | | | | |
| **SP-03**<br>**episil®**<br>[Medical Device]<br>Pain associated oral mucositis | Originator:<br>Camurus<br><br>Partner:<br>Meiji Seika Pharma<br>Lee's Pharma | Japan (Launched in May 2018) | | | | | | |
| | | China | | | | | | |
| | | Korea | | | | | | |
| | | US, EU, over 9 countries (episil® by other companies) | | | | | | |
| **SP-04**<br>**PledOx®**<br>Chemotherapy Induced Peripheral Neuropathy | Originator:<br>PledPharma | Japan, Korea, Taiwan, HK (Initiated Phase III, pivotal study) | | | | | | |
| | | China | | | | | | |
| | | US and EU (by Originator) | | | | | | |

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

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

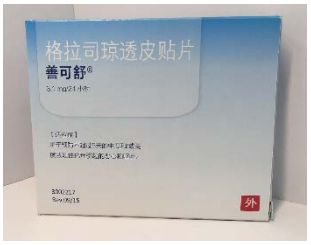
Current status

- We have rights in China (including Hong Kong and Macau), Taiwan, Malaysia and Singapore. We out-licensed rights in Hong Kong, Macau Taiwan, Malaysia and Singapore to Kyowa Hakko Kirin.
- We obtained approval from the Chinese authorities in July 2018 and are currently preparing for sales, as out lined below.

Product manufacturing

- We have completed final commercial product manufacturing for launch.

Building of distribution channels




SP-01Chinese Product Package

- We have entered into a sales agency agreement for China with Itochu Corporation (hereinafter “Itochu”) and have 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 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 Pharmaceutical (HK) Limited (hereinafter “Lee’s”).
- The Company’s direct sales partner is Itochu. We commenced initial product shipments to Itochu in 2018.

Plans

- We expect to launch in the first quarter of the fiscal year ending December 31, 2019.

## 2. SP-02 (darinaparsin): Development in Japan and other parts of Asia

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

Current status

- We have worldwide rights.
- We out-licensed rights in Japan to Meiji Seika Pharma Co., Ltd. (hereinafter “Meiji”) and rights in Latin America to HB Human BIoScience SAS.
- 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 around 90% 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, we plan to apply NDA to the relevant authorities in 2020.

Expansion of indications

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

**3. SP-03 (episil® oral liquid): Development and commercialization**

**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 for cancer)**

- We have 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 review for the New Medical Device Approval of episil® at the Center for Medical Device Evaluation (CMDE) has been completed and presented to the National Medical Products Administration (NMPA, formerly CFDA or CNDA).

SP-03 Japanese Product

Building distribution channels

- Same as SP-01, we have entered into a sales agency agreement for China with Itochu and have 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 described below in these areas.
- In other parts of China, the Company is preparing for sales on the basis of sales and other licensing agreements with Lee's.

China Plans

- We expect to obtain approval and plan to launch in 2019.

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.

South Korea Plans

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

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

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

We have rights in Japan, China (including Hong Kong and Macau), South Korea, and Taiwan.

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Current status

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

Plans

- We plan 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 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. Furthermore, we have established of an in-house sales structure with 30 medical representatives (MRs), comprising around 10 each in Beijing, Shanghai, and Guangzhou.

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)

Bases

- Solasia Medical Information Consulting (Shanghai) Co. Ltd., a wholly owned subsidiary, is taking charge of the Company's sales activities in China.
- The Company has completed the establishment of bases in Shanghai, Beijing and Guangzhou (opened in Dec. 2018).