Solasia

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To: All Concerned Parties

Company Name: Solasia Pharma K.K.
Representative: Yoshihiro Arai, President & CEO
(Code number: 4597, TSE Mothers Section)
Contact: Toshio Miyashita, CFO, Director
Tel: 81-3-5843-8049

Business Overview of Pipeline Products (First Quarter of the Fiscal Year Ending December 31, 2019)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2019. We hereby supplement this information by providing notice of the status of our major pipeline products.

Pipeline Code / Estimated initial indication	Originator	Pre-clinical	Clinical Study: Phase I	Clinical Study: Phase II	Clinical Study: Phase III	NDA	Approval	Launch	Out-licensed Partner (Region)
SP-01 **Sancuso®** Chemotherapy Induced Nausea and Vomiting	Kyowa Kirin (UK)	China (Launched in Mar. 2019)							Kyowa Hakko Kirin (TW etc.), Lee's Pharma (China*) *excl. Beijing, Shanghai and Guangzhou *own sales by Solasia in above big 3 cities Distribution partner; Itochu Corp.
		Taiwan, Singapore, HK etc. (by Kyowa Hakko Kirin)							
SP-02 **darinaparsin** 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)			
SP-03 **episil®** [Medical Device] Pain associated oral mucositis	Camurus (Sweden)	Japan (Launched in May 2018)							Meiji Seika Pharma (Japan), Lee's Pharma (China*) *excl. Beijing, Shanghai and Guangzhou *own sales by Solasia in above big 3 cities Distribution partner; Itochu Corp.
		China (Approved in Feb. 2019, Preparation for Launch)							
		Korea (NDA in Mar. 2019)							
SP-04 **PledOx®** Chemotherapy Induced Peripheral Neuropathy	PledPharma (Sweden)	Japan, Korea, TW, HK				(Initiated Phase III, pivotal study)			—
		China							

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

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

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.

Current status

- The commercial products for launch have been shipped during FY2018.
- We obtained approval from the Chinese authorities in July 2018 and launched(provided to clinical sites) in March 18, 2019.

Sancuso® Chinese Product Package

Building of distribution channels;

- We have entered into a sales agency 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 described below in these areas.
- 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 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)

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.

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 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 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)

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

- We obtained approval from the Chinese authorities in February 2019 and are currently preparing for sales.

episil® 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, Lee's is preparing for sales on the basis of sales and licensing agreements with the Company.

China Plans

- The Company's sales partner is Itochu Group. We expect to commence initial product shipments to Itochu in the 1st half of the fiscal year ending December 31, 2019. After shipment to Itochu and following Chinese customs proceedings, SP-03 will be provided to clinical sites (launch). We expect to launch in 2019.

South Korea Current status

- We have filed a New Medical Device Application to the relevant authorities in March 2019.

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

<u>Intracellular superoxide removing agent (Expected Indication: Chemotherapy-induced peripheral neuropathy)</u>

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

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. <u>Building of an in-house sales structure in China</u>

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

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, 114 companies have market capitalization of more than ¥100 billion. Of those, 82 are posting operating losses as of April 30, 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.