Solasia

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To: All Concerned Parties

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Business Overview of Pipeline Products (Fiscal Year Ended December 31, 2019)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Fiscal Year Ended 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: 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, 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)							
SP-02 **darinaparsin** Peripheral T-Cell Lymphoma	ZIOPHARM Oncology (US)	Japan, Korea, TW, HK			(Phase II, pivotal study : recruiting completion)				- 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, May 2018)							- Meiji Seika Pharma (Japan), - Lee's Pharma (China*) *excl. BJ, SH and GZ - Solasia sales force (above 3 big cities in China) - Synex (South Korea) Distribution partner; Itochu Corp.
		China (Launched, Jul. 2019)							
		Korea (Approved, Oct. 2019)							
SP-04 **PledOx®** Chemotherapy Induced Peripheral Neuropathy	PledPharma (Sweden)	Japan, Korea, TW, HK			(Initiated Phase III, pivotal study) POLAR-A : recruiting completion POLAR-M : undergoing				- Maruho (Japan)
		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. In China, the Company pursues direct sales and sales through its partner Lee's Pharmaceutical (HK) Limited ("Lee's").
- The Company out-licensed rights in Hong Kong, Taiwan etc. to Kyowa Kirin.

China - Current status

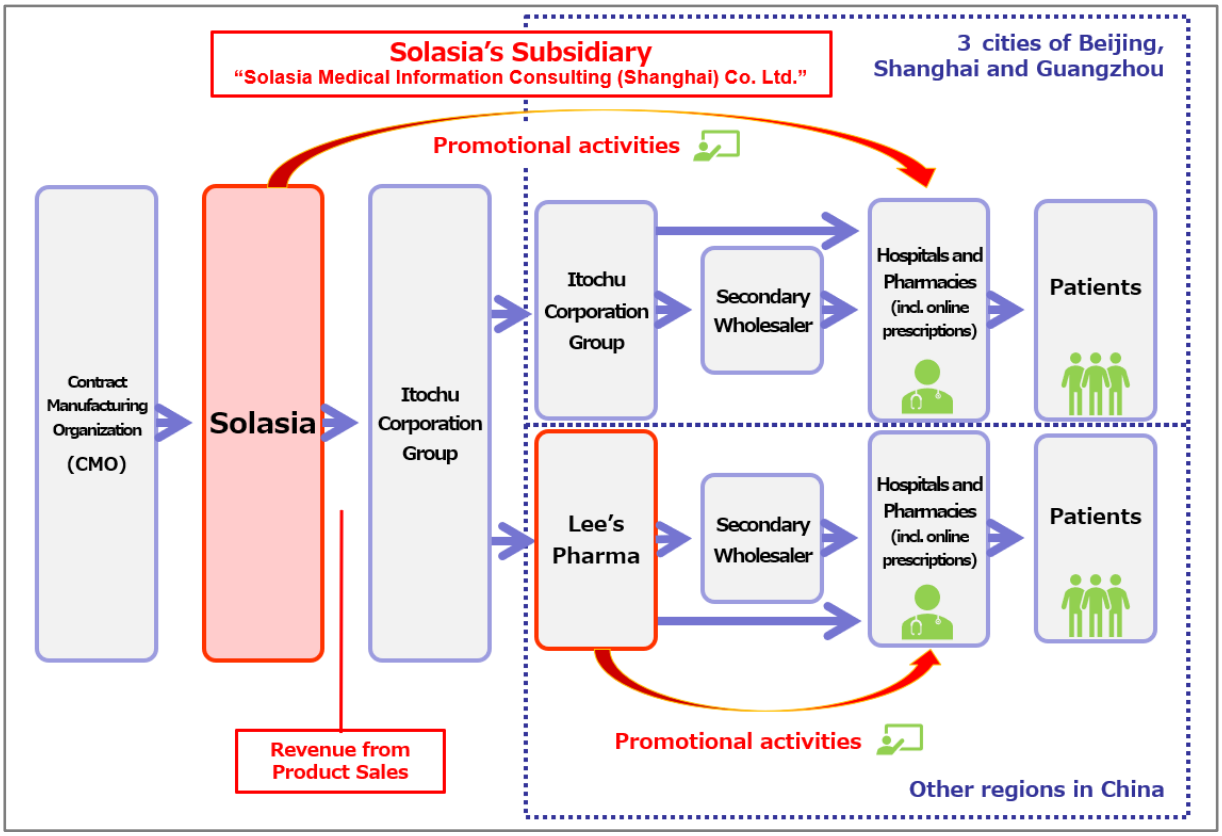
- The Company launched (provided to clinical sites) on March 18, 2019.
- The first new Guideline was published by CSCO, recommended Sancuso® as a new standard of care for CINV (Chemotherapy induced nausea and vomiting) treatment in June 2019.

Building of distribution channels;

Sancuso® Chinese Product Package

- The Company has entered into a sales distribution agreement for China with Itochu Corporation ("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 launched with the basis of sales and licensing agreements between the Company.
- The Company's direct sales partner is Itochu Group.

[Distribution of Solasia products in China]



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: Relapsed or Refractory Peripheral T-cell Lymphoma)

- The Company has worldwide rights.
- The Company out-licensed marketing and other rights in Japan to Meiji

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Seika Pharma Co., Ltd. (“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 a final study before New Drug Application (NDA). In September 2019, all patient-enrollments have been completed.

Plans

- The Company expects to announce the study results in 2020. If the results of this study are positive, the Company plans to apply NDA to the authority.

Line-Extension

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

3. SP-03 (episil® oral liquid): Commercialization in Japan, China, and South Korea

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 authority in February 2019 and has launched on July 19, 2019.

episil® Japanese Product

Building distribution channels

- Same as Sancuso®, 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 authority in March 2019, and obtained approval in October 2019.
- In January 2020, the Company entered an out-licensing agreement for the commercialization with Korean company Synex Consulting Ltd (“Synex”).

South Korea – Plans

- Synex plans to launch the product from the middle of FY2020.

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.
- In December 2019, the Company out-licensed marketing and other rights of SP-04 in Japan to Maruho Co., Ltd.

Current status

- The Company initiated the multinational phase III clinical studies (POLAR-A and POLAR-M) on colorectal cancer patients who undergo mFOLFOX6 therapy in December 2018.
- For POLAR-A study, all patient-enrollments have been completed in December 2019.

Plans

- POLAR-M study is expected to be fully enrolled in 2Q FY2020.
- The Company expects to announce the study results in 2021.

Indication Expansion

- In October 2019, the Company agreed to explore indication expansion, and entered the amendment of license agreement with the licenser, PledPharma AB ("Pled"). Currently, Pled has initiated pre-clinical studies for the target to CIPN induced by paclitaxel.

Other

- Global phase III clinical studies (POLAR-A and POLAR-M) are currently conducted in regions where Solasia holds rights (Japan, South Korea, Taiwan, and Hong Kong) and in Europe and the US. Pled is in charge of the clinical studies in Europe and the US, and Solasia retains the rights to commercialize the drugs in those regions. Concerning the POLAR-M study, the US Food and Drug Administration (FDA) issued a clinical hold in January 2020, thereby temporarily suspending patient recruitment and drug administration in the ongoing study in the US. As of today, none of the authorities in other countries have issued similar clinical holds, and the present clinical studies are proceeding according to schedule. The independent Data Safety Monitoring Board (DSMB) established for the study has determined it can continue as planned. Pled and Solasia also examined the SP-04 comprehensive safety profile and came to the same judgment.

5. Initiative toward building a drug development business that utilizes RNA editing technology

- In December 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 drugs in the field of oncology based on DNA/RNA editing technology.

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

In-house sales strategy

- Within China, the Company is conducting in-house sales and marketing activities for Sancuso® and episil® 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 Company has established an in-house sales structure with a total of 30 medical representatives (MRs), comprising around 10 each in Beijing, Shanghai, and Guangzhou. As of today, no employees of the Company or its subsidiaries have been confirmed to be infected with novel coronavirus (2019-nCoV).

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

- The Company 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, 121 companies have market capitalization of more than ¥100 billion. Of those, 87 are posting operating losses as of January 31, 2020.) 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.

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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.