Solasia

November 13, 2020

To: All Concerned Parties

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Business Overview of Pipeline Products (Third Quarter of the Fiscal Year Ending December 31, 2020)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2020. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

Pipeline Code / Target 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				(Pivotal PII study completion, preparing for NDA filing)			- Meiji Seika Pharma (Japan), - HB Human BioScience (Latin America)
		China				(PII/III, pivotal study preparation)			
		US				(PIIA, 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 (Launched, Sep. 2020)							
SP-04 **PledOx®** Chemotherapy Induced Peripheral Neuropathy	PledPharma (Sweden)	Japan, Korea, TW, HK				(Pivotal PIII study; Finished made early data cut-off in Q3/'20, preparing for statistical analysis of results			- Maruho (Japan)
		China				(Clinical study preparation)			
SP-05 **arfolitixorin** Increase efficacy of fluorouracil (5-FU)	Isofol Medical (Sweden)	Japan				(Pivotal PIII study)			

[Joint R&D 1]
Nucleic acid drug candidate for peritoneal metastases (disseminated metastases developing in the peritoneum)
: Option agreement for in-license of worldwide rights with GeneCare Research Institute Co., Ltd.

[Joint R&D 2]
New drug candidates for rare disease and/or oncology based on RNA editing technology utilizing pentatricopeptide repeat (PPR) protein platform technology
: Joint R&D agreement with EditForce Inc.

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

Granisetron transdermal delivery system (Indication: Chemotherapy-induced

nausea and vomiting)

- The Company holds 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

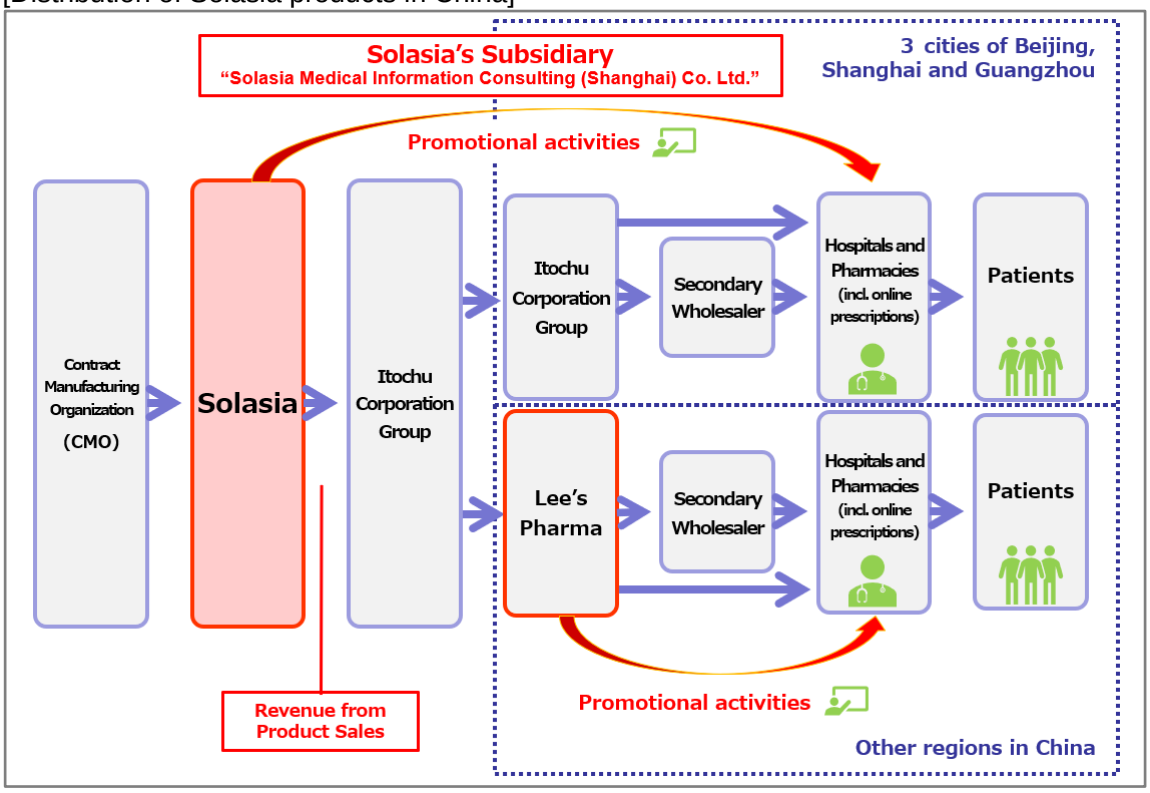
- The Company launched (provided to clinical sites) in March 2019.
- The shipments of Sancuso®, initially scheduled for September 2020, has been delayed to November 2020 due to circumstances on the contract manufacturer's side. This change, is not expected to affect the full-year earnings forecast announced in February.
- 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.

Sancuso® Chinese Product Package

Building of distribution channels;

- 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]



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

Mitochondria-targeted apoptosis inducer (Target Indication: Relapsed or Refractory Peripheral T-cell Lymphoma)

- The Company holds worldwide rights.
- The Company out-licensed marketing and other rights in Japan to Meiji Seika Pharma Co., Ltd. ("Meiji") and rights in Latin America to HB Human BioScience SAS.

Current status

- This product has achieved the primary endpoint (antitumor effect) in the Asian multinational phase II clinical study on patients with relapsed or refractory peripheral T-cell lymphoma in Japan, South Korea, Taiwan, and Hong Kong.

Plans

- The Company is preparing for the NDA Filing.

Line-Extension

- Currently, the Company is conducting non-clinical studies on other hematologic cancers (ATL: Adult T-cell Leukemia, AML: Acute Myeloid Leukemia).

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 holds rights in Japan, China (including Hong Kong and Macau), and South Korea.

Japan - Current status

- Meiji launched 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 launched in July 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 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 obtained approval by the South Korean authorities in October 2019. In September 2020, episil® was launched by its commercialization and promotion partner, Synex Consulting Ltd.

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

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

- The Company holds 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 PledOx® 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.
- Based on a recommendation from the independent Drug Safety Monitoring Board (DSMB) to stop the studies due to a number of severe allergic reactions, the Company decided to suspend both new patient enrollment and study drug administration in April 2020 and to bring this study to its conclusion after making an early cut-off of case data collection (data cut-off) in Q3 FY2020.
- The number of subjects enrolled in the studies have been 590 cases compared to the initially planned 700 cases.
- As of today, the study has been finished, meeting the early data cut-off, and the Company is preparing for statistical analysis of the results.

Plans

- The Company plans to disclose the top line results of its statistical analysis by the end of FY2020. After that, the Company will conduct detailed and robust evaluations of the safety and effectiveness of PledOx® focusing on information acquired through the completion of the above studies.

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 is conducting pre-clinical studies for the target to CIPN induced by paclitaxel.

5. SP-05 (arfolitixorin): Development in Japan

Increase in antitumor efficacy, folic acid compound (Target Indication: Increase in antitumor efficacy of fluorouracil

- The Company holds development and commercialization rights in Japan.

Current status

- In August 2020, the Company obtained the development and

commercialization rights for arfolitixorin in Japan from Isofol Medical AB ("Isofol").

- In December 2018, Isofol initiated a Global Phase III clinical study (AGENT study) in patients with advanced colorectal cancer in Japan, North America (US, Canada), Europe, and Australia. After obtaining rights for arfolitixorin, Solasia took over the AGENT study in Japan.
- In July 2020, Isofol enrolled 330 cases, which is the number of registered patients required for the interim analysis of this study.

Plans

- The Company plans to disclose the results of its interim analysis by the end of Q1 FY2021.
- Based on its results, the Company will set the final target number of cases (n=440 to 660) for the AGENT study.

6. 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 RNA editing technology.

7. Obtained exclusive option rights to in-license a nucleic acid drug candidate for peritoneal metastases

- In July 2020, the Company entered an agreement with GeneCare Research Institute Co., Ltd. for exclusive negotiating rights (option rights) to in-license their nucleic acid drug candidate RECQL1-siRNA and related technologies. Based on development progress of the drug candidate from the non-clinical study stage onward, the Company will decide whether to exercise the option rights to in-license the drug candidate.

8. 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 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.

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 established the bases in Shanghai, Beijing and Guangzhou.

9. Impact of the COVID-19 pandemic on the Company's business activities and efforts to prevent the spread of infection

- As of today, no executives or employees at the Company or its subsidiary in China have been found to be infected by COVID-19.

Japanese business

- The Company adopted a telework system for all employees of the Tokyo office as of today.

Chinese business

- All employees of our Chinese subsidiary began working at home this February. Since mid-March, however, operations have returned to normal, with employees returning to the workplace.
- MRs' sales activities, such as making visits to medical settings, were severely curtailed. However, as of the current date some activities - making visits to hospitals and contacting medical personnel - in the cities where the Company is conducting sales in-house are recovering.

Product supply

- The Company's products are manufactured in Europe and the United States. At present, provision almost continues uninterrupted.

Clinical development

- The spreading pandemic is having a limited impact on clinical development activities. To ensure the safety of subjects and lessen the burden on the medical systems, visits to medical institutions by subjects and employees handling clinical studies have been curtailed to some extent, and we are utilizing telephone and online methods of communication instead.

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, 119 companies have market capitalization of more than ¥100 billion. Of those, 85 are posting operating losses as of October 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.

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.