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
Tel: 81-3-5843-8049

Business Overview of Pipeline Products
(Fourth Quarter of the Fiscal Year Ended December 31, 2020)

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

1. Overview of the fourth quarter of the fiscal year ended December 31, 2020

- SP-01: Sales activities were affected by the COVID-19 pandemic. However, business structure remains unchanged.
- SP-02: In June 2020, the Company achieved the primary endpoint (antitumor effect) in the Global Phase II clinical trial (pivotal study), is preparing to submit for NDA filing to the regulatory authorities. Activities aimed at out-licensing SP-02 in the US, Europe, China, and other regions were hampered by the COVID-19 pandemic, as the pandemic restrained negotiations and discussions with prospective licensees. As a result, the Company has yet to conclude an out-licensing agreement for SP-02.
- SP-03: Sales activities were affected by the COVID-19 pandemic. However, business structure remains unchanged.
- SP-04: In December 2020, the Company confirmed that the primary endpoint of the Global Phase III clinical trial, had not been achieved.
- SP-05: The Company acquired exclusive rights to develop and market the product in Japan in August 2020. A Global Phase III clinical trial (pivotal study) of the pipeline product is currently underway. The number of patients enrolled in the study reached 440 in December 2020.

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) Taiwan, HK etc. (by Kyowa Kirin)							- 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.
SP-02 **darinaparsin** Peripheral T-Cell Lymphoma	ZIOPHARM Oncology (US)	Japan, Korea, TW, HK China US EU			(PII/III, pivotal study preparation) (PIIA, completion) (Pre-clinical, completion)	(Pivotal PII study completion, preparing for NDA filing)			- Meiji Seika Pharma (Japan), - HB Human BioScience (Latin America)
SP-03 **episil®** [Medical Device] Pain associated oral mucositis	Camurus (Sweden)	Japan (Launched, May 2018) China (Launched, Jul. 2019) Korea (Launched, Sep. 2020)							- 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.
SP-04 **PledOx®** Chemotherapy Induced Peripheral Neuropathy	Egetis Therapeutics (Sweden)	Japan, Korea, TW, HK				(Closed Pivotal PIII study, under analysis of secondary endpoints)			- Maruho (Japan)
SP-05 **arfolitixorin** Increase efficacy of fluorouracil (5-FU)	Isofol Medical (Sweden)	Japan				(Pivotal PIII study)			

2. SP-01 (Sancuso®): 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

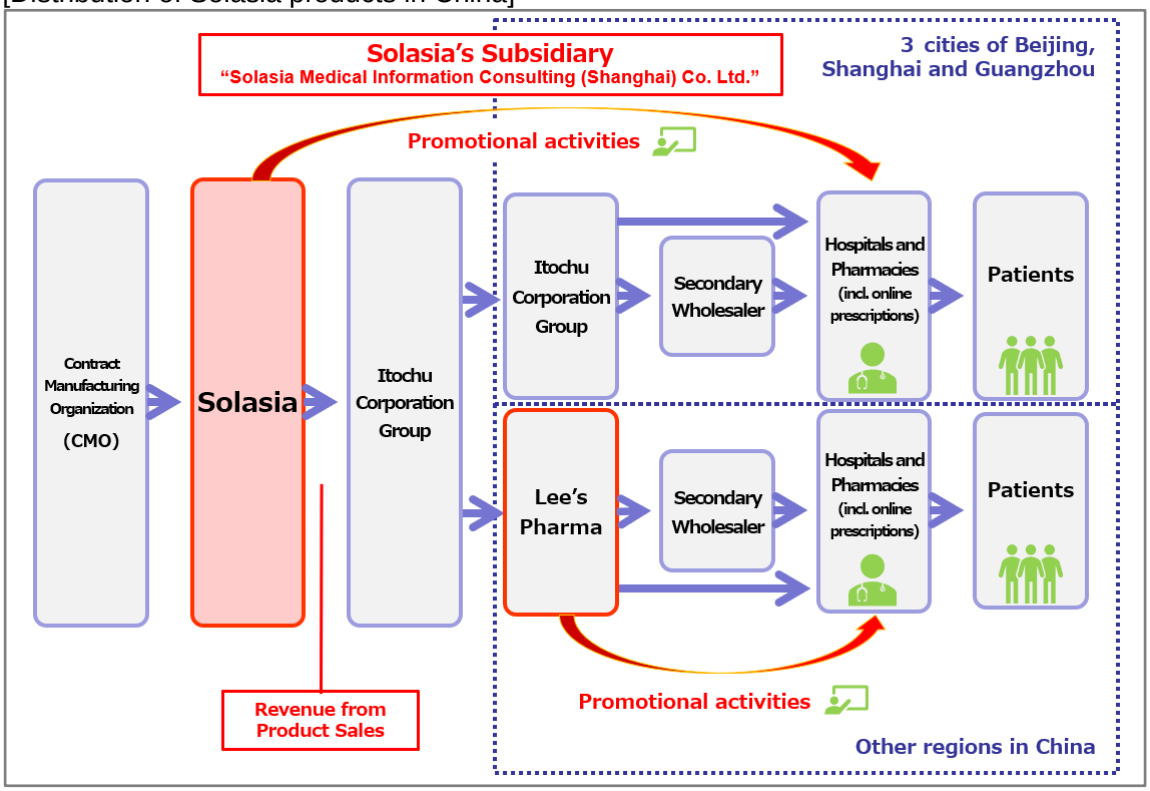
- The Company launched (provided to clinical sites) in March 2019.
- The first new Guideline was published by CSCO, recommended Sancuso® as a new standard of care for CINV (Chemotherapy induced nausea and vomiting) treatment in June 2019.

Sancuso® Chinese Product Package

Building of distribution channels in China;

- 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]



3. SP-02 (darinaparsin): 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 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, plans to submit in 1H FY2021.

Line-Extension

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

4. SP-03 (episil® oral liquid): 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 in May 2018, based on a license and collaboration agreement for episil®.

China - Current status

- The Company launched in July 2019.

South Korea - Current status

- Synex Consulting Ltd. Launched in September 2020, based on a license and collaboration agreement for episil®.

episil® Japanese Product

Building of distribution channels in China;

- 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.

5. SP-04 (PledOx®): 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.
- The Company out-licensed marketing and other rights of PledOx® in Japan to Maruho Co., Ltd.

Current status

- In December 2020, the Company confirmed that the primary endpoint of the Global Phase III clinical trial, conducted in Japan, South Korea, Taiwan and Hong Kong, in addition to the US and EU, had not been achieved.

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Plans
- The Company will further evaluate the results of the above-mentioned trial, including secondary endpoints, and discuss and consider our future development strategy.

6. SP-05 (arfolitixorin): Increase in antitumor efficacy, folic acid compound (Target Indication: Increase in antitumor efficacy of fluorouracil

- The Company holds development and commercialization rights in Japan.

US&EU - Current status

- In December 2018, Isofol Medical AB ("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. It is designed to be conducted in 440 to 660 patients.
- In July 2020, Isofol enrolled 330 cases, which is the number of registered patients required for the interim analysis of this study. Furthermore, the number of patients enrolled in the study reached 440 in December 2020.

Japan - Current status

- In August 2020, the Company obtained the development and commercialization rights for arfolitixorin in Japan from Isofol Medical AB ("Isofol").
- After obtaining rights for arfolitixorin, the Company took over the AGENT study in Japan.

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.

7. New Drug Candidates:

Drug discovery business 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 gene therapy drugs in the field of oncology based on RNA editing technology.

Nucleic acid drug candidate for peritoneal metastases

- In July 2020, the Company entered an agreement with GeneCare Research Institute Co., Ltd ("GC"). for exclusive negotiating rights (option rights) to in-license their nucleic acid drug candidate RECQL1-siRNA and related technologies. GC discovered RECQL1-siRNA and related technologies based on technologies in-licensed from US company Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), a world leader in RNA interference (RNAi) 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.

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8. 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 40 medical representatives (MRs) 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

Japanese business

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

Chinese business

- The COVID-19 pandemic significantly restrained marketing activities of the Group's and sales partners' medical representatives (MRs), including their access to medical sites. This in turn had an impact on the prescription and delivery volumes of the products. Hospital visits and contacts with healthcare providers by the MRs began to recover in 2H FY2020. However, as of today, the situation remains largely unpredictable in these regions due to signs of resurgence in COVID-19 cases; for instance, the local government ordered the closure of outpatient clinics at cancer hospitals in response to the resurgence.

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 online methods of communication instead.

Business alliances

- Restrictions on overseas travel are impeding discussions with potential alliance partners necessary for negotiations on in- and out-licensing. The Company is instead using online alternatives and working through local distributors.

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, 169 companies have market capitalization of more than ¥100 billion. Of those, 135 are posting operating losses as of January 31, 2021.) 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.