Solasia

Nov 14, 2022

To: All Concerned Parties

Company Name: Solasia Pharma K.K.
Representative: Yoshihiro Arai, President & CEO
(Code number: 4597, TSE Growth)
Contact: Toshio Miyashita, CFO
Tel: 81-3-5843-8046
URL: https://solasia.co.jp/en/

Business Overview of Pipeline Products
(Third Quarter of the Fiscal Year Ending December 31, 2022)

Solasia Pharma K.K. (hereinafter "the Company") today announced its Consolidated Financial Results for the Nine months of the Fiscal Year Ending December 31, 2022. The Company hereby supplements this information by providing notice of the status of its major pipeline products.

【Commercial Products】

Product (Development code)	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
Sancuso® (SP-01)	Chemotherapy induced nausea and vomiting (CINV)	China							Launched in 2019 Preparing to apply for change of manufacturing facility	Lee's Pharm
DARVIAS® (SP-02)	Peripheral T-cell lymphoma (PTCL)	Japan							Launched in August 2022 Began searching for additional indications	Nippon Kayaku (Japan) HB Human BioScience (South America)
		South Korea, Taiwan, Hong Kong							Phase II (pivotal) study completed Out-licensing activities ongoing	
		South America							Preparations to file for approval underway in each country based on approval granted in Japan	
		China							Development strategy being drafted based on US study data and approval in Japan; out-licensing activity ongoing	
		US							Early Phase II study completed; out-licensing activity ongoing	
		Europe							NPP strategy being evaluated based on approval in Japan	
episil® oral liquid (SP-03)	Pain associated oral mucositis (medical device)	Japan							Launched in 2018	Meiji Seika Pharma
		China							Launched in 2019	Lee's Pharm
		South Korea							Launched in 2020	Synex

Note: For the development stage of DARVIAS® in South America, China, the US, and Europe, clinical studies conducted primarily in the US or approval granted in Japan is shown as sharable data.

【Pipelines Under Development】

Pipeline Code	Indication	Area	Pre-clinical	Clinical study PI	Clinical study PII	Clinical study PIII	NDA	Approval / Launch	Progress	Partner
SP-04	Chemotherapy induced peripheral neuropathy (CIPN)	Japan, etc.							Pre-clinical study in taxane-induced peripheral neuropathy ongoing* *PIII study of oxaliplatin-induced peripheral neuropathy completed; results not achieved	Maruho (Japan)
SP-05	Colorectal cancer	Japan							Subgroup analysis of global Phase III study underway	–

Solasia

1. **Commercial Products:**

➢ **Sancuso® (SP-01): Granisetron transdermal delivery system (Indication: Chemotherapy-induced nausea and vomiting)**

- The Company holds rights in China, etc. In China, the Company pursues sales through its partner Lee's Pharmaceutical (HK) Limited ("Lee's").

China - Current status

- The Company launched in March 2019.
- The Company dissolved its own sales structure covering Beijing, Shanghai, and Guangzhou, China (hereafter the "three cities") as of July 31, 2022, and on August 1 of the same year, transferred its sales functions to sales partner Lee's Pharmaceutical.
- The Company previously disclosed product shipment volumes in the three cities covered by its own sales force, but after the transfer of sales functions to Lee's Pharmaceutical, it no longer discloses the metric, starting third quarter of the fiscal year under review.

➢ **DARVIAS® Injection 135mg (development code: SP-02, generic name: darinaparsin): organic arsenic compound (indication: peripheral T-cell lymphoma)**

- The Company holds worldwide rights.

Japan - Current status

- The Company out-licensed for marketing and other rights in Japan to Nippon Kayaku, and the company will conduct sales activities in the future.
- On June 20, 2022, the Company obtained marketing approval from the Ministry of Health, Labour and Welfare for DARVIAS ® Injection 135mg for the treatment of relapsed or refractory peripheral T-cell lymphoma. The Company expects sales to begin in August 2022.

Other - Current status

- The Company out-licensed marketing rights to DARVIAS® in South America to HB Human BioScience SAS, which, after the drug was approved in Japan, began preparing to apply for regulatory approval in the region. The commercialization of the product in regions other than Japan and South America will be pursued through the establishment of a sales partner. Further, the Company, as a marketing rights holder, plans to use the Named Patient Program (NPP) to provide DARVIAS® on an individual basis to physicians wishing to use the drug in regions where the drug has yet to obtain approval or be assigned a reimbursement price, namely in India and European countries, provided these physicians have completed necessary procedures to obtain the drug.

Line-Extension

- Currently, the Company is conducting non-clinical studies targeting hematologic cancers other than peripheral T-cell lymphoma with an eye to expanding the drug's indications.

➢ **episil® oral liquid (SP-03): 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)**

- On July 8, 2022, the Company obtained worldwide rights, including manufacturing rights, to episil ® oral liquid from Camurus AB. The Company will continue supplying the product in Japan, China, and Korea.

The business transfer from Camurus AB, primarily manufacturing and regulatory procedures for the product, is expected to be completed by May 2024, and Solasia plans to make a decision regarding development of the business in other regions by then.

Japan - Current status

- Meiji Seika Pharma Co., Ltd. launched in May 2018, based on a license and collaboration agreement for episil®.

China - Current status

- Sales of episil ® oral liquid began in July 2019. The Company dissolved its own sales structure covering Beijing, Shanghai, and Guangzhou, China, as of July 31, 2022, and on August 1 of the same year transferred its sales functions to sales partner Lee's Pharm. Currently, Lee's Pharm is conducting sales activities for the product throughout China.
- The Company previously disclosed product shipment volumes in the three cities covered by its own sales force, but after the transfer of sales functions to Lee's Pharmaceutical, it no longer discloses the metric, starting third quarter of the fiscal year under review.

South Korea - Current status

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

2. Pipelines Under Clinical Development:

➢ **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

- The Company halted the development of SP-04 as a treatment for peripheral neuropathy cased by multidrug chemotherapy containing oxaliplatin, based on the results of the global Phase III study of the drug for the said indication. It is currently conducting animal studies in collaboration with licensor Egetis Therapeutics (formerly PledPharma) to investigate the possibility of developing the drug for the treatment of taxane-induced peripheral neuropathy. Results of animal studies conducted thus far suggest potential efficacy of the drug in suppressing the onset of peripheral neuropathy, but the effect was not clearly demonstrated enough. Going forward, the Company plans to conduct new animal studies with an eye to resuming clinical development of SP-04.

➢ **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.

Current status

- Global Phase III clinical trials in patients with advanced colorectal cancer were conducted in Japan, the US, Canada, Europe, and Australia. On August 4, 2022, the Company released preliminary results of the study, indicating that no statistically significant difference was found in the

outcomes of patients between the arfolitixorin group (5-FU + oxaliplatin + bevacizumab therapy in combination with SP-05 [arfolitixorin]) and the control group receiving standard treatment (5-FU + oxaliplatin +bevacizumab therapy in combination with leucovorin), in terms of overall response rate (ORR), the primary endpoint, and progression-free survival (PFS), one of the secondary endpoints of the study.

- The Company plans to continue with an updated analysis of the secondary point of PFS, subgroup analysis for criteria including specific gene expression, and safety information analysis for the global Phase III clinical trials, and announce the results in the fourth quarter of the fiscal year under review. The Company will determine the future direction of the development for SP-05 based on the results of these analyses and the discussion with licensor Isofol Medical AB.

3. New Drug Candidates:

➢ Drug discovery business utilizes RNA editing technology

- In 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.
- The Company has selected a potential target disease and gene mutations causing the disease, and is preparing and examining various conditions necessary to confirm the efficacy of the pentatricopeptide repeat (PPR) candidate discovered using the RNA editing technology of EditForce.

➢ Nucleic acid drug candidate for peritoneal metastases

- In 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.
- Currently, the Company is examining various conditions necessary for the expression of the effects of new, potentially more effective siRNA sequences discovered in collaboration with Ui-Tei Laboratory of the Graduate School of Science, the University of Tokyo, with a view to product development.

4. Organizational structure and capital relationship:

Dissolution of the China Vending Structure

- Solasia began operating its own sales structure in the three cities in China in 2019. Shipment volumes of Sancuso ® to hospitals and pharmacies in the three cities expanded from 10,000 units in FY2019 to 15,000 units in FY2020 and 30,000 units in FY2021 supported by the Company's sales activities, and shipment volumes of episil ® were also on a growth trajectory. However, prolonged impacts of the COVID-19 pandemic and the lockdown of Shanghai and other regions since Mach 2022 have depressed sales volumes, which together with other factors, resulted in the sales volumes lagging the necessary amount to reach the breakeven point. Further, maintaining the Company's own sales structure requires about 1 billion yen each year, primarily for marketing activities and personnel expenses. As a

result, profitability of China operations continued to suffer, and costs for maintaining the sales structure had become a key factor behind the Group's losses.

- In light of these factors, the Company dissolved its own sales organization in China as of July 31, 2022, curtailing personnel expenses for sales staff and suspending expenditures on marketing activities. As a result, the number of employees on a consolidated basis fell from 77 at the end of March 2022 to 27, and the Company anticipates this to contribute to cost reductions of approximately 1 billion yen for the full year.

Capital and business alliance with Nippon Kayaku

- On June 28, 2022, Solasia entered into a capital and business alliance agreement with Nippon Kayaku Co., Ltd., a pharmaceutical company with an extensive track record and sales experience in the oncology field. Based on the terms of the agreement, on July 14, the Company issued 12,000,000 shares of its common stock to Nippon Kayaku and raised funds of 1.02 billion yen. As a result of the share issue, Nippon Kayaku became the second largest shareholder of Solasia with a 7.7% stake in the Company.
- Based on the terms of the alliance agreement, the Company granted Nippon Kayaku the preferential negotiating rights to in-license the Company's pipeline products, as well as the preferential negotiating rights for the manufacture of the Company's commercialized and pipeline products.

5. 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

- Sales activities of the Group's and sales partners' medical representatives, including their visits to medical institutions, were restrained due to the spread of COVID-19, negatively affecting the prescription and shipment volumes of the Company's products.
- Throughout the second quarter of the fiscal year under review, about 80%of medical institutions that were the main targets for the Company's sales activities were closed in Shanghai due to the lockdown of the city since March 2022. This resulted in a substantial drop in treatment opportunities for cancer patients, the main targets of the Company's products, subsequently depressing the prescription volume of these products.

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

- Overseas travel resumed, and the Company is proceeding with negotiations with licensing partner candidates.

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, 151 companies have market capitalization of more than ¥100 billion. Of those, 100 are posting operating losses as of November 08, 2022.) We believe that this situation exists because the marketplaces 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 our business information on this report.