Solasia

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To: All Concerned Parties

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Solasia Announces Revision to Full-Year Earnings Forecast

Solasia Pharma K.K. today announced that in light of recent earnings trends, it revised its full-year earnings forecast for the fiscal year ending December 31, 2021 (January 1 – December 31, 2021) released on February 10, 2021, at a board of directors' meeting held on the same day.

1. Revision to consolidated earnings forecasts for the fiscal year ending December 31, 2021 (January 1 – December 31, 2021)

(Unit: Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit attributable to owners of parent	Basic earnings per share (Yen)
Previous forecast (A)	1,600 ～2,600	(2,800) ～(1,800)	(2,800) ～(1,800)	(2,800) ～(1,800)	(22.83) ～(14.68)
Revised forecast (B)	600	(2,500)	(2,500)	(2,500)	(18.73)
Difference (B – A)	(1,000) ～(2,000)	300 ～(700)	300 ～(700)	300 ～(700)	—
Difference (%)	(62.5) ～(76.9)	—	—	—	—
Reference: Fiscal year ended December 31, 2020	454	(4,116)	(4,159)	(4,127)	(35.16)

2. Reasons for revision

[Revenue]

In the earnings forecast announced on February 10, 2021, Solasia forecast revenue to be in the range of 1,600–2,600 million yen. Of this range, 500 million yen were expected to come from the sale of Sancuso® (SP-01) and episil® (SP-03), factoring in a certain degree of impact from the COVID-19 pandemic. Remaining 1,100–2,100 million yen were anticipated upfront payments from out-licensing pipeline products SP-02 and/or SP-05.

As of the date of this release, the revenue forecast has been revised down to 600 million yen, comprising revenue from sales of Sancuso® (SP-01) and episil® (SP-03) and upfront payments for out-licensing domestic marketing rights to pipeline product SP-02.

In October 2021, Sancuso® (SP-01) was listed on GPO (Group purchasing organizations) system in Guangzhou, China, where Solasia has its own sales infrastructure. With this, Sancuso® is expected to be included in the procurement lists of hospitals located in the city and prescribed to patients. In May 2021, episil® (SP-03) was recommended in the guidelines for oral mucositis caused by anticancer therapy by the Chinese Society of Clinical Oncology. Solasia expects these developments to serve as important stepping stones for expanding sales of Sancuso® and episil® in China in the medium to long term. Meanwhile, even as of the date of this release, marketing activities of the Company's medical representatives are being restrained by the temporary closure of medical institutions in China in the wake of the pandemic. As such, the impact of the pandemic on the Company's product sales is more prolonged than initially expected.

Solasia submitted an application for approval of SP-02 to the Ministry of Health, Labour and Welfare in June 2021, and expects to obtain approval and begin sales in FY2022. For SP-05, the Company obtained interim analysis results of the Phase III clinical trial in March 2021, and plans to disclose the topline data from the trial in the first half of 2022. The previous revenue forecast assumed upfront payments from out-licensing marketing rights to these pipeline products in the final stage of development (in Europe, the US, and China for SP-02; in Japan for SP-05), and as of the date of this release, Solasia is continuing to negotiate the terms of agreements with candidate licensees. Candidate licensees of SP-02 are likely to agree to the terms of the agreement if SP-02 has already been approved in Japan; and likewise for SP-05, candidate licensees would be more willing to sign the agreement after they have confirmed the topline data from the Phase III clinical trial. Hence, with the aim of maximizing the financial benefits of out-licensing these pipeline products, Solasia revised the expected timing of concluding out-licensing agreements and receiving upfront payments from by the end of FY2021 to by the end of FY2022.

[Expenses]
In the earnings forecast announced on February 10, 2021, operating expenses were budgeted at 4,400 million yen. Solasia revised this to 3,100 million yen, taking into account its efforts to restrain some investments in development pipeline and operational expenses in light of the status of product sales, out-licensing activities, and clinical development, as well as the impact of COVID-19 pandemic.

[Loss]
Solasia revised its projections for operating loss, loss before tax, and loss attributable to owners of the parent from 1,800–2,800 million yen (as announced on February 10, 2021) to 2,500 million yen.