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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, 2022 (January 1 – December 31, 2022) released on February 9, 2022, at a board of directors' meeting held on the same day.

1. Revision to consolidated earnings forecasts for the fiscal year ending December 31, 2022 (January 1 – December 31, 2022)

(Unit: Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit attributable to owners of parent	Basic earnings per share (Yen)
Previous forecast (A)	2,300 –3,800	(1,100) –150	(1,100) –150	(1,200) –50	(8.99) –0.37
Revised forecast (B)	1,150	(2,150)	(2,175)	(2,250)	(13.41)
Difference (B – A)	(1,150) – (2,650)	(1,050) – (2,300)	(1,075) – (2,325)	(1,050) – (2,300)	—
Difference (%)	(50.0) – (69.7)	—	—	—	—
Reference: Fiscal year ended December 31, 2021	559	(2,419)	(2,442)	(2,478)	(19.04)

2. Reasons for revision

[Revenue]

In the earnings forecast announced on February 9, 2022, Solasia forecast revenue to be in the range of 2,300–3,800 million yen. Of this range, 1,100 million yen was expected to come from sales of Sancuso® (SP-01), DARVIAS® (SP-02), and episil® (SP-03). The remaining 1,200–2,700 million yen comprised anticipated upfront payments from out-licensing DARVIAS® (SP-02) and/or the pipeline product SP-05.

As of the date of this release, the revenue forecast has been revised down to 1,150 million yen, comprising revenue from sales of Sancuso® (SP-01), DARVIAS® (SP-02) and episil® (SP-03).

Solasia commenced Japanese sales of DARVIAS® (SP-02) in August 2022, after obtaining marketing approval from the Ministry of Health, Labour and Welfare in June. The company has global rights to SP-02, which already has been out-licensed to Nippon Kayaku in Japan and HB Human BioScience in South America, and in FY2022 Solasia has kept up efforts to commercialize the drug by out-licensing the rights for Europe, the U.S., and China. Out-licensing activity in China commenced in earnest after the August 2022 start of sales in Japan, but although a degree of progress has been made including a discussion of financial terms, negotiations have not advanced to the point that an agreement is certain to be signed by the end of FY2022. In the U.S., some years already have passed since the launch of several other drugs with the same indication as DARVIAS® (SP-02), for use in relapsed or refractory peripheral T-cell lymphoma, and the regulatory agency may well require data from clinical studies comparing DARVIAS® (SP-02) with these competitors. In Europe, since approval filing must be supported by data from

comparative studies, there is no track record of approval and launch for competing drugs, and licensing activity for DARVIAS® (SP-02) is also proving difficult. With a view to making DARVIAS® (SP-02) available to patients as soon as possible against this circumstance, Solasia now is laying the groundwork for commercialization in 2023 by first performing all the procedures required by regulators in each European market, and then using the Named Patient Program (NPP) to provide access to DARVIAS® on an individual basis to physicians wishing to use the drug. Based on the above, Solasia now expects the out-licensing and monetization of DARVIAS® (SP-02) to take place in FY2023, rather than FY2022 as originally planned.

The Company had expected to out-license and monetize the pipeline product SP-05 during FY2022, premised on favorable results from a global Phase III study. In August 2022, Solasia announced that this study results neither the primary endpoint of Overall Response Rate (ORR) nor the key secondary endpoint in Progression Free Survival (PFS) achieved statistical significance. Prospects for commercialization and out-licensing of SP-05 now hinge on the updated analysis of PFS and subgroup analysis for criteria including specific gene expression, which are currently underway. As results from these additional analyses are scheduled to be announced during the fourth quarter of FY2022 and remain unavailable as of the date of this release, it likely will prove difficult to use the results to support an out-licensing deal during FY2022. While favorable data from subgroup analysis would pave the way to out-license rights in FY2023 onward, Solasia no longer assumes monetization from out-licensing rights to SP-05 during FY2022.

[Expenses]

In the earnings forecast announced on February 9, 2022, operating expenses were budgeted at 3,400-3,650 million yen. In July 2022, the Company dissolved its in-house sales structure in China with a view to saving approximately 1,000 million yen in HR and marketing expenses, bringing the number of consolidated employees down from 77 to 27. Since the first quarter of FY2022, Solasia has persisted with efforts to reduce costs, by such means as curtailing some investment in pipeline products and lowering remuneration for all directors and auditors (including outside officers). On the other hand, Solasia expects to incur approximately 320 million yen in one-time costs in the process of dissolving the in-house sales structure in China, and there have been other previously unforeseen costs including those for the episil® (SP-03) rights acquisition announced in July 2022. As a consequence, the Company now forecasts full-year operating expenses of 3,300 million yen, including 480 million yen in amortization of intangible assets resulting from the capitalization of past expenditure on development.

[Loss]

In its previous earnings forecast for FY2022 (announced on February 9, 2022), Solasia had projected operating profit (loss) and profit (loss) before tax in the range of 1,100 million yen loss to 150 million yen profit, and profit (loss) attributable to owners of the parent in the range of 1,200 million yen loss to 50 million yen profit. The Company has revised these projections and forecasts operating loss of 2,150 million yen, loss before tax of 2,175 million yen, and loss attributable to owners of the parent of 2,250 million yen.