Solasia

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To: All Concerned Parties

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## Solasia Announces Notice of Status of Progress in Out-licensing SP-02 (DARVIAS®) in China and Revision of Full-year Earnings Forecast

Solasia Pharma K.K. (the "Company") had been negotiating the out-licensing of SP-02 in China with a major local pharmaceutical company with the goal of reaching an agreement by the end of FY2023, but it became clear that doing so by the end of the year would be difficult. At a Board of Directors' meeting held today, the Company, in light of the status of out-licensing negotiations and recent earnings performance, decided to revise the earnings forecast for the fiscal year ending December 31, 2023 (January 1, 2023–December 31, 2023), released on February 14, 2023, as below.

1. Status of progress in out-licensing SP-02 in China

The Company has the global rights to SP-02. SP-02 was launched in Japan in August 2022, and taking advantage of the drug's domestic launch, the Company has been working diligently to out-license the drug in China. At the beginning of the fiscal year, we narrowed the potential licensee candidates to 10 companies, including several major Chinese pharmaceutical companies, and since the middle of the fiscal year, had been engaged in an exclusive negotiation with one of the major pharmaceutical companies toward reaching an agreement. We strove to conclude an out-licensing agreement by the end of FY2023, but as the negotiation of terms and conditions became more complex and the negotiation dragged on, the expected degree of contribution from successfully reaching a deal on our corporate value diminished. As a result, we determined that re-initiating negotiations, including with other companies, will lead to enhancing the product value of SP-02 and our corporate value, and decided to forgo the plan to conclude an agreement by the end of the fiscal year. We will continue negotiating with the abovementioned major Chinese pharmaceutical company, but considering that we will resume and advance negotiations with other candidates as well, we now aim to conclude an out-licensing agreement for SP-02 in China in the first quarter of FY2024.

2. Revision to consolidated earnings forecasts for the fiscal year ending December 31, 2023 (January 1 – December 31, 2023)

(Unit: Millions of yen)

| | Revenue | Operating profit | Profit before tax | Profit attributable to owners of parent | Basic earnings per share (Yen) |
|---|---|---|---|---|---|
| Previous forecast (A) | 1,000 ～1,800 | (1,150) ～(350) | (1,150) ～(350) | (1,150) ～(350) | (6.85) ～(2.08) |
| Revised forecast (B) | 620 | (1,150) | (1,150) | (1,150) | (6.62) |
| Difference (B – A) | (380) ～(1,180) | — ～(800) | — ～(800) | — ～(800) | — |
| Difference (%) | (38.0) ～(65.6) | — | — | — | — |
| Reference: Fiscal year ended December 31, 2022 | 1,092 | (2,470) | (2,492) | (2,548) | (16.77) |

3. Reasons for change

[Revenue]
In the full-year earnings forecast released on February 14, 2023, the Company provided a revenue forecast in a range, projecting revenue of 1,000 million yen–1,800 million yen. This forecast included projected product sales revenue from the sale of Sancuso® (SP-01), DARVIAS® (SP-02), and episil® (SP-03), and estimated upfront payments resulting from the conclusion of out-licensing agreements.
As of today, the Company expects revenue of 620 million yen for the fiscal year under review, consisting of revenue from sales of Sancuso®, DARVIAS®, and episil®. Product sales revenue is expected to be substantially lower than initial projections, due to the restricted shipment of Sancuso® and episil® from the middle of the fiscal year resulting from the relocation of the manufacturing facility in a bid to lower costs and difficulty carrying out normal sales activities amid anti-corruption campaigns in China. In addition, sales of DARVIAS® fell significantly short of expectations due to a delay in the launch of the drug in overseas markets under the Named Patient Program (NPP). Further, as stated above, it became clear that the Company will not be receiving any upfront payment from the out-licensing of DARVIAS®. As a result, the Company revised the earnings forecast as above.

[Expenses]
In the earnings forecast released on February 14, 2023, the Company projected full-year operating expenses of 2,150 million yen. However, owing to the ongoing implementation of cost reduction measures first launched in FY2022 from the first quarter of the current fiscal year, the Company has revised down the full-year forecast for operating expenses, including cost of sales, to 1,770 million yen. Note that of this amount, 450 million yen is for depreciation for the past development expenditures capitalized as intangible assets.

[Profit/loss]
In the earnings forecast released on February 14, 2023, the Company projected an operating loss, a loss before tax, and a loss attributable to owners of parent of 1,150 million yen–350 million yen, but revised the projection for each loss item to 1,150 million yen.