



## Statement

### Takeda Provides Update on Soticlestat (TAK-935)

**OSAKA, Japan and CAMBRIDGE, Massachusetts, January 30, 2025** – Takeda (TSE:4502/NYSE:TAK) today announced the decision to discontinue its soticlestat (TAK-935) development program.

This decision follows the June 2024 [announcement](#) that the soticlestat Phase 3 SKYLINE study in Dravet syndrome (DS) and Phase 3 SKYWAY study in Lennox-Gastaut syndrome (LGS) missed their primary endpoints.<sup>1</sup> Subsequently, Takeda discontinued the soticlestat LGS development program<sup>2,3</sup> and engaged with the U.S. Food and Drug Administration (FDA) around the totality of evidence for soticlestat treatment for DS. The FDA informed Takeda that the current clinical data package would not be capable of demonstrating substantial evidence of effectiveness to support a New Drug Application (NDA) for soticlestat in DS. Data from SKYLINE and SKYWAY studies are publicly available on ClinicalTrials.gov.<sup>4,5</sup>

In the quarter that ended June 30, 2024, Takeda recorded a full impairment loss on the intangible assets for soticlestat amounting to JPY 21.5 billion, based on the topline readout of the SKYLINE and SKYWAY trials.<sup>6</sup> Therefore, a financial impact on the full year results for the fiscal year ending March 31, 2025 (FY2024), resulting from the decision, is expected to be immaterial.

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## References

1. Takeda Announces Phase 3 Topline Results for Soticlestat (TAK-935) in Patients with Dravet Syndrome and Lennox-Gastaut Syndrome. Published June 17, 2024. Accessed January 13, 2025. <https://www.takeda.com/newsroom/newsreleases/2024/soticlestat-drevat-syndrom-phase3-results/>.
2. Takeda Quarterly Financial Report. Published July 31, 2024. Accessed January 13, 2025. [https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024\\_q1\\_qfr\\_en.pdf](https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024_q1_qfr_en.pdf).
3. Committed to Growth & Shareholder Returns. Published July 31, 2024. Accessed January 13, 2025. [https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024\\_q1\\_p01\\_en.pdf](https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024_q1_p01_en.pdf).
4. A Study of Soticlestat as an Add-on Therapy in Children and Young Adults With Dravet Syndrome. Published January 1, 2025. Accessed January 13, 2025. <https://clinicaltrials.gov/study/NCT04940624?tab=results>.
5. A Study of Soticlestat as an Add-on Therapy in Children, Teenagers, and Adults With Lennox-Gastaut Syndrome. Published August 21, 2024. Accessed January 13, 2025. <https://clinicaltrials.gov/study/NCT04938427?tab=results>.
6. Earnings Report (Kessan Tanshin) for the Three-month Period Ended June 30, 2024 (IFRS, Consolidated). Published July 31, 2024. Accessed January 15, 2025. [https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024\\_q1\\_er\\_en.pdf](https://assets-dam.takeda.com/image/upload/Global/Investor/Financial-Results/FY2024/Q1/qr2024_q1_er_en.pdf).