



Positive Results from Phase 3 Clinical Trial of Digital Therapeutic App SDT-001 and Submission for Marketing Approval in Japan

OSAKA, Japan, February 26, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announces the submission of a marketing approval application for the digital therapeutic app SDT-001, for commercialization and sale in Japan, as of February 26, 2024.

SDT-001 is a digital therapeutic app designed for the treatment of pediatric patients with attention deficit hyperactivity disorder (ADHD). Developed by Akili, Inc. (Headquarters: Massachusetts, USA; CEO: Matt Franklin; hereafter "Akili"), SDT-001 is the Japanese, localized version of Akili's AKL-T01 (marketed as EndeavorRx® in the United States), which has already obtained authorization from the U.S. Food and Drug Administration (FDA) as the world's first prescription digital therapeutic app for improving attentional functioning in pediatric ADHD patients aged 8 to 17. Additionally, Akili has acquired the CE mark for distribution in Europe.

The submission for marketing approval in Japan is based on the favorable results of the Phase 3 clinical trial conducted by Shionogi in the country. The trial aimed to evaluate the efficacy and safety of SDT-001 in 164 pediatric ADHD patients aged 6 to 17 who received conventional treatments such as environmental adjustments and psychosocial therapies. The SDT-001 group, undergoing approximately 25 minutes of treatment once daily for 6 weeks (1 cycle), demonstrated statistically significant improvements in the change from baseline in the Attention-Deficit/Hyperactivity Disorder Rating Scale IV (ADHD-RS-IV) Inattention score compared to the control group (continuing conventional treatments) at the 6-week mark ($p < 0.05$), achieving the primary endpoint of the trial. Moreover, statistically significant improvements were observed in the change from baseline in the total ADHD-RS-IV score and the hyperactivity/impulsivity score at the 6-week mark in the SDT-001 group compared to the control group ($p < 0.05$). No safety concerns or serious adverse events related to SDT-001 were observed. Furthermore, symptom improvements were sustained even after two cycles of SDT-001 use, with no safety concerns noted.

Shionogi is committed to realizing the SHIONOGI Group Vision of "Building Innovation Platforms to Shape the Future of Healthcare" by transforming into a "Healthcare as a Service (HaaS)" company. While enhancing our strengths as a research-based pharmaceutical company, we aim to provide diverse treatment options beyond medicinal products, including collaborations with external partners, to contribute to improving the quality of life for patients and their families.

【About SDT-001】

SDT-001 is a digital therapeutic application developed by Akili, exclusively licensed by SHIONOGI for clinical development, commercialization and distribution in Japan and Taiwan. By engaging with this application on smartphones or tablets, it is designed to improve attentional functioning in patients with ADHD¹. Designed to activate the prefrontal cortex, a crucial area for cognitive functions, and based on Akili's Selective Stimulus Management Engine (SSME™) core technology, SDT-001 provides optimized dual tasks tailored to individual

patients to stimulate cortical activity, shown to be associated with improvements in the patient's attentional control.

[About Akili]

Akili is pioneering the development of cognitive treatments through game-changing technologies. Akili's approach of leveraging technologies designed to directly target the brain establishes a new category of medicine – medicine that is validated through clinical trials like a drug or medical device, but experienced like entertainment. Akili's platform is powered by proprietary therapeutic engines designed to target cognitive impairment at its source in the brain, informed by decades of research and validated through rigorous clinical programs. Driven by Akili's belief that effective medicine can also be fun and engaging, Akili's products are delivered through captivating action video game experiences. For more information, please visit www.akiliinteractive.com.

Reference:

1. [Press release on March 7, 2019](#)

Akili and Shionogi Announce Strategic Partnership to Develop and Commercialize Digital Therapeutics in Key Asian Markets

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>