PRESSRELEASE

SHIONOGI

Shionogi Obtains Domestic Manufacturing and Marketing Approval for the Digital Therapeutic App "ENDEAVORRIDE®" for Pediatric Attention-Deficit/Hyperactivity Disorder (ADHD)

OSAKA, Japan, February 18, 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") is pleased to announce that it has obtained manufacturing and marketing approval in Japan for the digital therapeutic app "ENDEAVORRIDE®" (Development Code: SDT-001; hereinafter "ENDEAVORRIDE") as of [February 13, 2025]. This app was developed by Akili, Inc. (Headquarters: Washington, USA; CEO: Dan Elenbaas; hereinafter "Akili"), from which Shionogi has acquired exclusive development and commercialization rights for Japan and Taiwan[1].

ENDEAVORRIDE is a digital therapeutic app designed for pediatric patients with attention-deficit/hyperactivity disorder (ADHD). Based on the favorable results of a Phase 3 clinical trial conducted in Japan[2], the app has been approved as an adjunctive therapy for pediatric ADHD. In Japan, therapeutic apps designed to promote behavioral changes have been available for patients with nicotine dependence and hypertension. However, ENDEAVORRIDE is the first therapeutic app in the country specifically developed for pediatric patients with ADHD. Moving forward, the availability of digital therapeutics, alongside psychosocial interventions such as counseling and pharmacological treatments, is expected to provide a new treatment option, contributing to symptom improvement and enhanced treatment satisfaction for pediatric ADHD patients.

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 ENDEAVORRIDE】

ENDEAVORRIDE is a digital therapeutic app targeting pediatric ADHD that is expected to improve symptoms of ADHD by engaging through smartphones and tablets. Based on the Akili Selective Stimulus Management Engine (SSME™) core technology, ENDEAVORRIDE is designed to activate the brain's prefrontal cortex, which plays a crucial role in cognitive function. SSME™ stimulates the cerebral cortex by performing optimized dual tasks for each patient, aiming to improve inattention, hyperactivity, and impulsivity in patients.

【About Akili】

Akili is a company dedicated to developing digital therapeutic apps and advancing their application to medical innovation through innovative technology. Utilizing technology that directly targets the brain, Akili continues to approach new medicine validated through clinical trials, such as high-quality digital therapeutic apps and medical devices. Akili has obtained authorization from the U.S. Food and Drug Administration (FDA) for the world's first digital therapeutic app for improving inattention symptoms in pediatric ADHD patients aged 8-17, sold in the U.S. under the product name EndeavorRx®. For more information about Akili, 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
2. Press release on Fbruary 26, 2024
   Positive Results from Phase 3 Clinical Trial of Digital Therapeutic App SDT-001 and Submission for Marketing Approval in Japan

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