

Akili, Shionogi to develop digital therapeutics in key Asian markets

11 March 2019 | News

AKL-T01 is currently under review with the U.S. Food and Drug Administration (FDA) as a potential digital treatment for children with attention-deficit/hyperactivity disorder



Akili Interactive, digital medicine company creating prescription treatments for people living with cognitive dysfunction and brain-related conditions, and Shionogi & Co., a major research-driven pharmaceutical company focused in two therapeutic areas: infectious diseases, and pain/CNS disorders, have announced that they have entered into a strategic partnership for the commercialization of Akili's digital medicines, AKL-T01 and AKL-T02, in Japan and Taiwan.

AKL-T01 is currently under review with the U.S. Food and Drug Administration (FDA) as a potential digital treatment for children with attention-deficit/hyperactivity disorder (ADHD); AKL-T02 is currently in late stage development as a potential digital treatment for cognitive dysfunction and related symptoms in children with Autism Spectrum Disorder (ASD). The digital treatments are delivered through immersive action video game experiences.

The partnership leverages each party's distinct expertise to build a novel commercial model and launch the new class of treatment to patients. Under the terms of the agreement, Shionogi will be responsible for regulatory filings and has exclusive rights to the clinical development, sales and marketing of AKL-T01 and AKL-T02 in Japan and Taiwan, which will represent the first such nationwide commitment to digital therapeutics in these territories.

Eddie Martucci, CEO of Akili said, "Over their 140-year history, Shionogi has been a model of innovation while placing the highest value on patient care. This agreement is indicative of their continued commitment to push the boundaries of medicine and be on the leading edge of next generation therapeutics. It is critical to Akili that we do everything in our power to maximize long-term growth of our medicines to patients in need, and we could not have found a better partner to work with us to deliver an entirely new treatment model in these territories as we grow our international capabilities."

Dr. Isao Teshirogi, President and Chief Executive Officer, Shionogi & Co., Ltd said, "ADHD and autism have a significant impact on children and their families in Japan and Taiwan, yet there remains a significant gap in treatment options and access to today's medicines. Akili is a clear leader in digital medicine, and their digital treatment systems represent game-changing solutions to treating these disorders and we look forward to working with them to lead the development of the first digital medicine in Japan and Asia while bringing new hope to children affected by cognitive dysfunction."

Akili will build and maintain control of a newly created Global Access Platform - an R&D and commercial platform including all global product development activities, distribution, technical support services. Akili will also be responsible for data collection and storage in compliance with local laws and regulation related to privacy and the management of personal health information. The Global Access Platform, including its regional platform covering the Japanese and Taiwanese markets, will serve as an independent prescription and patient support system designed specifically for digital therapeutics.

Shionogi makes upfront payments to Akili totaling \$20 million and Akili will be eligible to receive development and commercial milestones of up to \$105 million. In addition, Akili will receive substantial royalties on sales of the products in Japan and Taiwan. Shionogi will also help fund development costs and commits to a future equity investment in Akili. Akili will maintain exclusive global rights to develop and commercialize AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.