



# PureTech Founded Entity Akili Announces Topline Results from Shionogi Phase 2 Study in Japan

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## **PureTech Founded Entity Akili Announces Topline Results from Shionogi Phase 2 Study in Japan**

*Shionogi successfully completes first-ever clinical study of Akili's video game-based cognitive treatment outside of the U.S.; plans to advance technology to the next step*

*Data show Akili's digital treatment was well-received and improved inattention in children with ADHD*

*Results demonstrate high engagement and similar magnitude of improvements as seen in prior studies of AKL-T01 in ADHD*

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company, is pleased to note that its Founded Entity, Akili Interactive ("Akili"), today announced topline results of a Phase 2 study of SDT-001 (Japanese version of AKL-T01), a digital therapeutic designed to improve measures of attention in children diagnosed with attention-deficit/hyperactivity disorder (ADHD). The study, conducted by Akili partner Shionogi & Co., Ltd. ("Shionogi"), was designed to evaluate the feasibility, safety and efficacy of the digital therapeutic in children with ADHD and to inform the design of a potential pivotal study.

To enable this clinical trial, Akili localized its AKL-T01 technology for use in the Japanese market, which included adapting for language and culture and establishing infrastructure in Japan to support the product. Results show the treatment was well-received by patients and demonstrated improvements in ADHD inattention symptoms consistent with those seen across previous studies of AKL-T01. Based on these results, Shionogi plans to advance SDT-001 into consultation with the Japanese regulatory authority PMDA regarding Phase 3 implementation.

Akili and Shionogi formed a strategic partnership in May 2019 for the commercialization of Akili's digital medicines, AKL-T01 and AKL-T02, as treatments of cognitive impairments in children with ADHD and Autism Spectrum Disorder (ASD), respectively, in Japan and Taiwan. Under the terms of the agreement, Akili received upfront payments totaling \$20 million with potential milestone payments for Japan and Taiwan commercialization of up to an additional \$105 million, in addition to substantial royalties on product sales. Shionogi will also help fund development costs. Shionogi has exclusive rights to the clinical development and is responsible for regulatory filings, sales and marketing of the technologies in Japan and Taiwan. Akili is responsible for building and maintaining R&D and commercial platforms

designed specifically for digital therapeutics, including all global product development activities, distribution and technical support services. Akili will maintain exclusive global rights to develop and commercialize AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.

AKL-T01, branded [EndeavorRx<sup>®</sup>](#), is [cleared for use by the U.S. Food and Drug Administration \(FDA\)](#) and has [received Conformité Européenne \(CE\) Mark certification](#) in Europe for use in pediatric ADHD. Please see below for full indication information on EndeavorRx and visit [EndeavorRx.com](#) to learn more.

The full text of the announcement from Akili is as follows:

**Topline Results from Shionogi Phase 2 Study in Japan Show Akili's Digital Treatment Was Well-received and Improved Inattention Symptoms in Children with ADHD**

*Shionogi successfully completes first-ever clinical study of Akili's video game-based cognitive treatment outside of the U.S.; plans to advance technology to the next step*

*Results demonstrate high engagement and similar magnitude of improvements as seen in prior studies of AKL-T01 in ADHD*

BOSTON, Mass. September 29, 2021, -- Akili Interactive ("Akili"), a leading cognitive medicine company improving health through game-changing technologies, today announced topline results of a Phase 2 study of SDT-001 (Japanese version of AKL-T01), a digital therapeutic designed to improve measures of attention in children diagnosed with attention-deficit/hyperactivity disorder (ADHD). The study, conducted by Akili partner Shionogi & Co., Ltd. ("Shionogi"), was designed to evaluate the feasibility, safety and efficacy of the digital therapeutic in children with ADHD and to inform the design of a potential pivotal study. Results show the treatment was well-received by patients and demonstrated improvements in ADHD inattention symptoms consistent with those seen across previous studies of AKL-T01. Based on these results, Shionogi plans to advance SDT-001 into consultation with the Japanese regulatory authority PMDA regarding Phase 3 implementation.

"This study marks the first time a clinical trial of Akili's technology has been conducted outside of the U.S., and we thank our partners at Shionogi who are helping us to develop this new treatment option for families of children with ADHD in Japan. We're pleased to not only see a meaningful treatment effect that continues to validate our core technology, but also high engagement in the treatment," said Anil S. Jina M.D., Chief Medical Officer of Akili. "Our goal is for all eligible children across the globe to be able to access our attention treatment, regardless of their spoken language and geographic location, this study represents an incredibly important milestone."

The randomized, controlled study of SDT-001 was conducted in Japan and enrolled children ages 6-17 years diagnosed with ADHD whose ADHD RS-IV Inattention score was 15 or over. A total of 262 patients were enrolled across three study groups: 1) participants who received the Akili SDT-001 digital treatment, 2) participants who continued treatment as usual (TAU), consisting of psychoeducation and environmental support, and 3) participants who received a version of the treatment with reduced cognitive tasks and adaptability ("Sham"). The SDT-001 treatment group showed larger improvements across the clinical endpoints compared to both the TAU and the Sham groups. In the total population, the improvements seen over Sham did not meet statistical significance, but post hoc analysis applying the propensity score suggested that SDT-001 improvements over TAU were statistically significant. While full data are still being analyzed, early data showed additional SDT-001 efficacy compared to both Sham and TAU groups in specific subsets of children, including those with inattentive-type ADHD.

SDT-001 was well-tolerated and there were no serious adverse events. Adverse events reported were consistent with previous clinical studies of the digital treatment. Adverse device reactions were reported in 4 patients (3.7%) treated

with SDT-001 and were mild in severity including irritability, somnolence, tinnitus and nausea.

To enable this clinical trial, Akili localized its AKL-T01 technology for use in the Japanese market, which included adapting for language and culture and establishing infrastructure in Japan to support the product. The technology is a disease agnostic proprietary technology designed to treat impaired cognitive function, specifically attention control. Delivered through an action video game experience, this first-in-class technology presents specific sensory stimuli and simultaneous motor challenges designed to target and activate the neural systems that play a key role in attention function while using adaptive algorithms to personalize the treatment experience for each individual patient. The technology has been evaluated as a potential treatment for cognitive impairments associated with nearly a dozen different disease areas and has been studied in more than 2600 patients across 30 clinical trials. AKL-T01, branded [EndeavorRx](#), is [cleared for use by the U.S. Food and Drug Administration \(FDA\)](#) and has [received Conformité Européenne \(CE\) Mark certification](#) in Europe for use in pediatric ADHD. Please see below for full indication information on EndeavorRx and visit [EndeavorRx.com](#) to learn more.

[Akili and Shionogi formed a strategic partnership](#) in May 2019 for the commercialization of Akili's digital medicines, AKL-T01 and AKL-T02, as treatments of cognitive impairments in children with ADHD and Autism Spectrum Disorder (ASD), respectively, in Japan and Taiwan. 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 has exclusive rights to the clinical development and is responsible for regulatory filings, sales and marketing of the technologies in Japan and Taiwan. Akili is responsible for building and maintaining R&D and commercial platforms designed specifically for digital therapeutics, including all global product development activities, distribution and technical support services. Akili maintains exclusive global rights to develop and commercialize AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.

### **EndeavorRx® Indication and Overview**

EndeavorRx is the first-and-only FDA-cleared treatment delivered through a video game experience. In the U.S., EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention (TOVA®) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder. EndeavorRx is available by prescription only. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication. The most common side effect observed in children in EndeavorRx's clinical trial was a feeling of frustration, as the game can be quite challenging at times. No serious adverse events were associated with its use. EndeavorRx is recommended to be used for approximately 25 minutes a day, 5 days a week, over initially at least 4 consecutive weeks, or as recommended by your child's health care provider. To learn more about EndeavorRx, please visit [EndeavorRx.com](#).

### **About Shionogi**

Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." Shionogi's research and development currently target two therapeutic areas: infectious diseases and psycho-neurological diseases. Shionogi is committed to "improve social productivity and extend healthy lifespans" as the key focus. We will endeavor to deliver breakthrough treatments for the patients of psycho-neurological diseases including ADHD, which still have high unmet medical needs, and contribute to improving the QOL of patients and their families. For more details, please visit [www.shionogi.com/global/en/](#).

### **About Akili**

Akili is pioneering the development of game-changing technologies to usher in a new era of cognitive medicine. Focused on delivering cutting-edge digital diagnostics, treatments and monitors for cognitive impairments across disease and disorders, Akili is combining scientific and clinical rigor with the ingenuity of the tech and entertainment industries and challenging the status quo of medicine. Akili's treatments are designed to directly activate the networks in the brain responsible for cognitive function and have been rigorously tested in extensive clinical studies, including prospective randomized, controlled trials. 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](http://www.akiliinteractive.com).

### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, including inflammatory, fibrotic and immunological conditions, intractable cancers, lymphatic and gastrointestinal diseases and neurological and neuropsychological disorders, among others. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 25 therapeutics and therapeutic candidates, including two that have received both U.S. FDA clearance and European marketing authorization, as of the date of PureTech's most recently filed Half Year Report and corresponding Form 6-K. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on the Company's unique insights into the biology of the brain, immune and gut, or BIG, systems and the interface between those systems, referred to as the BIG Axis.

For more information, visit [www.puretechhealth.com](http://www.puretechhealth.com) or connect with us on Twitter @puretechh.

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains statements that are or may be forward-looking statements, including statements that relate to our expectation regarding the use of Akili's AKL-T01 technology in the Japanese market, Shionogi's plans to initiate a Phase 3 trial for SDT-001 in Japan and the associated timing, and Akili's future prospects, development plans, and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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