



## **Akili Interactive Labs Opens Enrollment for Pivotal Trial of Novel ADHD Treatment**

*Large-scale trial designed to validate digital medicine treatment for children with ADHD*

**BOSTON, Massachusetts**, May 6, 2016 – [Akili Interactive Labs, Inc.](#) ("Akili"), a company developing a novel, non-pharmacological technology for cognitive disorders, today announced open enrollment for its pivotal STARS-ADHD trial. The trial will evaluate the safety and efficacy of the company's proprietary platform, Project: EVO, for the treatment of children with Attention Deficit Hyperactivity Disorder (ADHD). This large-scale pivotal trial marks an important inflection point in the advancement of digital medicine as a clinically-validated treatment for diagnosed patient populations.

ADHD is a neurological condition marked by inattention and/or hyperactivity-impulsivity, and though about 75 percent of young children with ADHD receive medication, there is a growing demand for non-pharmacological interventions.

The mechanics of the Project: EVO platform are designed to directly target an individual's core ability to process multiple streams of information, which has the potential to change specific neural networks and improve attention, inhibition and working memory. STARS-ADHD is a double-blind, randomized, controlled, parallel-group, interventional trial to evaluate the effects of Project: EVO on attentional functioning and symptoms in ADHD-diagnosed children. In a recent [open-label study](#), Project: EVO improved attention, inhibition and working memory in children with ADHD. Akili seeks to further validate the benefits of Project: EVO through the STARS-ADHD pivotal trial, which has been in piloting phase since November. If the STARS-ADHD trial meets its endpoints, the company plans to seek approval from the United States Food and Drug Administration for this potential first-in-class treatment. Akili has been conducting multiple clinical trials of its platform across a variety of patient populations including autism spectrum disorder (in collaboration with Autism Speaks), depression, Alzheimer's disease (in collaboration with Pfizer, Inc.) and traumatic brain injury, and it is also actively exploring clinical collaborations in other neurodegeneration indications.

"Project: EVO has demonstrated strong clinical potential in children with ADHD," said Eddie Martucci, Ph.D., Co-founder and Chief Executive Officer of Akili. "The high-bar and rigor of a pivotal trial is an important next step toward clinically validating Project: EVO as a treatment. This validation is critical for doctors, patients and parents to have confidence in the safety and efficacy of this drug-free approach."

The STARS-ADHD study aims to enroll a minimum of 300 children aged 8 to 12 years who have been diagnosed with ADHD. Eligible individuals include those who are either not currently being treated with pharmaceutical interventions, or are being treated with a methylphenidate or amphetamine-based therapy and are willing and deemed appropriate to discontinue use for the duration of the study.

Participants, who will be enrolled at up to ten sites across the United States, will use the intervention software at home on a tablet device for 4 weeks. After the 4-week period, an in-clinic assessment will measure changes from baseline on a continuous performance test, a standard measure of attention and impulsivity. In addition to this primary outcome, several secondary outcomes – including those measuring symptom relief, memory, function and impairment – will be examined.

“Project: EVO has shown early promise to help improve attention and neurocognition in cognitive disorders like ADHD,” said STARS-ADHD study principal investigator, Scott Kollins, Ph.D., M.S., Professor of Psychiatry and Director of the ADHD Program, Duke University School of Medicine. “We look forward to enrolling patients and advancing the study and validation of this potential new treatment option for young patients with ADHD.”

### **About Project: EVO**

Akili’s lead product candidate, Project: EVO, is based on a platform technology exclusively licensed from the lab of [Dr. Adam Gazzaley](#) at the University of California, San Francisco. The mechanics of the platform are designed to directly target an individual's core neurological ability to process multiple streams of information, which has the potential to improve problem solving, working memory and self-regulation. The innovative technology can adapt difficulty automatically in real-time, allowing individuals of wide-ranging ability levels to interact with the product without the need for physician calibration. Akili is currently conducting multiple clinical trials of its digital medicine platform across a variety of patient populations, including pediatric ADHD, autism spectrum disorder (in collaboration with Autism Speaks), depression, Alzheimer’s disease (in collaboration with Pfizer, Inc.) and traumatic brain injury.

### **About Akili Interactive Labs**

[Akili](#) is building clinically validated cognitive treatments and assessments that are delivered in an action video game interface. Leveraging medical-grade science and consumer-grade software technology, the company is seeking to produce a new type of healthcare product that is both highly-effective and highly-engaging. The company was founded by [PureTech Health \(PRTC.L\)](#), together with leading neuroscientists and game designers. Akili has garnered investment from Shire PLC and has strategic partnerships with Pfizer Inc. and Autism Speaks.

PureTech Health plc (PRTC.L) owns approximately 63% of the company on a diluted basis (assuming the investment of the second tranche of the January 2016 financing round).

### **Forward Looking Statement**

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments 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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