



Pilot Study Results Demonstrate Akili’s Mobile Digital Intervention Improved Attention and Working Memory in Pediatric Attention Deficit Hyperactivity Disorder

BOSTON, October 28, 2015 – [Akili Interactive Labs, Inc.](#) ("Akili"), a company focused on developing clinically validated digital medicine for cognitive assessment and personalized treatment, announced today data from the Akili-001 pediatric attention deficit hyperactivity disorder (ADHD) pilot study of *Project: EVO*, its lead therapeutic product candidate. The study confirmed *Project: EVO*’s safety and feasibility. Additionally, exploratory outcome measurements demonstrated that *Project: EVO* improved attention, inhibition and working memory in children with ADHD. These data were presented today at the American Academy of Child and Adolescent Psychiatry’s 62nd annual meeting.

“These data demonstrate that *Project: EVO* improved attentional functioning and working memory in children with ADHD,” said Scott Kollins, PhD, lead author and principal investigator for the study, and Professor of Psychiatry and Director of the ADHD Program, Duke University School of Medicine. “While results are preliminary, these data provide a strong rationale for continued work to develop this novel, digital intervention for ADHD.”

In the Akili-001 open-label pilot study, *Project: EVO* was tested in a total of 80 children between the ages of 8 and 12 years, 40 of whom were diagnosed with ADHD and not taking a medication, and 40 of whom had no psychiatric diagnosis. The regimen consisted of using the digital intervention delivered through an action video game interface on a tablet device at home for approximately 30 minutes per day, five times a week over the span of four weeks. The primary aims of the study were to confirm feasibility and safety of the at-home intervention, as well as to measure the difference in baseline attentional functioning between the two groups. Exploratory measures of attention, impulsivity, and working memory were also assessed at one month. Improvement was seen across these domains in the ADHD group.

Statistically-significant improvements were observed in the ADHD group on multiple outcome measures, including the Attention Performance Index (API) of the Test of Variable of Attention (T.O.V.A.®), a continuous performance test used to measure attentional function; in the ADHD group ($p = 0.033$, Cohen’s $d = 0.35$, $n=40$); there was no statistically significant change in the non-ADHD group ($p = 0.30$, Cohen’s $d = 0.16$, $n=40$). Other statistically significant improvements for the ADHD group were observed in impulsivity and variability measurements on T.O.V.A., and in multiple measurements on the CANTAB (Cambridge Cognition) spatial working memory test.

Additionally, a post-hoc analysis of participants’ API scores showed that the intervention had a significantly larger attention effect on a subgroup of the children with ADHD who exhibited more substantial attention impairment at the beginning of the study ($p = 0.003$, Cohen’s $d = 0.71$, $n=22$). This sub-group displayed similar improvements to the full ADHD group on the working memory tests, on impulsivity measures and a parent-reported scale of executive function.

There was an 81 percent compliance rate for use of the digital intervention among those tested (on average, 9.1 hours of playtime over 4 weeks). A large majority of the parents of the ADHD participants indicated in reports that the game was worthwhile for their child. A total of nine adverse events were reported during the study, but none were deemed related to the *Project: EVO* intervention. Importantly, there were no dropouts within the ADHD group.

"*Project: EVO* was designed as medical-grade software that could potentially offer a viable new option or adjunct to pharmaceuticals," said Eddie Martucci, co-founder and CEO of Akili. "This study supports that hypothesis, and we are excited to continue to explore *Project: EVO's* utility in pediatric ADHD in larger confirmatory studies."

Akili's 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 and was previously published as the cover story of [Nature](#), where a prototype of the technology showed large improvements in attention and working memory in healthy older adults after at-home intervention. The mechanics are designed to directly target an individual's ability to process "cognitive interference" – specifically, the ability to deal with multiple streams of sensory information, which has the potential to improve higher-order executive functions such as problem solving, working memory, and self-regulation. The *Project: EVO* platform targets cognitive interference processing while also adapting difficulty automatically in real-time, allowing individuals of wide-ranging ability levels to interact with the product without the need for physician calibration.

Based on these promising data, Akili plans to initiate a large, randomized, controlled pivotal study in the coming months to further validate the efficacy and safety of *Project: EVO* as a treatment for pediatric ADHD. Akili is currently conducting multiple clinical studies of the technology platform across a variety of patient populations, including pediatric Autism Spectrum Disorder (in strategic collaboration with Autism Speaks), depression, Alzheimer's disease (in strategic collaboration with Pfizer, Inc.) and traumatic brain injury.

About Akili Interactive Labs

[Akili](#) is building clinically validated cognitive therapeutics, assessments, and diagnostics delivered through 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 effective and engaging. The company was founded by [PureTech Health](#), together with leading neuroscientists and game designers. Akili has garnered investment from Shire PLC and has strategic partnerships with Pfizer Inc. and Autism Speaks.

About PureTech Health

[PureTech Health](#) (PureTech Health plc, PRTC.L) is a cross-disciplinary healthcare company, developing innovative products that could potentially improve the lives of billions of patients. PureTech has a pipeline of 12 operating companies, seven of which are "growth stage" with external validation including strategic partnerships, outside funding, proof-of-concept and/or peer review in prestigious scientific journals. PureTech also has a pipeline of ten "concept phase" initiatives resulting from review of more than 650 ideas annually. PureTech is focused on areas including immune and inflammatory disorders; cognitive and psychiatric disorders; diabetes and obesity; oncology; and infectious diseases, and has over 110 patents and patent applications. PureTech's leading team and board, along with an advisory network of more than 50 expert founder-scientists and advisors across multiple disciplines, gives PureTech access to potentially ground-breaking science and technological innovation. For more information, visit www.puretechhealth.com and connect with us on [Twitter](#).

As of June 30th, 2015, PureTech had holdings of 59.8% in Akili on a diluted basis. This calculation of PureTech's holding includes issued and outstanding shares as well as options to purchase shares and written commitments to issue options, but excludes unallocated shares authorized to be issued pursuant to equity incentive plans.

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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