



PureTech Founded Entity Akili Announces ENDEAVOR™ Digital Attention Treatment is Now Available for Children with Attention Deficit Hyperactivity Disorder (ADHD) under FDA's COVID-19 Enforcement Discretion Guidance

April 22, 2020

[PureTech Health plc](#) (LSE: PRTC) ("PureTech," or the "Company") is pleased to note that its Founded Entity, Akili, today announced that ENDEAVOR™ (AKL-T01) is now available in the US for use by children with attention deficit hyperactivity disorder (ADHD) and their families. Akili is pursuing US Food and Drug Administration (FDA) clearance of ENDEAVOR as a prescription treatment for use in paediatric ADHD. In parallel, the current release of ENDEAVOR is in response to new [guidance](#) from FDA recognising the need for access to certain low-risk clinically-validated digital health devices for psychiatric conditions, including ADHD during the COVID-19 pandemic. Akili is releasing ENDEAVOR to families with children diagnosed with ADHD and struggling with chronic attention issues. ENDEAVOR is downloaded from the App Store, and a separate companion app is also available to help parents track and better understand changes in their child's behaviour. For a limited time, Akili is providing access to ENDEAVOR to those who qualify at no cost.

Daphne Zohar, founder and chief executive officer of PureTech, said: "The launch of Akili's ENDEAVOR is a milestone for the field of digital medicine and for the millions of children with ADHD. When we founded Akili, the PureTech team envisioned an effective and evidence-based, non-pharmacological treatment for ADHD that physicians and parents would be comfortable supporting and children would enjoy using. We believe the large body of data generated to date supports this vision and distinguishes ENDEAVOR as a first of its kind, non-pharmaceutical digital treatment to help children address inattentiveness, one of the most pervasive symptoms of ADHD.

"Today's launch also highlights the importance of telehealth, a broad theme carried across several of our Founded Entities. Remote treatment and monitoring enable patients to access support from the comfort and safety of their own homes, removing one of the steepest barriers to care. As the parent of a child with ADHD, I have been eagerly awaiting this day and I am proud to be associated with Akili and ENDEAVOR."

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

Akili Announces ENDEAVOR™ Attention Treatment is Now Available for Children with Attention Deficit Hyperactivity Disorder (ADHD) under FDA's COVID-19 Enforcement Discretion Guidance

BOSTON, Mass – April 22, 2020 – [Akili](#) today announced that ENDEAVOR™ (AKL-T01) is now available for use by children with attention deficit hyperactivity disorder (ADHD) and their families. Delivered through a captivating video game experience, ENDEAVOR is a digital treatment that has been shown in a rigorously designed and conducted clinical research programme 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. Attention impairments are a component of ADHD in more than 85% of children diagnosed and can significantly impact daily functioning.

Akili is pursuing US Food and Drug Administration (FDA) clearance of ENDEAVOR as a prescription treatment for use in paediatric ADHD. In parallel, the current release of ENDEAVOR is in response to new [guidance](#) from FDA recognising the need for access to certain low-risk clinically-validated digital health devices for psychiatric conditions including ADHD during the COVID-19 pandemic.

"The current environment is hard for any child. Increased stress and upended schedules and routines have a direct impact on our cognition, increasing our distractibility and making it harder to stay focused and to be organised," said Scott Kollins, PhD, professor of psychiatry, director of the ADHD Program at Duke University School of Medicine. "For children with attention issues associated with ADHD, their daily challenges are exacerbated and many of their support systems are no longer accessible."

Akili is releasing ENDEAVOR to families with children diagnosed with ADHD and struggling with chronic attention issues. For a limited time, Akili is providing access to ENDEAVOR to those who qualify at no cost.

"At Akili, we've been steadfast in our commitment to build a future where effective medicine is not only easily accessible but also can treat patients in an entirely new and engaging way," said Eddie Martucci, PhD, chief executive officer of Akili. "During this time of increased need, we're proud to be able to immediately offer our new clinically validated digital medicine experience to the ADHD community."

While often underrecognised in the face of more overt externalising symptoms of ADHD, inattentiveness experienced by many children living with ADHD can be substantial.

"The impact of inattentiveness on functioning in children with ADHD is apparent to me on a daily basis in my practice. It affects making and keeping friends, completing tasks, building confidence and succeeding in school. In a clinical trial setting, I've seen ENDEAVOR have positive impacts on these areas, and my hope is that this intervention could play a valuable role as part of an integrated and comprehensive treatment approach for children with attentional challenges," said Raun Melmed, MD, behavioral pediatrician and director of Melmed Center, Scottsdale, Ariz. and author of a series of books on mindfulness for children including "Marvin's Monster Diary: ADHD Attacks!"

ENDEAVOR is the centrepiece of the Endeavor Treatment System™ care programme, which includes ENDEAVOR, Akili Assist™ personal support services, and the ADHD Insight™ companion app, designed to help parents track and better understand changes in their child's behaviour over time. Easily accessible from home, ENDEAVOR is downloaded from the App Store by families on their mobile devices and does not require any additional equipment.

Driven by the core belief at Akili that effective medicine can also be fun and engaging, ENDEAVOR is delivered through an action video game experience. Using ENDEAVOR, patients navigate a character through different worlds while avoiding obstacles and collecting targets to unlock new worlds and receive awards. The captivating experience of ENDEAVOR is designed to drive engagement and compliance.

With neuroscience and technology as its foundation, ENDEAVOR is built on the Akili Selective Stimulus Management engine (SSME™) core technology, a proprietary technology designed for the targeted activation of specific neural systems in the brain to treat diseases with associated cognitive dysfunction. SSME presents specific sensory stimuli and simultaneous motor challenges designed to target and activate the neural systems that play a key role in attention function. The technology implements algorithms that adapt in both real-time and between treatment sessions to automatically adjust the difficulty level for a treatment experience that is personalised to the needs of each individual patient. This enables second by second monitoring of patient progress completing the treatment sessions, and continuously challenges each patient to an optimised level, encouraging patients to improve their performance.

Clinical Studies of ENDEAVOR

Akili has rigorously tested ENDEAVOR across five clinical trials, which included more than 600 children diagnosed with ADHD. The research programme included three studies in ADHD (STARS-ADHD, STARS-Adjunct and [ADHD-POC](#)) and two pilot studies in ADHD with different comorbidities ([Sensory Processing Disorder](#) and [Autism Spectrum Disorder](#)). The pivotal STARS-ADHD study was a multi-centre, randomised, blinded, controlled study in 348 children diagnosed with ADHD, and results were recently published in [The Lancet Digital Health](#) journal. In the pivotal study, ENDEAVOR showed a statistically significant improvement compared to an educational-style video game control (p=0.006) on a change in the Attention Performance Index (API) of the Test of Variables of Attention (TOVA®), a computerised test cleared by FDA to evaluate the effects of interventions in ADHD. In the [STARS-Adjunct](#) open-label study, statistically significant improvement was seen in the IRS (a parent-reported clinician-administered scale of ADHD impairments) from baseline to after 4-weeks of treatment in both children on stimulants and off any ADHD medication. No serious adverse events have been associated with ENDEAVOR in any study to date. Some study participants (9.3%) experienced non-serious treatment-related adverse events with ENDEAVOR, including frustration, headache, dizziness, emotional reaction, nausea or aggression.

Access and Use of ENDEAVOR

The current release of ENDEAVOR is enabled by new [guidance](#) from FDA in response to the COVID-19 public health emergency. ENDEAVOR is available today for qualified families with children diagnosed with ADHD and struggling with chronic attention issues and who are willing to commit to following the ENDEAVOR instructions for use. ENDEAVOR is currently available for use on iOS devices. To check if they are eligible, parents of children with ADHD can visit Akili's enrolment site at [GetEndeavor.com](#). Parents should contact a physician before their child begins using ENDEAVOR.

About Akili

Akili is combining scientific and clinical rigor with the ingenuity of the tech and entertainment industries to challenge the status quo of medicine. Akili has pioneered the development of video game-based digital medicine to improve cognitive function. Akili's flagship product, ENDEAVOR, is a digital treatment to address inattention in children with attention deficit hyperactivity disorder (ADHD). ENDEAVOR is currently available under FDA's enforcement discretion policy for use during the COVID-19 pandemic; it has not yet received FDA clearance. Akili's patented technology serves as the foundation of its products and is designed to directly activate the networks in the brain responsible for cognitive function. Driven by Akili's belief that effective medicine can also be fun and engaging, Akili's treatments are delivered through captivating action video game experiences that drive engagement and compliance. For more information, please visit [www.Akiliinteractive.com](#).

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, including intractable cancers, lymphatic and gastrointestinal diseases, central nervous system disorders and inflammatory and immunological diseases, 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 23 product candidates and one product that has been cleared by the US Food and Drug Administration (FDA). All of the underlying programmes and platforms that resulted in this pipeline of product 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](#) or connect with us on Twitter [@puretechh](#)

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.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.