PureTech Founded Entity Akili Receives Approval to Market EndeavorRx™ in Europe as a Digital Treatment for Children with ADHD

June 23, 2020

Approval of CE Mark enables the marketing of EndeavorRx in European Economic Area member countries

Delivered through a video game experience, EndeavorRx has been studied across five clinical studies including a large, randomised controlled trial

PureTech Health plc (LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Akili, today announced that it has received a Conformité Européenne (CE) Mark for EndeavorRx (AKL-T01) as a prescription-only digital therapeutic software intended for the treatment of attention and inhibitory control deficits in paediatric patients with Attention Deficit Hyperactivity Disorder (ADHD). While EndeavorRx is not yet available in Europe, the CE Mark enables Akili to market EndeavorRx in European Economic Area (EEA) member countries. ADHD is one of the most common psychiatric disorders in childhood and nearly five per cent of children in Europe are diagnosed with the disorder.

The CE Mark follows last week's US Food and Drug Administration (FDA) decision, which made EndeavorRx the first FDA-cleared prescription treatment delivered through a video game and the first game-based therapeutic to be granted marketing authorisation by the FDA for any type of condition. With a near-term focus on launching the EndeavorRx prescription treatment in the US, Akili is exploring expansion opportunities in Europe as part of its global strategy. In March 2019, Akili announced a strategic partnership with Shionogi & Co., Ltd. to develop and commercialise EndeavorRx in Japan and Taiwan.

Daphne Zohar, founder and chief executive officer of PureTech said: "Akili's European marketing authorisation today is an important milestone for families in Europe looking to help their children with ADHD. This is on the heels of the exciting news of Akili's FDA clearance last week and Gelesis' receipt of a European CE Mark for Plenity® earlier this month. We are so proud that two products developed from our unique R&D engine have now received marketing authorisation in both the US and Europe."

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

Akili Announces CE Mark Approval of EndeavorRx™ Digital Treatment for Children with ADHD

Approval enables the future marketing of EndeavorRx in European Economic Area member countries

Delivered through a video game experience, EndeavorRx has been studied across five clinical studies including a large, randomised controlled trial

BOSTON, Mass – June 23, 2020 – Akili today announced that it has received Conformité Européenne (CE) Mark certification for EndeavorRx (AKL-T01), as a prescription-only digital therapeutic software intended for the treatment of attention and inhibitory control deficits in paediatric patients with Attention Deficit Hyperactivity Disorder (ADHD). ADHD is one of the most common psychiatric disorders in childhood and nearly five per cent of children in Europe are diagnosed with the disorder.

The CE Mark follows last week's US Food and Drug Administration (FDA) decision, which made EndeavorRx the first FDA-cleared prescription treatment delivered through a video game.

"Following our recent FDA clearance, the CE Mark is another important milestone for Akili," said Anil Jina, MD, chief medical officer of Akili. "This approval provides a path for the future expansion into Europe and will allow us to offer a new non-drug treatment option to families of children living with ADHD."

The CE Mark confirms that EndeavorRx meets quality standards for design, manufacture and final inspection. While EndeavorRx is not yet available in Europe, the certification enables Akili to market EndeavorRx in European Economic Area (EEA) member countries. With a near-term focus on launching the EndeavorRx prescription treatment in the US, the company is exploring expansion opportunities in Europe as part of its global strategy. In March 2019, Akili announced a strategic partnership with Shionogi & Co., Ltd. to develop and commercialise EndeavorRx in Japan and Taiwan.

EndeavorRx is built on the Akili Selective Stimulus Management engine (SSME™) proprietary technology that 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 personalise the treatment experience for each individual patient.

Clinical Evidence Supporting EndeavorRx

EndeavorRx has been studied across five clinical studies in more than 600 children diagnosed with ADHD, including a prospective, randomised, controlled study published in *The Lancet Digital Health* journal, which showed EndeavorRx improved objective measures of attention in children with *ADHD.* After four weeks of EndeavorRx treatment, one-third of children no longer had a measurable attention deficit on at least one measure of objective attention. Further, about half of parents saw a clinically meaningful change in their child's day-to-day impairments after one month of treatment with EndeavorRx; this increased to 68% after a second month of treatment. Improvements in ADHD impairments following a month of treatment with EndeavorRx were maintained for up to a month. No serious adverse events have been associated with EndeavorRx in any study to date. Some study participants (9.3%) experienced non-serious treatment-related adverse events with EndeavorRx, including frustration, headache, dizziness, emotional reaction, nausea or aggression.

About Akili

Akili is combining scientific and clinical rigour 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, EndeavorRx, is a prescription digital treatment to address inattention in children with attention deficit hyperactivity disorder (ADHD). 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 AkiliInteractive.com.

EndeavorRx™ is a registered trademark of Akili Interactive Labs, Inc. Digital assets of EndeavorRx are available here for download, credit Akili Interactive.

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 24 products and product candidates, including two that have 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.