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PureTech Founded Entity Akili Releases EndeavorOTCTM Video Game Treatment to Improve Attention in Adults with ADHD

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PureTech Health plc

## PureTech Founded Entity Akili Releases EndeavorOTC<sup>TM</sup> Video Game Treatment to Improve Attention in Adults with ADHD

Amid growing mental health crisis, the product release enables immediate access to non-drug treatment option as

Akili prepares FDA submission

Available nationwide without a prescription, clinical data shows improvements in focus in 83% of adults with ADHD

<u>PureTech Health plc</u> (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company noted today that its Founded Entity, Akili, Inc. (Nasdaq: AKLI) ("Akili"), a leading digital medicine company, today released EndeavorOTC<sup>TM</sup>, a new immersive mobile video game treatment that is clinically proven to improve attention and focus, specifically in adults with ADHD. EndeavorOTC is built on the same technology as Akili's EndeavorRx<sup>®</sup>, the world's first and only <u>FDA-authorized</u> video game treatment now being prescribed for children 8-12 years old with ADHD. EndeavorOTC is now available without a prescription for adults 18 years and older nationwide.

This announcement comes on the heels of <u>recently announced</u> clinical trial data showing that EndeavorOTC (AKL-T01) significantly improved focus, attention, and overall quality of life in adults struggling with ADHD symptoms:

- 83% of participants reported clinical improvements in their focus
- On average, participants' ability to focus improved by 85%
- Over one-third of participants no longer exhibited an attention deficit following treatment
- 73% of participants reported quality of life improvements, including completing tasks on time, managing multiple tasks at once, and keeping track of important items like wallets or keys

Amid a persistent mental health crisis, an <u>increasing number of adults</u> are seeking help for ADHD symptoms including inattention and lack of focus while facing an <u>ongoing nationwide shortage of ADHD medication</u>. As the gap between demand for care and availability of effective treatments widens, Akili released EndeavorOTC under FDA's enforcement policy established shortly after the onset of the COVID-19 pandemic to facilitate rapid access to certain low-risk, mental health-related digital health devices.

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

Akili Releases EndeavorOTC<sup>TM</sup> Video Game Treatment to Improve Attention in Adults with ADHD

Amid growing mental health crisis, the product release enables immediate access to non-drug treatment option as

#### Akili prepares FDA submission

Available nationwide without a prescription, clinical data shows improvements in focus in 83% of adults with ADHD

BOSTON, MA, June 7, 2023 - Akili, Inc. (Nasdaq: AKLI), a leading digital medicine company, today released EndeavorOTC<sup>TM</sup>, a new immersive mobile video game treatment that is clinically proven to improve attention and focus, specifically in adults with ADHD. EndeavorOTC is built on the same technology as Akili's EndeavorRx<sup>®</sup>, the world's first and only <u>FDA-authorized</u> video game treatment now being prescribed for children 8-12 years old with ADHD. EndeavorOTC is now available without a prescription for adults 18 years and older nationwide.

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"Compared with children, adults with ADHD are generally overlooked and under-treated. Current treatments are not sufficient, and adults need more effective options, including non-pharmacological solutions. Untreated ADHD can affect an adult in many adverse ways, from their personal to their professional lives, causing undue stress and other significant mental health challenges," said Dr. Stephen Faraone, Distinguished Professor and Vice Chair for Research, Department of Psychiatry, SUNY Upstate Medical University and President of the World Federation for ADHD.

"New, easily accessible treatments are needed to effectively support adults with ADHD," said Duane Gordon, President, Attention Deficit Disorder Association (ADDA). "I'm delighted to see new technology used to develop a unique approach to treatment, and a video game treatment is a fun and engaging way to empower adults with ADHD."

The release of EndeavorOTC provides immediate access to this clinically-proven non-drug option for those seeking new safe and effective solutions to their treatment needs. The first generation of EndeavorOTC is available now in the Apple App Store for adults 18 and older with ADHD. Akili will actively involve adults using EndeavorOTC in the ongoing development of the product, gathering feedback that will help shape future generations of the game. By working closely with the community and embracing their perspective, Akili will continue to enhance EndeavorOTC to make the experience even more engaging, enjoyable and impactful.

"Without reliable access to ADHD medication or sufficient mental healthcare professionals to meet demand, millions of Americans are in urgent need of new validated and accessible treatment options. Patients want better, and they want non-drug treatment options," said Eddie Martucci, chief executive officer of Akili. "The core technology inside EndeavorOTC has helped thousands of children with ADHD, and recently has shown it dramatically helped adults in our clinical trial improve their focus, time management and organizational skills, and their ability to keep track of important items. We're thrilled to make EndeavorOTC available to adults who can benefit."

Akili's Endeavor suite of products, EndeavorOTC and EndeavorRx, combine the best of medicine and mobile gaming and were developed through the collaboration of world-renowned cognitive neuroscientists and acclaimed

entertainment and technology designers. The digital treatments run on Akili's patented Selective Stimulus Management Engine (SSME™) core technology. SSME has been validated in more than a dozen clinical trials across a variety of diseases that impact cognition, including <u>ADHD</u>, <u>depression</u>, <u>multiple sclerosis</u>, and <u>autism spectrum disorder</u>. By completing tasks while simultaneously filtering out distractions, the treatments target areas of the brain responsible for cognitive functions including focus, which helps improve attention and day-to-day functioning. Algorithms adapt to each user in real time, delivering a personalized experience and challenging the user at an optimized level to improve the targeted cognitive function.

EndeavorOTC is now available for download on the Apple App Store<sup>®</sup>, and those who sign up for the mailing list will be notified when it becomes available on Android. For more information, visit EndeavorOTC.com.

#### About EndeavorOTC and EndeavorRx

Akili's suite of cognitive treatment products for ADHD includes EndeavorOTC and EndeavorRx.

EndeavorOTC is a digital therapeutic indicated to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. EndeavorOTC utilizes the same proprietary technology underlying EndeavorRx, a prescription digital therapeutic indicated to improve attention function in children ages 8-12. EndeavorOTC is available under the U.S. Food and Drug Administration's current Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. EndeavorOTC has not been cleared or authorized by the U.S. Food and Drug Administration for its indications. It is recommended that patients speak to their health care provider before starting EndeavorOTC treatment. No serious adverse events have been reported in any of our clinical studies. To learn more, visit EndeavorOTC.com.

EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8 to 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 trials 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 Akili**

Akili is pioneering the development of cognitive treatments through game-changing technologies. Akili's approach of leveraging technologies designed to directly target the brain establishes a new category of medicine - medicine that is validated through clinical trials like a drug or medical device, but experienced like entertainment. Akili's platform is powered by proprietary therapeutic engines designed to target cognitive impairment at its source in the brain, informed by decades of research and validated through rigorous clinical programs. 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.

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

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are

predictions, projections, and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties.

These forward-looking statements include, without limitation, statements in this press release related to: the ability of EndeavorOTC to improve attention function, ADHD symptoms and quality of life in adults with ADHD and the growing need for ADHD treatment and non-pharmacological options. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to: the risk that prior results, such as signals of efficacy or safety observed from clinical trials will not continue or be repeated in EndeavorOTC or our ongoing or planned clinical trials, or will be insufficient to support regulatory submissions or support or maintain marketing approval in the United States or other jurisdictions, or that long-term adverse safety findings may be discovered; the risk that our products will not be further developed or commercialized successfully; the timing and results expected from our and our partners' clinical trials and our reliance on third parties for certain aspects of our business; our ability to accurately estimate expenses, capital requirements, and needs for additional financing; and other risks identified in our current filings and any subsequent filings made with the Securities and Exchange Commission (SEC). We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof and should not be relied upon as representing the company's views as of any subsequent date. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

#### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 27 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both US FDA clearance and European marketing authorization and a third (KarXT) that is expected to be filed soon for FDA approval. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration enabling studies. 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.

For more information, visit <u>www.puretechhealth.com</u> or connect with us on Twitter @puretechh.

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