



PureTech Founded Entity Akili Announces Adults with ADHD See Significant Improvements in Attention, ADHD Symptoms, and Quality of Life in Clinical Trial of Akili's EndeavorRx® Video Game-Based Therapeutic

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PureTech Founded Entity Akili Announces Adults with ADHD See Significant Improvements in Attention, ADHD Symptoms, and Quality of Life in Clinical Trial of Akili's EndeavorRx® Video Game-Based Therapeutic

Attention improved in more than 80 percent of adults with ADHD, and over one-third of participants no longer exhibited an attention deficit following treatment

Improvements in attention were nearly seven times larger than those seen in the pivotal trial that supported EndeavorRx's FDA authorization for 8-12 year olds with ADHD

Nearly half of adults treated with EndeavorRx met a prespecified threshold for clinically meaningful improvement in their quality of life

[PureTech Health plc](#) (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, announced topline results of the STARS-ADHD-Adult clinical trial evaluating the efficacy and safety of EndeavorRx® (AKL-T01) in adults with attention-deficit/hyperactivity disorder (ADHD). STARS-ADHD-Adult was designed as a pivotal clinical trial to enable registration with the U.S. Food and Drug Administration (FDA). The trial demonstrated statistically significant improvement in attention functioning after six weeks of treatment, achieving its predefined primary efficacy outcome. Significant improvements were also seen across a range of secondary and exploratory outcomes, including clinical assessments of ADHD-related symptoms and a validated measure of quality of life. EndeavorRx treatment was well-tolerated, with minimal side effects and no serious device-related adverse events reported.

The multi-center open-label study (NCT05183919) enrolled 221 adults, 18 years of age and older, with inattentive or combined-type ADHD. Patients used the video game-based digital treatment on a mobile device in their homes for six weeks. In the study, EndeavorRx demonstrated a statistically significant improvement in the Test of Variables of Attention (TOVA®)-Attention Comparison Score (ACS) of sustained and selective attention from baseline after six weeks of treatment ($p < 0.0001$), the study's predefined primary efficacy outcome. The change from baseline on the TOVA ACS was 6.46 points, which is more than twice as large as the changes seen in the recent pivotal study in adolescents (2.64 points) and nearly seven times as large as the changes seen in STARS-ADHD (0.93 points), a large randomized controlled trial of children with ADHD ages 8-12 that served as the basis for EndeavorRx's FDA authorization in that age group. [TOVA](#) is a computerized test authorized by the FDA to aid in the diagnosis of ADHD and evaluate the effects of interventions in ADHD.

Akili plans to present full data from the STARS-ADHD-Adult study at a future scientific meeting and will submit the

data to the FDA later this year.

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

Adults with ADHD See Significant Improvements in Attention, ADHD Symptoms, and Quality of Life in Clinical Trial of Akili's EndeavorRx® Video Game-Based Therapeutic

Attention improved in more than 80 percent of adults with ADHD, and over one-third of participants no longer exhibited an attention deficit following treatment

Improvements in attention were nearly seven times larger than those seen in the pivotal trial that supported EndeavorRx's FDA authorization for 8-12 year olds with ADHD

Nearly half of adults treated with EndeavorRx met a prespecified threshold for clinically meaningful improvement in their quality of life

BOSTON-May 3, 2023 -- [Akili, Inc.](#) (Nasdaq: AKLI), a leading digital medicine company, today announced topline results of the STARS-ADHD-Adult clinical trial evaluating the efficacy and safety of EndeavorRx® (AKL-T01) in adults with attention-deficit/hyperactivity disorder (ADHD). STARS-ADHD-Adult was designed as a pivotal clinical trial to enable registration with the U.S. Food and Drug Administration (FDA). The trial demonstrated statistically significant improvement in attention functioning after six weeks of treatment, achieving its predefined primary efficacy outcome. Significant improvements were also seen across a range of secondary and exploratory outcomes, including clinical assessments of ADHD-related symptoms and a validated measure of quality of life. EndeavorRx treatment was well-tolerated, with minimal side effects and no serious device-related adverse events reported.

Millions of American adults are diagnosed with ADHD, and recent reports suggest that rates have risen in recent years. This is magnified by the substantial challenges this large group of patients face in accessing effective treatment.

EndeavorRx is currently [authorized](#) by the FDA for the treatment of inattention in children ages 8-12 with ADHD (see full indication below), and in January Akili [announced](#) topline data from a successful pivotal study of EndeavorRx in adolescents with ADHD ages 13-17. For both objective measures of attention and clinical outcomes, the improvements observed in adults surpassed those in both the pediatric and adolescent patient populations.

"Not only did the benefit of EndeavorRx in adults with ADHD exceed what we've seen in kids and adolescents, adults using the treatment experienced meaningful improvements in their quality of life," said Scott Kollins, Ph.D., chief medical officer of Akili. "These data come at a critical time when there is growing demand among adults with ADHD for safe, effective, and accessible non-drug treatments. It is increasingly recognized that current available options are not working, and/or are not available. We are deeply committed to getting this treatment to patients as quickly as possible. We are evaluating regulatory strategies and look forward to sharing more soon."

The multi-center open-label study (NCT05183919) enrolled 221 adults, 18 years of age and older, with inattentive or combined-type ADHD. Patients used the video game-based digital treatment on a mobile device in their homes for six weeks. In the study, EndeavorRx demonstrated a statistically significant improvement in the Test of Variables of Attention (TOVA®)-Attention Comparison Score (ACS) of sustained and selective attention from baseline after six weeks of treatment ($p < 0.0001$), the study's predefined primary efficacy outcome. The change from baseline on the TOVA ACS was 6.46 points, which is more than twice as large as the changes seen in the recent pivotal study in adolescents (2.64 points) and nearly seven times as large as the changes seen in STARS-ADHD (0.93 points), a large randomized controlled trial of children with ADHD ages 8-12 that served as the basis for EndeavorRx's FDA authorization in that age group. [TOVA](#) is a computerized test authorized by the FDA to aid in the diagnosis of ADHD and evaluate the effects of interventions in ADHD.

Adults using EndeavorRx also showed significant improvement in their ADHD symptoms, as measured by the clinician-administered Attention Deficit Hyperactive Disorder Rating Scale-5 (ADHD-RS). Following treatment, participants in the study showed significant improvement on both the inattention subscale and total score of the ADHD-RS ($p < 0.0001$ for both). A prespecified responder analysis also showed that 32.7% of all participants in the study demonstrated at least a 30% reduction in total scores on the ADHD-RS, surpassing findings in the STARS-ADHD-Adolescents study in

13-17 year olds with ADHD (27.1%) and the STARS-ADHD study in 8-12 year olds with ADHD (24%).

Nearly three-quarters (72.5%) of adults reported at least some improvement in their quality of life as measured by the [validated](#) Adult ADHD Quality of Life Scale (AAQoL), and nearly 50 percent (45.8%) of adults met a prespecified threshold for clinically meaningful improvement.

Overall, 11 of the participants in the trial (5%) reported a treatment-emergent adverse device event, most commonly nausea (1.8%) and headache (1.4%). There were no serious adverse device events.

Additional study information and results:

- 83% patients demonstrated a clinical response to the treatment on the TOVA-ACS (post hoc analysis as measured by at least a 1.4 improvement on the TOVA)
- More than one-third (36.6%) of adults with ADHD moved into the non-clinical, or normative, range (TOVA ACS score of >0)
- Quality of life improvements seen included an increased ability to complete projects and tasks on time, ability to balance multiple projects at a time, and ability to keep track of important items such as keys and wallet
- Approximately 70% of the adults with ADHD in the study were women
- 40% of patients enrolled were taking ADHD medication; a similar magnitude of effect was seen both in those taking stimulant medications and in those not taking stimulants

Akili plans to present full data from the STARS-ADHD-Adult study at a future scientific meeting and will submit the data to the FDA later this year.

EndeavorRx Indication and Overview

EndeavorRx is the first-and-only FDA-authorized treatment delivered through a video game experience. 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: our expectations with respect to future regulatory submissions for the clearance of AKL-T01 in expanded patient populations; the potential market opportunity for AKL-T01; and the timing at which we may receive regulatory clearance and bring AKL-T01 to market for expanded patient populations. 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 of AKL-T01 will not continue or be repeated in our ongoing or planned clinical trials of AKL-T01, 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 AKL-T01 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 www.puretechhealth.com or connect with us on Twitter @puretechh.

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This press release contains statements that are or may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation those statements that relate to the results of the STARS-ADHD-Adult clinical trial and expectations related to the timing of the filing of data to the FDA, and Akili's and PureTech's future prospects, development plans, and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, the following: our history of incurring significant operating losses since our inception; our need for additional funding to achieve our business goals, which may not be available and which may force us to delay, limit or terminate certain of our therapeutic development efforts; our limited information about and limited control or influence over our Non-Controlled Founded Entities; the lengthy and expensive process of preclinical and clinical drug development, which has an uncertain outcome and potential for substantial delays; potential difficulties with enrolling patients in clinical trials, which could delay our clinical development activities; side effects, adverse events or other safety risks which could be associated with our therapeutic candidates and delay or halt their clinical development; our ability to obtain regulatory approval for and commercialize our therapeutic candidates; our ability to realize the benefits of our collaborations, licenses and other arrangements; our ability to maintain and protect our intellectual property rights; our reliance on third parties, including clinical research organizations, clinical investigators and manufacturers; our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events; and those additional important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2022

filed with the SEC and in our other regulatory filings. 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, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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