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PureTech Founded Entity Akili Announces the Results of EndeavorRx™ Clinical Study in Pediatric ADHD Published in Nature Digital Medicine

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*Significant improvements in impairments and symptoms seen by parents in daily life, both when used alone and alongside stimulant medication*

*Improvements observed by parents and clinicians increased with longer duration of treatment and persisted one month following treatment*

Mar. 26, 2021-- PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Akili Interactive (Akili), today announced the publication of full data from a multi-site open-label study (the STARS Adjunct study) evaluating the impact of EndeavorRx™ (AKL-T01) on symptoms and functional impairments in children with attention-deficit/hyperactivity disorder (ADHD).

Statistically significant improvement was demonstrated in all predetermined endpoints of the study, which included parent and clinician ratings of children's ADHD symptoms and related impairments in daily life. The results have been [published](#) in the international peer-reviewed journal, *Nature Digital Medicine*.

The STARS Adjunct study data, along with data from four other clinical studies of EndeavorRx in pediatric ADHD, were presented to the U.S. Food and Drug Administration (FDA) and part of the data package which led to FDA clearance of EndeavorRx™ in June 2020.

**Results of Akili's EndeavorRx™ Clinical Study Published in *Nature Digital Medicine*, Demonstrate Improvements in Pediatric ADHD Impairments and Symptoms in Daily Life**

*Data on the treatment's effect on daily functioning support existing evidence showing improvements across objective measures of attention*

*Significant improvements in impairments and symptoms seen by parents in daily life, both when used alone and alongside stimulant medication*

*Improvements observed by parents and clinicians increased with longer duration of treatment and persisted one month following treatment*

**BOSTON – March 26, 2021 – [Akili Interactive](#)** ("Akili" or "Company"), today announced the publication of full data from a multi-site open-label study (STARS Adjunct) evaluating the impact of EndeavorRx™ (AKL-T01) on symptoms and functional impairments in children with attention- deficit/hyperactivity disorder (ADHD). Statistically significant improvement was demonstrated in all predetermined endpoints of the study, which included parent and clinician ratings of children's ADHD symptoms and related impairments in daily life. The results have been [published](#) in the international peer-reviewed journal, *Nature Digital Medicine*.

Building on the results of the STARS-ADHD pivotal study of EndeavorRx [published](#) in *The Lancet Digital Health* in February 2020, the STARS Adjunct study evaluated the safety and efficacy of EndeavorRx when used alone and alongside stimulants. The study also assessed the effect of increasing the duration of treatment. Standard clinician ratings of impairments and symptoms were measured, as well as ratings by parents of their children in daily life. The STARS Adjunct study data, along with data from four other clinical studies of EndeavorRx in pediatric ADHD, were presented to the U.S. Food and Drug Administration (FDA) and part of the data package which led to FDA clearance of EndeavorRx in June 2020.

"The results of this study highlight the impact EndeavorRx can have on patients' day-to-day lives and show the potential benefits of incorporating digital therapeutics into multifaceted treatment plans, including those with traditional pharmacological interventions," said Anil Jina, M.D., Chief Medical Officer of Akili.

A change in the ADHD Impairment Rating Scale (IRS), a parent-reported assessment scale of ADHD- specific impairments observed in their child's day-to-day life, was the primary outcome measure of the study. All children participating in the study received the EndeavorRx treatment, with one group also taking stimulant medications and the other not taking medications. Both groups of children demonstrated statistically significant improvements in the IRS compared to baseline (children on stimulants: -0.7, p<0.001; children not on stimulants: -0.5, p<0.001). Half of children (50.0%) were clinical responders to treatment following one month of treatment and over two-thirds (68.3%) of children showed a clinical response following two months of treatment (clinical response pre-defined as IRS improvement of one point or more).

"The findings from this latest study offer additional information about the effectiveness of EndeavorRx in children treated with front-line pharmacotherapy for ADHD," said Scott Kollins, Ph.D., Professor of Psychiatry and Director of the ADHD Program at the Duke University School of Medicine, faculty member at the Duke Clinical Research Institute (DCRI), and lead author of the publication. "As a clinician who works with children with ADHD, I am happy to see these results from an innovative treatment that can improve both symptoms and impairments in children with ADHD."

Also measured were clinician-reported assessments of the ADHD Rating Scale (ADHD-RS) and the mean clinical global impression of improvement (CGI-I). Statistically significant improvements were seen across both assessments in children, regardless of whether they were using EndeavorRx alone or alongside stimulants. ADHD-RS symptom response rates

were similar for children both on and off ADHD medication, with 27.2% of children responding to treatment following one month of treatment and 45.3% following two months of treatment (clinical response on ADHD-RS predefined as  $\geq 30\%$  reduction in symptoms).

The STARS Adjunct study also looked at the duration of effects of EndeavorRx. Four weeks following treatment, ADHD-RS scores remained significantly improved for participants in both children who used EndeavorRx alone and those who used the treatment alongside stimulants (all  $p < 0.001$ ).

The safety profile of EndeavorRx was consistent with that seen in all previous clinical studies of the product; the treatment was well-tolerated with no serious adverse events.

EndeavorRx has been studied in more than 600 children with ADHD across five clinical trials, including a large, multicenter prospective randomized controlled study. Based on the totality of data from those studies which showed clinical benefit in attention as measured by computer-based testing, academic performance measures, and other assessment tools, EndeavorRx was cleared by the U.S. Food and Drug Administration (FDA), making it the first prescription treatment delivered through a video game.

### **EndeavorRx™ Indication and Overview**

EndeavorRx is indicated 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. 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.

EndeavorRx (AKL-T01) is built on the Akili Selective Stimulus Management Engine (SSME™) core technology, a proprietary technology designed to target key attentional control systems in the brain. 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 while using adaptive algorithms to personalize the treatment experience for each individual patient. This enables second by second monitoring of patient progress completing the treatment sessions, and continuously challenges each patient to an optimized level, encouraging patients to improve their performance. Driven by the core belief at Akili that effective medicine can also be fun and engaging, EndeavorRx is delivered through an action video game experience. The captivating experience of EndeavorRx is designed to drive engagement and compliance. To learn more about EndeavorRx, please visit [www.EndeavorRx.com](http://www.EndeavorRx.com).

### **STARS Adjunct [NCT03649074] Study Overview**

The STARS Adjunct study was a three-month open-label, multi-site study of AKL-T01 in 206 pediatric participants aged 8-14 years with a diagnosis of ADHD. AKL-T01 treatment was evaluated across two groups of participants, one group of children who were taking ADHD stimulant medications ( $n=130$ ) and one group of children who were not taking ADHD medications ( $n=76$ ) for the duration of the study. The primary outcome measure of the study was the change from baseline in the ADHD Impairment Rating Scale (IRS) for each cohort after one month. Secondary and exploratory outcome measures included the ADHD Rating Scale (ADHD-RS), Tests of Variables of Attention (TOVA), Clinical Global Impression - Improvement Scale (CGI-I), as well as academic measures. The study was conducted by the DCRI.

### **Primary Endpoint: ADHD Impairment Rating Scale (IRS)**

The Impairment Rating Scale (IRS) is a parent-reported clinician-administered scale of ADHD-specific impairment across domains such as social functioning, academic progress and self-esteem, including an overall impairment. The domains of ADHD-specific impairment assessed by the IRS correspond to DSM criteria of impaired functioning in social or academic areas for ADHD. The assessment provides measures of real-world consequences of ADHD symptoms.

### **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 is pioneering the development of digital treatments and care solutions to help people affected by cognitive impairments. Akili's treatments are designed to directly activate the networks in the brain responsible for cognitive function and have been rigorously tested in extensive clinical studies, including prospective randomized, controlled trials. 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. For more information, please visit [www.AkiliInteractive.com](http://www.AkiliInteractive.com).

EndeavorRx™ is a registered trademark of Akili Interactive Labs, Inc.

### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing 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, as of the date of PureTech's most recently filed Registration Statement on Form 20-F, was comprised of 24 therapeutics and therapeutic candidates, including two that have received FDA clearance and European marketing authorization. All of the underlying programs 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](http://www.puretechhealth.com) or connect with us on Twitter @puretechh.

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

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, our expectations regarding the potential therapeutic benefits of our therapeutic candidates, expectations regarding the results from Akili's STARS Adjunct study evaluating EndeavorRx™ (AKL-T01), its potential therapeutic benefits and 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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