PureTech Founded Entity Akili Announces Presentation of New Outcome Data for Digital Therapeutic EndeavorRx™ in Paediatric ADHD

October 21, 2020

Two-thirds of parents reported real-world improvements in child's ADHD-related impairments following two months of treatment, both when used alone and alongside stimulants

Improvements in attention during treatment were associated with improvements in math and reading performance

Data across four clinical trials consistently demonstrate over one-third of children with ADHD no longer showed attention impairment on at least one measure of objective attention

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 multiple data presentations on EndeavorRx™ (see prescribing information below), including results from the STARS-Adjunct trial, a multi-site open-label study designed to evaluate the impact of EndeavorRx™ on impairments in daily life in children with attention-deficit/hyperactivity disorder (ADHD) and inform prescribing practices. Also presented were analyses across four clinical trials of EndeavorRx, evaluating the impact of treatment on children's attention function compared to normative ranges. The data were presented for the first time this week at the *American Academy of Child and Adolescent Psychiatry (AACAP) 2020 Virtual Annual Meeting.*

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

Researchers Present New Outcome Data for Akili Digital Therapeutic EndeavorRx™ in Paediatric ADHD

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Data across four clinical trials consistently demonstrate over one-third of children with ADHD no longer showed attention impairment on at least one measure of objective attention

BOSTON, Mass – October 21, 2020 – Akili today announced multiple data presentations on EndeavorRx™ (see prescribing information below), including results from the STARS-Adjunct trial, a multi-site open-label study designed to evaluate the impact of EndeavorRx™ on impairments in daily life in children with attention-deficit/hyperactivity disorder (ADHD) and inform prescribing practices. Also presented were analyses across four clinical trials of EndeavorRx, evaluating the impact of treatment on children's attention function compared to normative ranges. The data were presented for the first time this week at the *American Academy of Child and Adolescent Psychiatry (AACAP) 2020 Virtual Annual Meeting.*

"The STARS-Adjunct study provides further evidence for physicians on the use of EndeavorRx in clinical practice, including duration of treatment and use alongside traditional ADHD medications," said Anil Jina, MD, Chief Medical Officer of Akili. "Building on the improvements in objective measures of attention demonstrated in our prior clinical studies of EndeavorRx, these data help show the benefits of treatment seen by parents assessing their child's ADHD-related impairments in everyday life."

Key results across the presentations include:

- **Improvements in the ADHD Impairment Rating Scale (IRS) were statistically significant compared to baseline and were similar in magnitude regardless of whether or not children were taking stimulant medication[1]:** Both children taking stimulants and those not taking any ADHD medication demonstrated similar and statistically significant improvements (children on stimulants: mean improvement −0.7, $p < 0.001$; and children off stimulants: mean improvement −0.5, $p < 0.001$).
- **Parent observations showed half of children responded to treatment following one month of EndeavorRx use and improvements remained stable for one month following treatment[2]:** Half of parents reported improvements in their child's ADHD-related impairments in daily life following one month of EndeavorRx treatment as measured by the IRS (responders/improvement of one point or more on the IRS scale: 50.0%).
- **Improvements increased with longer duration of treatment, with more than two-thirds of children responding to treatment following two months of EndeavorRx use[2]:** More than two-thirds of parents reported improvements in their child's ADHD-related impairments following a second month of treatment as measured by the IRS

(responders/improvement of one point or more the IRS scale: 68.3%).

- **Over one-third of children no longer showed attention impairment on at least one measure of objective attention following treatment[3]:** Analyses across four studies in paediatric ADHD[4] showed that overall 34.5% of children moved into the normative range on at least one TOVA objective measure of attention following four weeks of EndeavorRx treatment (N=296 children aged 8 to 15 years old with ADHD and TOVA impairment at baseline).
- **Early exploratory evidence showed children who improved in attention functioning following treatment also improved their math and reading skills[4]:** Performance on the Test of Silent Reading Efficiency and Comprehension (TOSREC) and the Mathematics Fluency and Calculation Tests (MFaCTS) improved in children whose Test of Variables of Attention (TOVA) Attention Comparison Score (ACS/API) improved.

EndeavorRx is an FDA-cleared digital treatment for children diagnosed with ADHD. Delivered through a video game experience, 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 behavioural symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic programme that may include clinician-directed therapy, medication, and/or educational programmes; which further address symptoms of the disorder. EndeavorRx is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication.

About the STARS-ADHD Adjunct Study

The STARS-ADHD Adjunct study (NCT03649074) was a three-month open-label, multi-site study of AKL-T01 (EndeavorRx) in 206 paediatric participants aged 8-14 years with a diagnosis of ADHD, across two cohorts: children who were taking ADHD stimulant medications (n=130) and children who were not taking ADHD medications (n=76) for the duration of the study. Children completed one month of treatment with AKL-T01, followed by a one-month pause and then another one-month treatment with AKL-T01. The primary outcome measure of the study was the change from baseline after one month in the Impairment Rating Scale (IRS) for each cohort. Secondary outcome measures included the ADHD Rating Scale (ADHD-RS), Test of Variables of Attention (TOVA), Clinical Global Impression - Improvement Scale (CGI-I), as well as exploratory outcomes of academic performance measures (TOSREC, MFaCTS).

About EndeavorRx

EndeavorRx (AKL-T01) is built on the Akili Selective Stimulus Management Engine (SSME^{TM}) 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 personalise 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 optimised 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.

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 randomised, 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.

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 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 received US Food and Drug Administration (FDA) clearance and European marketing authorisation. 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, our expectations regarding the potential therapeutic benefits of EndeavorRx 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.

[1]Kollins S.H., Heusser A., Lutz J. (2020, Oct 12-24). *A Home-Based, Digital Treatment for Pediatric ADHD as Adjunct to Stimulant Medication: Insights on Repeat Administration and the Stability of Effects.* [Conference poster]. Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP); Virtual.

[2]Childress, A.C., Lutz, J., Kollins, S.H. (2020, Oct 12-24). *AKL-T01, a Digital Treatment for Pediatric ADHD as an Adjunct to Stimulant Medication: Response Rates with Repeat Administration.* [Conference poster]. Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP); Virtual.

[3]Melmed R., Lutz J., Jina A. (2020, Oct 12-24). *Improving Objective Measures of Attention in Test of Variables of Attention (TOVA) into Normative Ranges with AKL-T01, a Digital Treatment for Attention in Pediatric ADHD.* [Conference poster]. Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP); Virtual.

[4]Davis N., Lutz J., Kollins S.H. (2020, Oct 12-24). *AKL-T01, a Home-Based Digital Intervention as an Adjunct to Stimulant Medication for Pediatric ADHD: Academic Performance and Relation to Objective Measures of Attention.* [Conference poster]. Sixty-seventh Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP); Virtual.