PureTech Founded Entity Akili Announces Pivotal Trial of EndeavorRx® in Adolescents with ADHD Shows Robust Improvements in Attention and Broader Clinical Outcomes

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Attention improvements were nearly three times as large as those in the pivotal trial that served as the basis for EndeavorRx's FDA authorization for children with ADHD ages 8-12

Study data will be used to file for EndeavorRx label expansion with FDA in 2023

Akili has stopped recruitment in separate adult ADHD trial to allow for earlier data analysis

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-Adolescents label expansion study evaluating the efficacy and safety of EndeavorRx® (AKL-T01) in adolescents ages 13-17 with attention-deficit/hyperactivity disorder (ADHD).

The pivotal study achieved its predefined primary efficacy outcome, showing statistically significant improvement in attentional functioning after four weeks of treatment. Consistent improvements were also seen in a range of secondary measures of ADHD-related inattention symptoms and functioning. EndeavorRx treatment was generally well-tolerated, with no serious device-related adverse events reported.

Akili plans to present full data from the STARS-ADHD-Adolescents study at a future medical meeting, and the company will file for EndeavorRx label expansion with FDA in 2023. As part of Akili's label expansion strategy for EndeavorRx, in addition to the study in adolescents, the company has been conducting a separate pivotal trial of EndeavorRx in adults with ADHD. As was previously noted during the company's last earnings call, recruiting for that adult study has been slower than projected. Based on this strong clinical data in adolescents and the desire to maximize capital efficiency, Akili has stopped recruitment of the adult study with 224 patients enrolled in order to analyze the trial data ahead of schedule.

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

Pivotal Trial of EndeavorRx® in Adolescents with ADHD Shows Robust Improvements in Attention and Broader Clinical Outcomes

Attention improvements were nearly three times as large as those in the pivotal trial that served as the basis for EndeavorRx's FDA authorization for children with ADHD ages 8-12

Study data will be used to file for EndeavorRx label expansion with FDA in 2023

Akili has stopped recruitment in separate adult ADHD trial to allow for earlier data analysis

BOSTON - January 5, 2023 - - Akili, Inc. (Nasdaq: AKLI), a leading digital medicine company, today announced topline results of the STARS-ADHD-Adolescents label expansion study evaluating the efficacy and safety of EndeavorRx®(AKL-T01) in adolescents ages 13-17 with attention-deficit/hyperactivity disorder (ADHD). The pivotal study achieved its predefined primary efficacy outcome, showing statistically significant improvement in attentional functioning after four weeks of treatment. Consistent improvements were also seen in a range of secondary measures of ADHD-related inattention symptoms and functioning. EndeavorRx treatment was generally well-tolerated, with no serious device-related adverse events reported.

"The results of this study extend the already substantial evidence base to support the efficacy of EndeavorRx for improving attentional functioning in patients with ADHD, and most importantly show the ability of this safe treatment to help teenagers, who have been significantly impacted by the current mental health crisis," said Scott Kollins, Ph.D., chief medical officer of Akili.

The multi-center open-label study enrolled 162 adolescents ages 13-17 with inattentive or combined-type ADHD. 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 one month of treatment ($p<0.0001$), the study's predefined primary efficacy outcome. The change from baseline on the TOVA ACS was nearly three times as large as the changes seen in STARS-ADHD, a large randomized controlled trial of children with ADHD ages 8-12 that served as the basis for EndeavorRx's U.S. Food and Drug Administration (FDA) authorization in that age group. In the STARS-ADHD-Adolescents study, nearly two-thirds (66%) of adolescents met the prespecified definition of clinical response on the TOVA-ACS and nearly a quarter (24.7%) moved into the non-clinical, or normative, range. TOVA is a computerized test cleared by FDA to assess attention deficits and evaluate the effects of interventions in ADHD.

Adolescents using EndeavorRx also saw significant improvement in ADHD symptoms, as measured by the Attention Deficit Hyperactive Disorder Rating Scale-5 (ADHD-RS) inattention subscale and total scale scores. ADHD-RS is a clinician-administered questionnaire based on information collected from the child's caregiver. 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 27.1% of all participants in the study demonstrated at least a 30% reduction in total scores on the ADHD-RS, a finding similar to the STARS-ADHD trial in children with ADHD (24%). Statistically significant improvements were also observed for parent and child ratings of attention improvement, as well as parent ratings of function across a number of domains, including peer relationships, academic functioning, behavioral functioning, homework functioning, and self-esteem. Overall, 4 (2.5%) participants experienced a treatment-emergent adverse device event (3 decreased frustration tolerance, 1 headache; all mild or moderate). There were no serious adverse device events.

Akili plans to present full data from the STARS-ADHD-Adolescents study at a future medical meeting, and the company will file for EndeavorRx label expansion with FDA in 2023. As part of Akili's label expansion strategy for EndeavorRx, in addition to the study in adolescents, the company has been conducting a separate pivotal trial of EndeavorRx in adults with ADHD. As was previously noted during the company's last earnings call, recruiting for that adult study has been slower than projected. Based on this strong clinical data in adolescents and the desire to maximize capital efficiency, Akili has stopped recruitment of the adult study with 224 patients enrolled in order to analyze the trial data ahead of schedule.

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 timing of a regulatory submission to FDA for EndeavorRx (AKL-T01) and our aim to expand the EndeavorRx label; our clinical development plans, including the timing of enrollment for and analysis of data from clinical trials as well as the release of additional clinical data; and the likelihood that data from clinical trials will be positive and support further clinical development and regulatory approval of AKL-T01. 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 biotherapeutics company dedicated to changing the treatment paradigm for devastating diseases. 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 26 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both U.S. FDA clearance and European marketing authorization and a third (KarXT) that will soon be filed for FDA approval, as of the most recent update by the Company. 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 based on unique insights in immunology and drug development.

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 pivotal trial of Akili's EndeavorRx in adolescents with ADHD and expectations related to the timing of the filing for EndeavorRx label expansion with FDA, the pivotal trial of Akili's EndeavorRx in adults, 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, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2021 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.

Contact:
PureTech
Public Relations
publicrelations@puretechhealth.com
Investor Relations
IR@puretechhealth.com

EU Media
Ben Atwell, Rob Winder
+44 (0) 20 3727 1000
ben.atwell@FTIconsulting.com

U.S. Media
Nichole Sarkis
+1 774 278 8273

nichole@tenbridgecommunications.com

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